DATE: November 21, 2019

TO: Honorable Members of the Board of Supervisors
    Jeffrey V. Smith, M.D., J.D., County Executive

FROM: René G. Santiago, Deputy County Executive and
      Director, County of Santa Clara Health System

SUBJECT: Board Referral on Cervical Cancer Prevention

On March 12, 2019, the Board of Supervisors approved a referral to Administration to work with the Arbor Vita Corporation and the Institutional Review Board to determine opportunities to address cervical cancer. This memo updates the current status of this referral.

Dr. Phuong Nguyen, Chief Medical Officer of SCVMC and Dr. Peter Lu, Chief Executive Officer of Arbor Vita Corporation have discussed the possibility of an SCVMC-sponsored study evaluating the effectiveness of OncoE5 Cervical Test as an innovative self-test approach to cervical cancer screening. Dr. Nguyen explained it would not be feasible for the Health System to adopt OncoE5 testing or sponsor the study as the test is not a part of current standard clinical practice and not FDA approved in the United States. Dr. Nguyen also provided Dr. Peter Lu with an overview of the approval process and offered to assist Dr. Lu with identifying a VMC physician who would be interested in being the principal research investigator for the research project.

SCVMC supports the performance of clinical research that may benefit our patients, which this potential study would qualify. Policy #638.0 (attached) describes the administrative approval process and requirements, including coverage of costs relating to the study. The Principal Investigator of any research study must be an employee who is credentialed and privileged at SCVMC in an appropriate specialty.
Also attached are a number of other documents that explain the IRB research approval process, as well as the forms associated with that process. If you have any questions, please feel free to contact us.

Attachments:

SCVMC Policy #638.0 Research – Administrative Approval and Management
Health System Policy #952.0 – Health Services Institutional Review Board (IRB) Policy
SCVMC Administrative Approval Instructions
SCVMC Research Administration Approval Form
IRB Standard Operating Procedures
Investigator Guidelines
Full Study New Application
2020 Meeting Schedule with Submission Deadlines
June 27, 2019

TO: SCVMC Employees

FROM: Paul E. Lorenz
Chief Executive Officer, SCVMC

SUBJECT: Research – Administrative Approval and Management

REFERENCE: TJC Standards 2014, RI.01.03.05
Code of Federal Regulations (CFR) Title 45, Part 46
VMC Policy # 638.1 Research Involving Human Subjects
HHS # 585.03 Uses and Disclosures of Protected Health
Information for Research
HHS # 585.14 Creating, Disclosing, and Using Limited
Data Sets from Protected Health Information
HHS # 585.17 Safeguarding Protected Health
Information

POLICY:

Santa Clara Valley Medical Center (SCVMC) supports the performance of approved clinical research, as such research benefits the organization and its patients and advances SCVMC’s mission by making available to the medical community and public the latest in experimental treatments, technology, equipment, devices, drugs, and protocols. In addition, clinical research and the related academic pursuits provide opportunities for publication, education, and promotion of SCVMC’s scholarly and clinical accomplishments.

This policy describes the administrative requirements related to obtaining grants, recovery of costs and reimbursements, use of personnel and space, conflict of interest, and the review and approval process. This policy is intended to support related existing County policies, including VMC #638.1, and the rules and policies of the Research and Human Subjects Review Committee. It is the responsibility of the Principal Investigator to assure that approved research is carried out in accordance with this policy.

PROCEDURE:

Administrative Approval

Prior to the commencement of the research project, the Principal Investigator must obtain administrative approval. The Research Administration Director will assist the Principal Investigator.

On behalf of Administration, the Research Administration Director will assist the Principal Investigator with the paperwork necessary to obtain administrative approval, evaluation of impacted departmental resources and staff, coordination with departmental managers, pricing and budget preparation, and contract negotiations.
Administrative Approval Forms and Documents

The Principal Investigator must notify the Research Administration Director of his/her intent to do a clinical research project and complete the paperwork and provide the documents required for administrative approval. The Principal Investigator may do this concurrently to the Institutional Review Board (IRB) approval process.

Department Impact

If the research involves other departments, such as Pharmacy, Laboratory or Radiology, or clinic visits, clinic time or space, etc. the Research Administration Director will work with the Principal Investigator and the participating department to determine if resources are available to support the research study proposed by the Principal Investigator and determine the pricing for departmental services.

The Clinical Research Pharmacist, Research Administration Director and the Principal Investigator will meet to discuss any study involving a drug. The Principal Investigator will provide the Clinical Research Pharmacist with the protocol concurrent to the submission of the protocol to IRB and to the Research Administration Director for IRB and Administration approval, respectively.

Study Costs

It is expected that the costs of clinical research will be fully funded by the sponsor. Investigators requesting discounts or other exceptions to this full reimbursement requirement are required to identify any in-kind contribution of the study and obtain approval of the discount or exception before commencing the research project. All patient charges incurred solely for the purpose of a clinical research project must be charged to and paid for by the clinical research fund and may not be billed to other SCVMC funds nor to a third party governmental or private medical insurance program. All patient bills must conform to federal and state law.

Any personnel or space costs (e.g., research nurse, data entry, etc.) whose expense will be the responsibility of the County must be identified in the application and review process. For all County expenses, a funding source or an approved in-kind contribution must be identified.

Residual funds, funds remaining after payment of all the expenses for the study, may be used to fund future research projects, for the purchase of equipment or materials to be used by the department conducting the research, or for individual, divisional, or departmental educational activities unless the funding agency requires the return of all residual funds. The expenditure of those funds will be consistent with Federal, State and County policies. Use of residual funds will require a budget approved by the Department Chair, Chief Medical Officer, and Chief Financial Officer.
Labor

If the research study involves the use of non-County employed personnel on County premises, the Principal Investigator and Research Administration Director must ensure that such personnel satisfy all health, safety, and other related requirements outlined in County policies (e.g., health screening, and clearance, universal precautions, patient confidentiality) and that their behavior is consistent with SCVMC’s mission and values. In addition, the Principal Investigator will perform an appropriate screen of such personnel to ensure that none of the personnel is an excluded provider or has been charged with a healthcare offense. Use of non-County employed staff will be reviewed and approved by the appropriate department Chair and the Chief Medical Officer. If the research study involves use of volunteers as labor, those volunteers must go through Volunteer Services application and training processes and be approved by the Volunteer Services Manager.

Use of County personnel must be in compliance with County policies. County personnel may not receive payment or other remuneration for work on research project without prior approval of the appropriate Department Chairperson and Chief Executive Officer of SCVMC or Chief Medical Officer.

Equipment

Equipment used on SCVMC’s premises for direct patient care must comply with all SCVMC health and safety standards. Equipment owned by the sponsor or the third party administrator, which will be used in patient care areas, must be certified by SCVMC Biomedical staff prior to its use.

Formal Agreement

Prior to the commencement of a research project, the Principal Investigator will ensure that an approved agreement for that project is in place. SCVMC staff may seek funded grants in the following ways:

Researchers may directly apply for grants, which will be performed in accordance with a formal agreement between the County of Santa Clara and the grant sponsor, consortium, medical center, research organization or funding source. The Research Administration Director will assist the Principal Investigator to budget, negotiate and finalize the agreement. An approved standard agreement is available and should be used whenever possible to expedite the review process. The Chief Medical Officer or the Chief Executive Officer of SCVMC, County Counsel, Chief Financial Officer, and the County Executive must approve the agreement. Certain agreements may need to go to the Board of Supervisors for approval.

- A third party grant administrator (TPA) may act as the grant administrator if the third party has a contract with the County of Santa Clara permitting it to perform such functions for investigators performing research at SCVMC, including the receipt and disbursement of funds in a manner acceptable to the sponsor and to the County. The Principal Investigator must inform the Research Administration Director of the TPA who will financially manage the study funds.

Collaborative research with other research organizations or institutions is permissible if those organizations have an approved agreement with the County or with an approved TPA for that research.
Advertisements will be approved by the Research and Human Subjects Review Committee and will comply with all applicable rules and regulations.

**Required Approvals**

Each clinical research project involves a multi-stage review and approval process, which is described below. These reviews will be completed prior to submitting the research proposal budget to the sponsoring organization. The application will be submitted to either the Chief Medical Officer or the Chief Executive Officer of SCVMC for review and approval following approval by the Department Chairperson or Administrative Director, evaluation of impacted departmental resources and staff, coordination with departmental managers, pricing and budget preparation, and contract negotiations.

**Departmental Review**

<table>
<thead>
<tr>
<th><strong>Responsible Party</strong></th>
<th><strong>Action</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator</td>
<td>Submits research project application to Department Chairperson for review and approval.</td>
</tr>
<tr>
<td>Department Chairperson</td>
<td>Reviews application for conformance with SCVMC policies, the resource impact of the study on the department and for conflict of interest.</td>
</tr>
<tr>
<td>Department Manager</td>
<td>In cases in which the investigator is the Department Chairperson, the Vice-Chair of the Department or the Chief Medical Officer will review such applications.</td>
</tr>
</tbody>
</table>

**Research and Human Subjects Review**

**Committee Responsible Party** | **Action**                                                                                                                                 |
| Research Committee             | Reviews and renders decision based on the proposal’s scientific merit, methodology, patient/risk assessment and ethical issues. Such review will be conducted in accordance with the rules and procedures of the committee. |

**SCVMC Administrative Review**

<table>
<thead>
<tr>
<th><strong>Principal Investigator</strong></th>
<th><strong>Action</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Works with the Research Administration Director in the pricing and budget preparation, evaluation of impacted departmental resources and staff, coordination with departmental managers, contract negotiations and approval and completes the paperwork necessary to obtain administrative approval as follows:</td>
</tr>
<tr>
<td></td>
<td>1. Completes the administrative approval form and the conflict of interest/financial disclosure form and sends with the protocol, consent form, HIPAA form and the IRB letter of approval to the Research Administration Director.</td>
</tr>
</tbody>
</table>
2. Indicates on the schedule of events in the protocol what is standard of care and what is study related to determine the budget and what should be reimbursed to SCVMC for the study related services, visits, procedures, etc.

3. Cooperates and assists the Research Administration Director with the negotiation and approval of the Research Agreement, if SCVMC will financially manage the money or notifies the Research Administration Director of the third party administrator (TPA) who will be financially managing the grant monies.

<table>
<thead>
<tr>
<th>Responsible Party</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator</td>
<td>4. Works with Research Administration Director to discuss and coordinate the potential impact of the study on the department and its resources.</td>
</tr>
<tr>
<td></td>
<td>5. Works with Research Administration Director to budget the study, set up patient stipends, translation services, department services, pharmacy dispensing, Patient Business Services (PBS) accounts and trust funds.</td>
</tr>
</tbody>
</table>

1. Research Administration Director

Assists the Principal Investigator in the completion of the administrative approval paperwork.

2. Reviews the study related services the study would require with the Departmental Manager to determine if there are resources and staff to support the services needed by the study.

3. Works with the Principal Investigator to determine standard of care services versus study related services to budget and charge appropriately.

4. Reviews the proposal and its budget with department managers and administrators involved in providing support to the study or otherwise affected by the study’s activities.

The review focuses on the following:

- Cost of labor, materials, availability of space,
- Compliance with accreditation standards for all drugs being ordered, stored, labeled, dispensed or distributed by the Pharmacy,
- Availability of staff to perform tests required by the study,
- Availability of staff required for other required activities, such as data collection or clerical assistance, and for any implications on SCVMC services associated with
research which may exceed the usual and customary costs of providing care to patients or which might affect SCVMC’s ability to provide timely and appropriate care to other patients.

5. Works with Departments to price the services that are study-related.

6. Reviews or writes, negotiates and obtains County approval for the Board Delegated clinical research agreement between the County and the funding source/sponsor or approves Third Party Administrator who will financially manage the study.

7. Submits, on behalf of the Principal Investigator, the administrative approval forms and appropriate documents and contracts to the Chief Medical Officer or the Chief Executive Officer of SCVMC for review and final approval.

Chief Medical Officer or Hospital Director

Reviews and approves or denies the proposal.

Research Administration Director

Assist the Principal Investigator, upon approval of the clinical research study, with the following:

1. Sets up a PBS account number to be used for all study related items, including but not limited to tests (i.e.: lab, radiology, pharmacy set up and processing, clinic visits, etc.).

2. Sets up process for translations, patient stipends, equipment and labor needed for the study.

3. Sets up the trust fund, if appropriate, for financial management of the study with SCVMC finance.

4. Works with individual departments and their staff, including pharmacy, laboratory, radiology, inpatient services, translation services, cashier for patient stipends and vendors whose equipment is used in the study to ensure services are appropriately utilized and paid for by the study if study related.

5. Manages the trust fund set up for the Principal Investigator’s research study.

Issued: 07/01/99
Revised: 03/03/06, 6/25/09, 01/14/13, 04/13/16, 06/27/19
July 5, 2017

TO: SCVHHS Executive Management Group

FROM: René G. Santiago, Deputy County Executive/Director, SCVHHS

SUBJECT: Health Services Institutional Review Board (IRB) Policy

BACKGROUND:

Staff, administrators, private institutions, agencies and others periodically request that the Behavioral Health Services Department and Public Health Department support and/or allow a research and/or evaluation project that will involve staff, clients, case records, or other Department resources.

The United States Department of Health and Human Services requires that all agencies for which it funds research be in compliance with 45 CFR Subtitle A Part 46. This regulation mandates the creation and maintenance of an IRB to review proposals for research activities in order to protect human subjects from research risks. The Health Insurance Portability and Accountability Act (HIPAA) requires that all covered entities using and disclosing information for research purposes are subject to special requirements under the HIPAA regulations.

POLICY:

It is the ethical standard of the Santa Clara Valley Health & Hospital System (SCVHHS) that research and evaluation are necessary activities to further the goal of improved health prevention and intervention services for the citizens of Santa Clara County, and that all such research and evaluation must maintain the highest standards of confidentiality, protection of human subjects, and scientific conduct. Such activities will be encouraged and supported within the reasonable resources of the SCVHHS, but only as approved within the administrative structure and by the Health Services Institutional Review Board (IRB). The regulations of the United States Department of Health and Human Services regarding protection of human subjects will be followed for all research without regard for funding source. Furthermore, the Health Services IRB will adhere to the regulations of the Health Insurance Portability and Accountability Act (HIPAA) as they relate to research unless more restrictive local, state or federal laws supersede.

RESPONSIBILITIES:

The Public Health Department joins the Behavioral Health Services Department in supporting the Health Services IRB. (Valley Medical Center has its own IRB, separate from this policy). The function of the IRB is to provide initial and continuing review of research and evaluation proposals, in accordance with the ethical procedures of research and all applicable regulations that have a bearing on the...
following three aspects of each Department's services:

A. Client's welfare
B. Clients' rights
C. Confidentiality of patient information

The IRB has the authority to approve, disapprove, or recommend modification of those parts of research and evaluation proposals that lie within the function of the board.

The IRB also has the authority to determine whether patient information may be used and disclosed for research purposes with or without a patient authorization, including (a) determining when patient information is de-identified, and thus not subject to the HIPAA regulations; (b) determining when use or disclosure of patient information for the purpose of research does not require a written patient authorization because the researcher has entered a "data use agreement" and the information constitutes a "limited data set"; (c) determining whether patient information can be used or disclosed for research using the researcher's proposed patient authorization form; and (d) determining whether to approve an alteration to, or waiver of, otherwise required written patient authorization.

The Public Health Department Epidemiology Program Manager can provide the name and contact information of the current IRB Chairperson upon request.

MEMBERSHIP:

The IRB will consist of a minimum of five members; the Directors of each Department may appoint two members. Appointment of the Chairperson shall rotate among the three Departments. Secretarial support for the IRB will be supplied by the Department who has appointed the Chairperson. Terms of membership shall be two years, with the possibility of a second two-year term immediately following.

IRB membership will consist of persons of more than one professional discipline; at least one male and one female; at least one person of an ethnic minority group; and a public member who acts as an advocate for the vulnerable client groups served by the three Departments. The member should be of nonscientific background and not affiliated with, or part of the immediate family of, anyone who is affiliated with the three Departments.

IRB members should be of varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

All members shall complete the training for National Institutes of Health Employees for Human Subjects Research & Confidentiality (at http://phrp.nihtraining.com/users/login.php) and submit a copy of the Certificate of Completion to the Chairperson’s secretary.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. An IRB may
invite non-voting individuals with competence in special areas to assist in the review of issues requiring expertise beyond that available on the IRB.

Persons who wish to propose a research project, or an evaluation project that is not a part of regular clinical or fiscal management of the Departments, and which involves the use of clients (current or prior) as subjects shall proceed as follows:

A. Obtain written approval of the project from the manager of the service program involved in the research, from the director(s) of the Department(s) originating the request, and any other required Departmental approvals, and attach it to the proposal.


C. Complete and submit with the proposal the necessary HIPAA attachments (See Health Services IRB Guidelines).

D. Submit eight copies of the proposal to the Chairperson’s secretary. Proposals must be received 10 business days prior to an IRB meeting to be eligible for review at that meeting. IRB meetings will be held monthly for all months in which business comes before the Board. The proposal shall include the following information:

1. Title.
2. Statement of purpose, specific aims, and hypotheses of the study.
3. Location of study
4. Budget, budget justification, space needs, source of funding.
5. Expected duration of study.
6. Relevant literature or background information.
7. Research Plan: Methods, protocols, and procedures to be used to obtain information. Analyses to be performed.
8. Expectations regarding report(s) of results to Department(s) originating the proposal.
9. Procedures for protection of privacy, confidentiality, and health and safety. Each proposal should ensure:

a. Protection from potential risk
b. Equitable selection of subjects. Applicants should indicate specifically how subjects are initially chosen or recruited, describe the type of subject (e.g., patient with substance abuse, a particular ethnic group) and the reason for using this subject population, and indicate factors that are the basis for exclusion from the study.

c. Absence of coercion. The informed consent form should stress the voluntary nature of the client’s participation.
d. Appropriate data collection. Applicants should include an estimate of the total time required of each subject.

e. Privacy and confidentiality. Applicants should describe procedures such as coding or removal of identifiers, limitation of access to data, use of locked cabinets, password-protected computer accounts, etc.
f. Informed Consent procedures, which must include a direct question to the subject: "Do you have any questions about this study?" Consent form guidelines are available to applicants and incorporate HIPAA requirements related to patient authorization.

g. Benefits of the study outweigh any risks to subjects. Risk of injury includes physical, psychological, or social injury; a subject is at risk if a study increases the ordinary risks of daily life. Applicants should discuss the benefits, if any, for the subject and/or the contribution to knowledge that the study might make.

h. Precautions are taken for potential hazards.

10. All forms to be used with research subjects, including consents, questionnaire, and referral forms.

11. References

12. Resume/CV of Principal Investigator and co-investigators

13. Written approvals from Division Director, Director of Department, program manager if only one program is involved, and results from other IRB(s), if applicable.

14. If a copy of a grant application is used, a cover sheet giving the page numbers for each element in this outline

15. Signed SCVMC #6852-80, Confidentiality of Patient Information forms, for all researchers who will have access to confidential client information.


E. The IRB will review proposals to assure that: risks to subjects are minimized; risks are reasonable in relation to anticipated benefits to subjects and/or importance of expected knowledge to be gained; selection of subjects is equitable; informed consent is obtained and documented; data are monitored to ensure safety of subjects where appropriate; privacy and confidentiality are protected; and especially vulnerable subjects are additionally protected. The IRB may seek consultation as needed from outside its own membership for specialized information or expertise.

F. There are three types of review, Exempt, Expedited and Full Board.

1. **Exempt Review**—can be given if proposal meets exempt review guidelines authorized by 45 CFR 64.110 guidelines in that it has no human subjects and/or it is not defined as research.

2. **Expedited Review**—can be given if a proposal meets expedited review guidelines authorized by 45 CFR 46.110 for research involving no more than minimal risk to human subjects. Such proposals may be reviewed and approved by the IRB Chairperson, who may elect to include one IRB member in the review. If not so approved, the proposal will be forwarded for full board review.

3. **Full Board Review**—is required for all other proposals. Procedures are outlined below. Reviewed proposals will be assigned to one of four categories as follows

   a. Approved: The proposal is approved and released. The investigator may begin the study.
   
   b. Approved contingent upon specific modifications/clarifications: The investigator will be notified in writing as to the nature of the required modifications/clarifications. As soon as the investigator complies in writing with all requirements, a release will be issued and the investigator may begin the study.
c. Tabled: The Board required a significant amount of additional information and/or has a serious concern. The Chair, Vice Chair, and/or a member of the Committee may be assigned to discuss the proposal with the investigator.

d. Disapproved: If a proposal is disapproved, the investigator has the right to appeal to the Committee. Every attempt will be made to resolve the identified problem(s). When necessary, the Committee will seek consultation from nationally recognized experts in the field, other Committees, and the Office of Protection from Research Risks (OPRR). The committee, however, retains final authority over whether or not a proposal can be approved.

G. The IRB will review the proposal for adherence to HIPAA regulations, including:

1. Determine when patient information is de-identified and thus, not subject to the HIPAA regulations. See 45 CFR 164.514(a)-(c).
2. Determine when patient information is used or disclosed for research using a “limited data set” if a “data use agreement” has been entered. See 45 CFR 164.514(e).
3. Determine whether the patient authorization form is appropriate. See 45 CFR 164.508(b)-(c).
4. Determine whether any requested waiver or alteration of patient authorization should be approved. See 45 CFR 164.512(f).

The IRB will document the decision regarding de-identification of patient information, patient authorization, or waiver thereof, consistent with HIPAA regulations, and provide said documentation to the researcher.

H. A majority of the IRB present will constitute a quorum for conducting business if at least one public member is present. A majority vote of those present will be required for approval, or for approval subject to required modifications of any proposal. Along with any approval, the IRB will specify frequency of re-review (at least annually). When applicable, the Department of Health and Human Services shall be notified of the results of the review within their required time limits. The chairperson of the IRB will provide the Director(s) of the originating Department(s) with the results of review and a written recommendation regarding approval of each proposal within 10 days of review. Each proposal requires the prior approval of the Director(s) of the Department(s) that would be involved in the research.

Following initial approval, it will be the responsibility of the researcher to provide the IRB with an interim report, at the interval specified by the IRB, on the progress of the study, any untoward outcomes, and documentation of compliance with informed consent procedures. The IRB may ask for this same information at any time it deems appropriate. In addition, it will be the responsibility of the researcher to promptly report to the IRB any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Research and Evaluation Policies of the SCVHHS or the determinations of the IRB. The IRB will handle any complaint concerning the conduct of approved research and evaluation projects by immediately bringing the complaint to the attention of the Principal Investigator of the project, and by re-reviewing the project if substantial grounds are found for doing so.
WAIVER OF IRB JURISDICTION:

For federally-funded or non-federally funded research, the Health Services IRB may enter into a joint review arrangement, rely upon the review of another qualified IRB such as a central or commercial IRB, or make similar arrangements for avoiding duplication of effort. Such instances typically involve oversight of a single project, such as a multi-site study using a commercial IRB where an agency under the jurisdiction of the Health Services IRB is one of many sites. When the Health Services IRB waives jurisdiction to rely on the oversight and continuing review of an external IRB, a written agreement among the involved institutions will be required, regardless of whether they maintain FWAs, under which the respective responsibilities of the two organizations will be described. An example of such an agreement is provided below (Institutional Review Board Authorization Agreement). The Health Services IRB can make exceptions to this requirement on a case-by-case basis, for example, for individual requests for review of medical records as part of an external research study funded by a public health agency for the purposes of quality assurance or health outcomes. If the Health Services IRB declines to approve a waiver of IRB jurisdiction, the IRB Chairperson will so notify the requestor and/or outside entity responsible for the research study. If the Health Services IRB recommends approval, the IRB Chairperson will arrange for the written agreement to be executed. A sample Institutional Review Board Authorization Agreement can be found here: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html.

Attachments:
- Attachment A—Guidelines for Submissions to Santa Clara County Health Services Institutional Review Board (IRB)
- Attachment B—Consent Form Guidelines
- Attachment C—Guidelines for Renewal Application to Santa Clara County Health Services Institutional Review Board

Issued: 01/27/2011
Revised: 07/05/2017
GUIDELINES FOR SUBMISSIONS
TO SANTA CLARA COUNTY HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD (IRB)

REQUIRED PRE-APPROVAL:

Letter of approval from the Administrator/Manager of the program you wish to study; and Director (or his/her designee) of the Department(s) in which the study is to take place.

SUBMITTING RESEARCH PROPOSAL:

1. All research proposals are to be submitted to Pamela Stoddard, Ph.D., Chairperson, Institutional Review Board at Pamela.Stoddard@phd.sccgov.org. Her phone number is (408) 792-5588. She will inform and notify the researcher(s) of the research proposal’s IRB application status.

2. The review of the research proposal can take one of the following forms:

   a) Exempt from IRB: As defined in 45CFR46.101.b.1-6. Please click the link below.
      http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

   b) Expedited IRB: Eligible for and approved under expedited review criteria (45CFR46.110a-b); IRB members shall be advised on research proposals approved under expedited review (45CFR46.110c).

Convened IRB: Submission & IRB Procedures may be found below. Only the full IRB can disapprove a research proposal (45CFR46.110b).

3. Research which is to take place at Santa Clara Valley Medical Center Emergency Psychiatric Services (EPS) or Barbara Arons Pavilion (BAP) psychiatric inpatient units, or other hospital sites will require concurrent review by the Research & Human Subjects Review committee (Kimberly Bellon, interim IRB Administrator, Old Main Building, Room 7C056, 751 South Bascom Avenue San Jose, CA 95128. Email: Kimberly.Bellon@hhs.sccgov.org). Phone: 408-885-3115.

4. Researcher(s) must complete the National Institutes of Health (NIH) web-based training course “Protecting Human Research Participants,” and provide a copy of the certificate of completion. Course registration and training may be found at: http://phrp.nihtraining.com/users/login.php.

5. Additional information: http://www.hhs.gov/ohrp/index.html
IRB PROPOSAL REVIEW SUBMISSION PROCEDURES & PROCESS:

Approval by the Santa Clara Valley Health & Hospital System, Health Services Department Institutional Review Board is required for all proposed research projects involving human subjects within Santa Clara County.

Submit eight (8) copies of proposal, questionnaire(s), informed consent form(s) and approvals to Pamela Stodard, Ph.D., Health Services IRB Chairperson, Public Health Department, 976 Lenzen Avenue, San Jose, CA 95126 or one copy via email to Pamela.Stodard@phd.sccgov.org. If the study has been submitted to any other IRB, include documentation of the results of that review. In addition, submit a copy of the certificate received from the NIH course and signed SCVMC #6852-80 Confidentiality of Patient Information forms for all researchers who will access confidential information.

Proposals must be received ten (10) business days prior to an IRB meeting, held the second Tuesday of each month. Contact Pamela Stoddard, Ph.D., at Pamela.Stodard@phd.sccgov.org or (408) 792-5588 to advise of your (Principal Investigator and/or project manager) schedule availability to attend a review and of any deadline related to your proposal. You will be notified of the time, date, and place for the review.

THE IRB REVIEW

The IRB will ask questions about the proposal and related implementation, and determine if changes need to be made or if additional materials or consents need to be submitted for review prior to official IRB approval/disapproval. The guidelines followed are contained in 45 CFR 46. There are special regulations pertaining to prisoners, children, and pregnant women. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

AFTER THE REVIEW

Written IRB approval/disapproval will be sent to the relevant investigators/institutions by the IRB chair, Pamela Stodard, Ph.D., within five (5) business days of completion of the IRB meeting, and will follow resolution of all issues or change requests made by the IRB, which may require further review at a future meeting. This written communication will include, as appropriate, a determination of which research proposals require more often than an annual IRB review. One copy of any changed materials or consents requested by the IRB should be submitted to the Chairperson, for the IRB files.

DOCUMENT RETENTION

Copies of all research proposals reviewed by the IRB, scientific evaluations (if any) that accompany the proposals, records of continuing review activities, copies of all correspondence between the IRB and the research investigators, statements of significant new findings provided to subjects, shall be retained for at least three (3) years after completion of the research. All records
PROPOSED FORMAT

The following outline may be used for your submission. If you use another format (e.g. grant application, another IRB proposal format, etc.), please review to ensure that you have covered all elements we mention. Please use language that a lay person is likely to understand.

1. **Title of research project**, Names of Principal Investigators and Co-Investigators, mailing address, email address, and phone numbers.

2. **Purpose, Significance, Specific Aims, and Hypotheses**
   There should be a brief statement of the intent and specific aims of your proposed research project. Explain the significance and potential importance of your proposed project. State your hypotheses.

3. **Location(s) of the Study**.

4. **Budget or Budget Estimate; Budget Justification, Space Needs, Source of Funding**.

5. **Expected Duration of the Study**.

6. **Background**
   Describe pertinent background information and relevant experimental and/or clinical findings.

7. **Research Plan**
   Describe in detail your research procedures, methodology, data to be collected, and relevant data analysis plans.

8. **Expectations Regarding Report(s) of Result(s) to the Department(s)**.

9. **Procedures for protection of privacy, confidentiality, and health and safety. Each proposal should ensure:**
   a. Protection from potential risk.
   b. Equitable selection of subjects.

   Applicants should indicate specifically how subjects are initially chosen or recruited, describe the type of subject (e.g., patient with substance abuse, a particular ethnic group) and the reason for using this subject population, and indicate factors that are the basis for exclusion from the study.
c. Absence of coercion.

The informed consent form should stress the voluntary nature of the client’s participation.

d. Appropriate data collection.

Applicants should include an estimate of the total time required of each subject.

e. Privacy and confidentiality.

Applicants should describe procedures such as coding or removal of identifiers, limitation of access to data, use of locked cabinets, password-protected computer accounts, etc.

f. Informed Consent Procedures

This must include instructions that the interviewer directly asks the subject: “Do you have any questions about this study?” Consent form guidelines are available to applicants that incorporate HIPAA requirements (see Attachment B Consent Form Guidelines).

g. Benefits of the study outweigh any risks to subjects.

Risk of injury includes physical, psychological, or social injury; a subject is at risk if a study increases the ordinary risks of daily life.

1. DHHS regulations define a subject at risk as follows: “... any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.”

2. Risk versus Benefit Ratio -- in order to justify approval of the study, it is essential that there be an appropriate risk/benefit ratio. The proposal should include a statement of the potential benefits of the project. It should also describe potential risks--physical, psychological, and social. Whenever possible, include statistical incidence of complications and the mortality rate of proposed procedures. If drugs are to be used, indicate status of the drug (e.g., investigational, experimental, etc.), the dosage, and provide data on toxicity and reactions. In describing risks, please use terms
and comparisons, which are meaningful to persons unfamiliar with medical terminology.

h. Precautions are taken for potential hazards.

10. Other Relevant Information

Include any other information the IRB should have in order to assist it in fulfilling its responsibilities as indicated on the following page.

ADDITIONAL IRB SUBMISSION REQUIREMENTS:

11. Consent Forms

See separate Consent Form Guidelines. State how informed consent will be obtained.

a. The consent form may be either of the following: Written or Oral.

b. A written informed consent document that embodies the elements of informed consent, as described above. This written informed consent form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

c. A short form written informed consent document, stating that “the elements of informed consent (as described above) have been presented orally to the subject or the subject's legally authorized representative.” When this oral method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be orally said to the subject or the representative. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

12. Questionnaires, Record Surveys, etc.

Please attach a complete set of questionnaires, record surveys, etc., proposed for the research.

13. References

List pertinent references.

14. Resume or curriculum vitae of principal investigator and co-investigator.
15. Attach the written approvals from the program manager and department director, and results from other IRB(s), if applicable.

16. If a copy of a grant application is submitted, please include a cover sheet giving the page numbers for each element in this outline.

17. Complete and attach the necessary HIPAA forms and documentation consistent with the SCVHHS policies:
   a. If using a Limited Data Set, Data Use Agreement, see also HHS Policy #585.14 Creating and Disclosing or Using Limited Data Sets from Protected Health Information.
   b. Provide documentation explaining Research Protocol Development, if appropriate. [(1) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research; (2) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and (3) The protected health information for which use or access is sought is necessary for the research purposes.]
   c. Provide documentation explaining Research on Decedents, if appropriate. [(1) Representation that the use or disclosure sought is solely for research on the protected health information of decedents; (2) Documentation, at the request of the covered entity, of the death of such individuals; and (3) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.]

OBLIGATIONS OF PRINCIPAL INVESTIGATOR DURING RESEARCH PERIOD

Any change in the research project which significantly alters the procedures or risks must be submitted for review by the IRB prior to the implementation of such change, including a change in investigators. Any complications should be reported at once to the IRB before continuing with the research. Inasmuch as the IRB includes both professionals and lay persons, proposals should be written in a language that can be understood by all IRB members.

All research projects and activities must be reviewed and re-approved: 1) At the beginning of a funded study (submit all materials as revised to obtain funding); and 2) At the end of the first year or end of the study, whichever comes first (submit findings or describe progress of study, problems relating to the protection of subjects, confidentiality, safety, design changes, etc). IRB approval of any project is for a maximum period of one year. As a courtesy, the Chairperson will contact the Principal Investigator about two months before the end of the proposal year to inquire if the Principal Investigator wishes to renew the project. Please refer to the Guidelines for Renewal of Application.

At the end of the study, the investigator is to provide the IRB with a report of the findings or copy of any published articles.
RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD

1. To determine if subjects are placed at risk and, if risk is involved, whether the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

2. To ensure that risks are minimized.

3. To adequately protect the rights and welfare of subjects.

4. To ensure that all qualified subjects are selected in an equitable manner for inclusion in the study.

5. To ensure that appropriate informed consent is obtained and documented.

6. To ensure that each subject’s privacy, safety, and confidentiality are maintained throughout a study consistent with HIPAA requirements or more restrictive federal, state or local requirements.

7. To provide documentation of HIPAA review related to research. See HHS Policy#585.03 Uses and Disclosures of PHI for Research.

8. To review for appropriate use of animals.

9. To review project activity at timely intervals.
INFORMED CONSENT FORM GUIDELINES

The subject’s consent form format suggested below is sufficiently flexible to cover the majority of research studies, and is designed to comply with federal regulations and Chapter 1.3 of the California Health & Safety Code. The format may be modified or expanded depending upon the nature of the particular study, but the consent form is to contain all of the following elements. Existing consent forms, regardless of approval elsewhere, will not be accepted unless they include these elements. The information that is given to the subject or the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence (45CFR46.116).

*************************************************

SUBJECT’S INFORMED CONSENT

TITLE OF RESEARCH PROJECT:

PRINCIPAL INVESTIGATOR:
Include your name, academic credential, job title, department, institution, mailing address, email address, and telephone number.

CO-INVESTIGATOR(S) (if applicable): Include name, academic credential, job title, department, institution, mailing address, email address, and telephone number.

PURPOSE: Include a statement to the effect that the study involves research. Explain the purpose of the research and the expected duration of the subject’s participation. State in simple terms why the patient/subject is being invited to participate in the research (45CFR46.116.a.1). State clearly which individuals are not eligible to take part in the study (e.g., pregnant women), and, if appropriate, indicate the approximate number of subjects that will be involved in the study (45CFR46.116.b.6).

PROCEDURE: Give a clear explanation, in non-technical language, of the procedures to be followed and identify procedures which are experimental (45CFR46.116.a.1). If the study is double-blind and/or involves placebos, or if subjects are to be randomized, this must be stated and treatment variables explained. If blood will be drawn, state the number of punctures and amounts drawn (convert to approximate household measures).

DRUG(S) TO BE USED: If applicable, identify by generic name, common brand name, and manufacturer. State whether the drug is investigational or has been approved for general use by the FDA. If a drug is to be given, as far as possible, the dosage, length of administration, etc., should be indicated. (The subject must be informed that he or she may not get the active
medication if the study is so designed. If the study is short-term and involves a drug not yet available on the market such that supplies will be cut off after conclusion of the trial (even though benefit may have occurred), this must be stated.

**RISKS/DISCOMFORTS:** Explain the risks, discomforts, side effects, etc., which might reasonably be expected to occur (45CFR46.116.a.2). If a drug is involved, the description of possible side effects should be limited to those that might occur at the doses to be used in the study. If appropriate, include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable (45CFR46.116.b.1).

If appropriate, include anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent (45CFR46.116.b.2).

This section must be clearly understood by a lay person at her/his appropriate level of understanding.

**BENEFITS:** Describe any benefits which might accrue to the subject from his/her participation in the project (45CFR46.116.a.3). Benefits to mankind, such as better understanding of the disease under study, may also be included.

The following statement must be included in all consent forms: “We cannot and do not guarantee or promise that you will receive any benefits from this study.”

**ALTERNATIVES:** If the proposal involves the treatment of a condition, explain the other treatment options or alternative procedures (if any) which are available and might be advantageous to the subject (45CFR46.116.a.4). If the alternative is “conventional” therapy, this must be stated and described, including the risks and benefits of all other alternatives.

**CONFIDENTIALITY:** Describe how confidentiality of records identifying the subject will be maintained (45CFR46.116.a.5). If there is to be any personal disclosure, it should be described.

A statement about protection of personal health information must be included if any personal health information is gathered during the study (from the client or from records). Consult your institution’s HIPAA policy and use their recommended wording if available. Following is an example of the type of statement which must be included:

By signing this document you are permitting _____ (PI and institution) to use the personal health information collected about you for research purposes. The information we will use includes the information from the questionnaires we will be asking you to complete [and supporting information from your medical records, results of laboratory tests, and both clinical and research observations made during your participation in the research. The information may not be disclosed for a purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. Your name will never appear in reports. The research will report information about groups of people, not individuals.

If personal health information gathered during the study (from the client or from records) will be divulged to others involved with the study (such as research collaborators in other institutions,
contract organizations involved in the interviewing process or data coding, FDA or other governmental or other funding agencies), these individuals and firms must be named in the informed consent document. Include specific language on what information will be disclosed and how you will assure that these external organizations will treat the data in a confidential manner. However if they are not covered by a Certificate of Confidentiality or other assurance that information is not protected by law, the following statement should be included.

While they normally protect the privacy of the information, they may not be required to do so by law.

If the study involves testing of a new drug/device, the following statement must be included:

"The United States Food and Drug Administration (FDA) and (INSERT NAME OF SPONSOR) may inspect and copy your medical records which are related to the study. The results of the study will be reported to the FDA, (INSERT NAME OF SPONSOR), and perhaps other regulatory agencies. This information will be treated in a confidential manner to the extent permitted by law, and in the event of any publication regarding this study, your identity will not be disclosed."

If a client is conserved or has a legal guardian, the guardian or conservator must sign the consent form. If so, include the following statement: I give permission to discuss with my legal guardian my participation in this study: ( ) YES ( ) NO

COSTS: Include a statement regarding any additional costs to the subject that may result from participation in the study. If subjects are to be offered cash payments as an inducement to participation, a clear statement in the consent form of the payment policy under various contingencies will avoid confusion and misunderstanding.

Suggested Wording: "There will be no charge to you for participating in this study. If you decide to participate, you will be paid $20 for your time and inconvenience every time that you are asked to visit the doctor’s office. The drug (INSERT NAME), all examinations, x-rays, and lab tests that are required as part of the study will be provided at no cost to you. Costs related to your routine medical care and not connected with this study will remain your responsibility."

If subjects involved in a research project will undergo testing or procedures that they would otherwise not undertake, and if the subjects will be expected to pay for these studies, there is obvious financial impact on the subject that constitutes a risk and must be mentioned in the consent form (45CFR46.116.b.3).

Suggested Wording: "You will be responsible for all costs related to your treatment in this study. These costs include: (INSERT APPLICABLE PROCEDURES AND ANTICIPATED COSTS). You should contact your insurance carrier to find out the extent of your coverage for these procedures. If you are not protected by insurance and costs would create a financial burden, you should discuss possible alternatives with (INSERT NAME OF PHYSICIAN/INVESTIGATOR)."
If applicable (i.e., in studies of drugs): Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

COMPENSATION: For research involving more than minimal risk, include an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained (45CFR46.116.a.6).

In accordance with Department policies, the following “compensation statement” must be included in all consent forms of projects involving more than “minimal risk.” As defined in the Code of Federal Regulations 45 CFR 46.102 (i), “minimal risk” means that risks of harm anticipated in the proposed research are not greater (considering probability and magnitude) than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests:

“It is the policy of the Alcohol & Drug, Mental Health, and Public Health Departments not to provide reimbursement for medical care or any form of compensation in the event of physical or psychological injury in the course of this research project. If injury does occur, I will immediately contact (INSERT NAME OF PHYSICIAN/INVESTIGATOR) to determine what alternatives for care are available.”

THE REMAINDER OF THE CONSENT FORM SHOULD BE COPIED AS FOLLOWS, BUT MAY BE ALTERED DEPENDING ON THE TYPE OF STUDY AND RISKS INVOLVED:

SUBJECT/PATIENT RIGHTS: Your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits and/or services to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation in the project at any time without prejudice to you or effect on your participation in county health programs. To do so send a written revocation of your authorization to ________________ [Name and address of principal investigator]. [If applicable] The authorization to continue collection of the supporting medical information expires at the end of the research study.

Any discomforts and inconveniences involved in this research study should have been explained to you. [AT THIS TIME THE INTERVIEWER MUST ASK: “Do you have any more questions about this study? I can answer them now.”] If you have additional questions, you may contact (INSERT NAME, TELEPHONE NUMBER, AND EMAIL ADDRESS OF INVESTIGATOR) or one of his/her associates at (INSERT NAME, TELEPHONE NUMBER, AND EMAIL ADDRESS). If you are not satisfied with the manner in which this study is being conducted, you may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. Pamela Stoddard, Ph.D., IRB Chairperson, may be reached at (408) 792-5588 or Pamela.Stoddard@phd.scgov.org or by writing to the Institutional Review Board, c/o Public Health Department, 976 Lenzen Avenue, San Jose, CA 95126.
WITNESSING AND SIGNATURES: Your signature indicates that the nature, demands, risks, and benefits of the project have been explained to you, and that you understand what your participation involves. Furthermore, you understand that you are free to ask questions and withdraw from the research at any time without affecting your health care. You have been offered a copy of the signed and dated consent form[ and of the Patient’s Bill of Rights (if applicable)]. You hereby voluntarily consent and offer to take part in this study.

______________________________________________  ____________________________
Signature of Subject                            Date Signed

______________________________________________  ____________________________
Signature of Witness                            Date Signed

______________________________________________  ____________________________
Signature of Parent/Legal Guardian                Date Signed  
(if applicable)

______________________________________________  ____________________________
Person obtaining consent                         Date Signed  
(print)
GUIDELINES FOR RENEWAL APPLICATION  
TO SANTA CLARA COUNTY HEALTH SERVICES  
INSTITUTIONAL REVIEW BOARD (IRB)

Periodic review and re-approval of research projects is required by the Institutional Review Board (IRB) on the following schedule: 1) At the beginning of a funded study (submit all materials as revised to obtain funding), and 2) At the end of the first year or end of the study, whichever comes first (submit findings or describe progress of study, problems relating to the protection of subjects, confidentiality, safety, design changes, etc.).

Please include the following:

1. Title of research, names of Principal Investigators and Co-Investigators, mailing address, email address, and phone numbers.
2. A statement that the study involves research.
3. An explanation of the purposes of the research.
4. The expected duration of the subject's participation.
5. A description of the procedures to be followed.
6. Identification of any procedures which are experimental.
7. A description of any reasonably foreseeable risks or discomforts to the subject, including any changes in anticipated risks.
8. A description of any benefits to the subject or to others which may reasonably be expected from the research, including any changes in anticipated benefits.
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
10. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
11. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
12. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
13. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
14. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
15. Any additional costs to the subject that may result from participation in the research.
16. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
17. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided.
to the subject.
18. The approximate number of subjects involved in the study, Total to date, total since last IRB approval.
19. Source of funding and proposed budget for next research period.
20. Any relevant information from other studies (i.e., results of reviews by other Review Boards).
21. A discussion of any side effects or problems encountered during the period covered by this report. (Note: If a report was filed with the IRB, it should be indicated).
22. A summary of any modifications in the protocol which were made during the previous year.
23. A short statement on the research plan for the coming year, including discussion of any proposed modifications of the approved protocol and/or consent form.
24. Previously approved questionnaires or other study instruments should be submitted ONLY if there were changes during the last year of the study or modifications are proposed for the coming year. Any new study instruments should be submitted.
25. The consent form may be either of the following: Written or Oral.
26. A written informed consent document that embodies the elements of informed consent, as described above. This written informed consent form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
27. A short form written informed consent document, stating that the elements of informed consent (as described above) have been presented orally to the subject or the subject's legally authorized representative. When this oral method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be orally said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
28. Even without significant changes to a protocol or informed consent document, periodic reiteration or affirmation of consent is often a good idea, especially if the study takes place over a long period of time or is particularly complex. Minor changes, such as correcting non-substantive typographical errors in the consent document, would not generally rise to a level requiring repeating the consent process. Otherwise, **it is appropriate to periodically repeat the informed consent process.**
29. If appropriate, the IRB will determine and communicate with investigators/institutions which research projects would need verification that no material changes have occurred since the previous IRB review, from sources other than the investigators.
Instructions for the 2019 Administrative Approval Form for Research

The new Word version of the Administration Approval form has pull down boxes and fill in text boxes. This should be an improvement over the Excel-based form. Please use DocuSign for signatures, whenever feasible.

Page 1

Project Director/Principal Investigator: This individual needs to be on staff at SCVMC/OCH/St. Louise. Sub-I’s do not need to be on staff.

Please include an attached protocol for the study. You can use the same protocol description that you submit to the IRB.

Desirability: This section details how the study would help meet strategic goals or fulfill the mission of SCVMC/OCH/St. Louise. Possibilities may include:

- Research may fulfill a certification/publication requirement (Level 1 Trauma, Nursing, Oncology, etc.)
- Research may be part of a required resident project
- Research may improve quality and safety
- Research may improve care coordination
- Research may improve patient experience
- Research may improve access or capacity
- Research may improve cost effectiveness
- Research may engage and/or develop staff

Feasibility: What additional departments will be involved (nursing, pharmacy, lab, radiology)? Will there be new space requirements, equipment, or supplies?

Page 2

Viability: If this is a funded study, please include or attach a budget. All studies involve some cost to the institution (staff time, facilities, use of equipment, HealthLink, attorney review for executed agreements, etc.). If the project is funded, please remember to include an overhead/indirect rate of 19.6%. This is the latest estimate of what the additional cost is to conduct research at SCVMC/OCH/St. Louise. The cost for IRB review is not captured in our indirect rate. Please budget for the IRB initial review ($2500), modifications ($750), and ongoing annual review ($1000). If a study is funded, these costs are not waived.

Page 3

Please include all staff involved and the time required for the study, even if you feel that the study is conducted "on your own time/on allocated non-clinical time". Please indicate whether you are asking for a release from clinical time, using administrative time, or working on your own time/allocated non-clinical time. For students (medical, nurse practitioner, etc.), please indicate their required time for the
study as being on “student volunteer time.” For residents and fellows, please indicate their required
time for the study as being on “residency/fellowship training time.”

Please include cost estimates of equipment and non-standard of care procedures for all studies (funded
or unfunded). If you are unaware of the cost information, Research Administration can find it, but it may
take additional time.

Page 4

Principal Investigator Acknowledgement: Please note that the responsibilities include that of the
conduct of any non-SCVMC/OCH/St. Louise staff or any volunteers that are employed to work on the
project. External volunteers and external research staff require a separate onboarding process (either
through the Research Administration office or through Volunteer Services) if they are on campus or
working with protected health information.

Page 5

Signee Acknowledgements: Department Chair and other signatures. Please use DocuSign whenever
feasible.

Page 6

Signee Acknowledgements: Other Department Chair signatures. Please use DocuSign whenever
feasible.

Page 7

Executive Signatures: Research Administration will obtain these signatures when necessary. These
signoffs are only necessary when the project is funded.
SCVMC/OCH/St. Louise Clinical Research Administrative Approval Form
To be completed by the Principal Investigator and/or the Administrative Representative.

Study Name: Click here to enter text.

Date: Click here to enter text.
Project Director/PI Name: Click here to enter text.
PI Title: Click here to enter text.
PI Department: Click here to enter text.
PI Email: Click here to enter text.
PI Phone: Click here to enter text.

Is there a Sub-I? Choose an item.
Sub-I Name: Click here to enter text.
Sub-I Title: Click here to enter text.
Sub-I Department: Click here to enter text.
Sub-I Email: Click here to enter text.
Sub-I Phone: Click here to enter text.

Have you received IRB approval for this project? Choose an item.
IRB #: Click here to enter text.

Please include the full protocol when submitting this form, with the following sections:

If the protocol changes during the grant period, Research Administration must be notified and will make the decision whether to seek Administrative Re-approval due to these changes.

Desirability:
How does this study align with the strategic goals and roadmap of County of Santa Clara Health System?

Feasibility:
What space, staff, equipment, supplies, pharmaceuticals, IT, etc., will be used?
Which stakeholders or departments will be impacted?
STUDY RISKS
Does the study involve any potential or actual:

- Vulnerable patient populations? Choose an item.
- Non-compliance with any County or SCVMC/OCH/St. Louise policy? Choose an item.
- Deviation from the quality goals of SCVMC/OCH/St. Louise? Choose an item.
- Deviation from the standard of care? Choose an item.
- Negative impact on patient care? Choose an item.
- Need for any additional or modification of facilities, equipment and supplies? Choose an item.
- Need for modification of HealthLink or other medical record? Choose an item.
- External research staff (non-County employees), including PI’s, coordinators, assistants, residents and students? Choose an item.
- Financial relationship between any research staff member and funding source? Choose an item.
- Any other risk not listed? Choose an item.
- If you have answered yes to any of the above questions, please explain in detail: Click here to enter text.

VIABILITY AND FINANCIAL REVIEW
Please include a complete budget for this project including all study revenue and expenses.

Study Revenue:

- Award Type: Choose an item.
- Lead Institution: Click here to enter text.
- Funding organization or source: Click here to enter text.
- Is there any additional funding sources? Choose an item.
- Is there a third party administrator? Choose an item. If yes, who?
- Total funding amount for this study: Click here to enter text.
- Total funding amount received by SCVMC/OCH/St. Louise for this study: Click here to enter text.
- Will this project recover full clinical costs (staff/procedures)? Choose an item.
  If no, explain why: Click here to enter text.
- Will this project include funds to pay for the IRB? Choose an item.
- Will this project include the 19.6% indirect rate for SCVMC/OCH/St. Louise? Choose an item.
- Budget Period: Click here to enter a date. - Click here to enter a date.
- Sponsor Address and Contact Person if applicable:
  Click here to enter text.
  Click here to enter text.
  Click here to enter text.
  Click here to enter text.

Study Expenses:

- Are any other departments collaborating on this study? Choose an item.
- If yes, what departments?.Click here to enter text.
Personnel Costs:

<table>
<thead>
<tr>
<th>Staff Name</th>
<th>Staff Title</th>
<th>Hours/Week</th>
<th>Number of Weeks</th>
<th>Type of Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Choose an item.</td>
</tr>
</tbody>
</table>

**Equipment:** Please detail the cost of purchasing any new material support for the study (equipment, supplies, software, etc.).

<table>
<thead>
<tr>
<th>Needed Item</th>
<th>Purpose</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Combined personnel and equipment costs for this project are:** Click here to enter text.

Please use this section to list all procedures, visits and/or tests done for research only and not standard of care. Please detail these procedures, their frequency and the charges associated.
As the PI of this research study, I understand that I am responsible for:

- Maintaining the standards of professional and ethical conduct in all phases of this project;
- Reporting any research misconduct to the IRB, Research Administration and the Department Chair;
- Listing my affiliation with SCVMC/OCH/St. Louise when research results are published and presented;
- Providing Research Administration with any changes to the research protocol, which may result in the need for Administration Re-Approval;
- The conduct of any external staff that are employed to work on this project;
- Validating any patient charges through HealthLink;
- Understanding County of Santa Clara Health System research policies and procedures (638.0, 638.1, 638.2);
- Understanding the external volunteer/research assistant onboarding process;
- Notifying Research Administration when the project is completed and results in dissemination;
- Completing a Research Administration annual project review as requested;
- Notifying my Department Chair of any costs incurred by County of Santa Clara Health System because of this project;
- Having the proper credentials and privileges from County of Santa Clara Health System if a clinical intervention is being performed;
- Understanding that Research Administration may revoke their approval for the project if time commitment and resource use change from the original approval form;
- Understanding the cost recovery payment system if I am utilizing staff and services outside of my own department.

Signature/Date
Signee Acknowledgements:

By signing below, I agree that I:

- Have thoroughly reviewed and understand the study protocol and budget;
- Understand, if applicable, the shortage incurred by my cost center for physician time as indicated on page 2 for funded or unfunded projects;
- Understand the impact this project will have on my department;
- Have had all my questions sufficiently answered regarding this study;
- Am committing the needed resources from my department to this research study;
- Am aware that the clinicians/staff in my department and myself cannot independently negotiate a compensation rate with the study sponsor (if applicable)
- Am supportive of my department’s participation in this project.

It is the responsibility of the PI to obtain the below signatures (as applicable) on pages 5 and 6 prior to form submission. These signatures indicate the signee approves reimbursement and/or staff and department participation. Research Administration may request additional sign-offs if determined to be necessary.

<table>
<thead>
<tr>
<th>Chair and Medical Director Sign-offs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department Chief (when applicable)</td>
</tr>
<tr>
<td>Signature/Date</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Signature/Date</td>
</tr>
</tbody>
</table>
Signee Acknowledgements:

By signing below, I agree that I:

- Have thoroughly reviewed and understand the study protocol and budget;
- Understand, if applicable, the shortage incurred by my cost center for physician time as indicated on page 2 for funded projects;
- Understand the impact this project will have on my department;
- Have had all my questions sufficiently answered regarding this study;
- Am committing the needed resources from my department to this research study;
- Am supportive of my department’s participation in this project.

Any department indicated on Page 2 as a collaborator must sign below. Research Administration may request additional sign-offs, if determined to be necessary.

<table>
<thead>
<tr>
<th>Ancillary Services Chair/Medical Director Sign-offs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
</tr>
<tr>
<td>Signature/Date</td>
</tr>
<tr>
<td>Department:</td>
</tr>
<tr>
<td>Signature/Date:</td>
</tr>
<tr>
<td>Department:</td>
</tr>
<tr>
<td>Signature/Date</td>
</tr>
</tbody>
</table>
Research Administration staff will determine the necessity of signatures below and obtain them as needed.

<table>
<thead>
<tr>
<th>Department Physician Executive</th>
<th>Chief Financial Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Signature/Date</strong></td>
<td><strong>Signature/Date</strong></td>
</tr>
<tr>
<td></td>
<td>John Cookingham</td>
</tr>
<tr>
<td>Chief Nursing Officer</td>
<td>Chief Operating Officer</td>
</tr>
<tr>
<td><strong>Signature/Date</strong></td>
<td><strong>Signature/Date</strong></td>
</tr>
<tr>
<td>Jill Sproul, RN</td>
<td>Benita McLarin</td>
</tr>
<tr>
<td>Interim Chief Medical Officer</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td><strong>Signature/Date</strong></td>
<td><strong>Signature/Date</strong></td>
</tr>
<tr>
<td>Phuong Nguyen, MD</td>
<td>Paul Lorenz</td>
</tr>
</tbody>
</table>
INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING POLICIES AND PROCEDURES
FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

SANTA CLARA VALLEY MEDICAL CENTER
O'CONNOR HOSPITAL
ST. LOUISE REGIONAL HOSPITAL

Revised: 5/6/2019
Approved by Enterprise Medical Executive Committee: 5/23/2019
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Identity</td>
<td>Page 4</td>
</tr>
<tr>
<td>II.</td>
<td>Statement of Ethical Principles</td>
<td>Page 4</td>
</tr>
<tr>
<td>III.</td>
<td>Institutional Policy</td>
<td>Pages 4-5</td>
</tr>
<tr>
<td>IV.</td>
<td>Objectives</td>
<td>Page 5</td>
</tr>
<tr>
<td>V.</td>
<td>Jurisdiction and Authority of the IRB</td>
<td>Page 5</td>
</tr>
<tr>
<td></td>
<td>A. Organizational Position of the IRB</td>
<td>Page 5</td>
</tr>
<tr>
<td></td>
<td>B. Jurisdiction of the IRB</td>
<td>Pages 5-6</td>
</tr>
<tr>
<td></td>
<td>C. Authority of the IRB</td>
<td>Pages 6-7</td>
</tr>
<tr>
<td>VI.</td>
<td>Relevant Documents</td>
<td>Page 7</td>
</tr>
<tr>
<td></td>
<td>A. Operating Policies and Procedures</td>
<td>Page 7</td>
</tr>
<tr>
<td></td>
<td>B. Guidelines for Investigators</td>
<td>Page 7</td>
</tr>
<tr>
<td></td>
<td>C. Assurance Statement (Cooperative)</td>
<td>Page 7</td>
</tr>
<tr>
<td></td>
<td>D. Protocol Files</td>
<td>Page 7</td>
</tr>
<tr>
<td></td>
<td>E. IRB Agenda and Minutes</td>
<td>Pages 7-8</td>
</tr>
<tr>
<td>VII.</td>
<td>Duties and Responsibilities</td>
<td>Page 8</td>
</tr>
<tr>
<td></td>
<td>A. President of the Medical Staff</td>
<td>Page 8</td>
</tr>
<tr>
<td></td>
<td>B. IRB Staff</td>
<td>Page 8</td>
</tr>
<tr>
<td></td>
<td>C. IRB Committee</td>
<td>Page 8</td>
</tr>
<tr>
<td></td>
<td>D. Individual Members of the IRB</td>
<td>Page 9</td>
</tr>
<tr>
<td></td>
<td>E. IRB Chair</td>
<td>Page 9</td>
</tr>
<tr>
<td></td>
<td>F. Contractual Review</td>
<td>Pages 9-10</td>
</tr>
<tr>
<td></td>
<td>G. Principal Investigator</td>
<td>Pages 9-10</td>
</tr>
<tr>
<td>VIII.</td>
<td>IRB Composition and Membership</td>
<td>Page 10</td>
</tr>
<tr>
<td></td>
<td>A. Composition</td>
<td>Pages 10-11</td>
</tr>
<tr>
<td></td>
<td>B. Selection</td>
<td>Page 11</td>
</tr>
<tr>
<td></td>
<td>C. Tenure</td>
<td>Page 11</td>
</tr>
<tr>
<td></td>
<td>D. Member Confidentiality</td>
<td>Page 11</td>
</tr>
<tr>
<td></td>
<td>E. Selection of the Chair</td>
<td>Page 11</td>
</tr>
<tr>
<td>IX.</td>
<td>Procedures</td>
<td>Page 11</td>
</tr>
<tr>
<td></td>
<td>A. Decisions and Voting</td>
<td>Pages 11-12</td>
</tr>
<tr>
<td></td>
<td>B. Circulation of Materials for Voting</td>
<td>Page 12</td>
</tr>
<tr>
<td></td>
<td>C. Final Decisions Available to the IRB</td>
<td>Page 13</td>
</tr>
<tr>
<td></td>
<td>D. Modifications of Approved Protocol</td>
<td>Page 14</td>
</tr>
<tr>
<td></td>
<td>E. Suspension or Termination of Approval</td>
<td>Page 14</td>
</tr>
<tr>
<td>Section</td>
<td>Pages</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>F. Unanticipated Problems</td>
<td>14-15</td>
<td></td>
</tr>
<tr>
<td>G. Serious or Continuing Noncompliance</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>H. Continuing Review</td>
<td>16-17</td>
<td></td>
</tr>
<tr>
<td>I. Study Closure</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>J. Emergency Use</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>K. Investigational New Drug (IND)</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>L. Investigational Device Exemption (IDE)</td>
<td>18-19</td>
<td></td>
</tr>
<tr>
<td>M. Humanitarian Use Device (HUD)</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>N. Expanded Access/Compassionate Use</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>X. Criteria for Approval</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>A. Review of Local Conditions</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>B. Protocol Review</td>
<td>20-21</td>
<td></td>
</tr>
<tr>
<td>C. Consent Review</td>
<td>21-23</td>
<td></td>
</tr>
<tr>
<td>XI. Exceptions to the Consent Requirement</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>A. DHHS/OHRP Requirements (Alteration of Consent Process)</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>B. DHHS/OHRP Requirements (Alteration of Consent Documentation)</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>C. FDA/OHRP Requirements (Exception from Informed Consent Requirement)</td>
<td>25-26</td>
<td></td>
</tr>
<tr>
<td>D. FDA/OHRP Requirements (Exception from Consent Documentation)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>XII. Special Subject Population</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>A. Principles involving Special Subjects Populations</td>
<td>26-27</td>
<td></td>
</tr>
<tr>
<td>B. Rules Regarding Specific Populations</td>
<td>27-29</td>
<td></td>
</tr>
<tr>
<td>XIII. Records and Reports</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>A. Records</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>B. Reports</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>XIV. Educational Requirements</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>XV. Recruitment-Only Projects</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>
I.  IDENTIFY

The Institutional Review Board (IRB) (also referred to as the “Research and Human Subjects Review Committee”) established for Santa Clara Valley Medical Center (SCVMC), VMC - O’Connor and VMC - St. Louise Regional Hospital (SLRH) hereinafter referred to as the “Institutions,” is a duly constituted IRB.

II.  STATEMENT OF ETHICAL PRINCIPLES

A. The Institutions are guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the “Belmont Report”]), regardless of whether the research is subject to federal regulations or with whom conducted or source of support (i.e., sponsorship).

B. All institutional and non-institutional performance sites for these Institutions, whether domestic or foreign, will be obligated by the Institutions to conform to ethical principles which are at least equivalent to those of the Institutions, as cited in the previous paragraph or as may be determined by the Department of Health & Human Services (DHHS) Secretary.

III.  INSTITUTIONAL POLICY

A. The Institutions have adopted these policies and procedures in order to assure that the IRB operates in compliance with all requirements set forth in the Food and Drug Administration (FDA) regulations found in 21 Code of Federal Regulations (CFR) 50, 56, 312, and 812 and, secondarily, with the DHHS regulations found in 45 CFR 46.

B. Except for those categories specifically exempted or waived under 46.101(b)(1-8) or 101(i) or 21 CFR 56.104, 56.105, all research will be reviewed and approved by the IRB. The IRB reviews all research to determine if it is exempt.

C. The Institutions assure that before human subjects are involved in nonexempt research, the IRB will give proper consideration to:

1. the risks to the subjects;
2. the anticipated benefits to the subjects and others;
3. the importance of the knowledge that may reasonably be expected to result; and
4. the informed consent process to be employed.

D. SCVMC has received a Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP). VMC – O’Connor and VMC – SLRH operate as components of the SCVMC FWA.

E. These Institutions will ensure that any collaborating entities materially engaged in the conduct of non-federal sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which the Institutions are committed.

F. These Institutions will comply with the regulations regarding cooperative research projects. When research is conducted at or in cooperation with another entity, all provisions of this document remain in effect for that research.
The Institutions will exercise appropriate administrative overview to ensure that policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied.

IV. OBJECTIVES

The objectives of the IRB are as follows:

A. Protection of the rights and welfare of human subjects involved in projects submitted to it by investigators from the Institutions and its satellite clinics. This includes but is not limited to:

1. the protection of the rights and welfare of patients and/or volunteers who participate in research and the assurance that patients and/or volunteers are provided with enough information about a study so they can give effective informed consent prior to their participation;

2. a determination that the risks are reasonable in relation to the benefits, if any, for subjects and the importance of the knowledge that may be expected to result;

3. providing a consent document that not only complies with the regulations but is also likely to be understood by the population being studied;

4. providing continuing review at intervals as required by the Code of Federal Regulations.

B. To determine that the safeguards required in 21 CFR 50 and 56 and 45 CFR 46 are met.

C. When requested, to render a decision regarding whether a device poses a significant or non-significant risk under the definitions offered in 21 CFR 812 and in accord with the criteria set forth in this document.

D. To provide objective and timely review services for the Institutions.

E. To assist and consult with investigators in difficult decisions regarding experimental activities that are not otherwise being subjected to oversight and review by this IRB. The review might include review of compassionate use of experimental procedures or medication, consent to experimental procedures or review of records issues.

V. JURISDICTION AND AUTHORITY OF THE IRB

A. Organizational Position of the IRB

The IRB reports to the Medical Executive Committee of the Institutions.

B. Jurisdiction of the IRB

1. By Location

Prior approval by the IRB is required for all research involving patients and/or conducted on patients in the Institutions or Ambulatory Care clinics. The IRB also has the authority to review research within the Santa Clara County jails.

2. By Title
Prior approval by the IRB is required for all research conducted by:

- privileged hospital staff; external Institutional personnel may only serve as sub-investigators with the ultimate responsibility for the research remaining with the employee serving as principal investigator.
- staff of this institution's satellite clinics when conducted under the authority of that person's professional relationship with the Institutions.
- research may be conducted by physicians and non-physicians; however, only physicians may conduct clinical trials involving prescription or investigational drugs and devices.

3. By Subject

Prior approval is required for all research involving this Institution’s patients and/or conducted on patients in Institutions or Ambulatory Care clinics.

4. By Activity

Research for purposes of the statement is any study fitting the definitions of and involving “human subjects” or “biospecimens” (45 CFR 46.102 (e1)(i)(ii)), “clinical investigation” (21 CFR 56.102(c)), or “research” (45 CFR 46.102(l)).

Research need not be funded or sponsored to meet these definitions.

The IRB can also make a determination that the project is quality improvement (QI), if the project is submitted to the IRB for review. If the IRB determines that the project, as described, does not meet the definition of research, the PI will be issued a letter that states the project is not under the purview of the IRB.

C. Authority of the IRB

1. Protocol Review

The IRB has the authority to approve protocols meeting the criteria established in this document.

It is the policy of the Institutions that IRB approved studies conducted by hospital staff may not be initiated until they are also approved by the Institution’s Administration.

The IRB has the authority to disapprove any protocol after written notice to the investigator about the issues in question. Disapproval by the IRB may not be reversed by any other authority in the Institutions. Any person whose protocol is disapproved may request a hearing before the IRB.

The IRB may suspend or terminate any protocol. All suspensions and terminations must be reported to the Institutional Official. It is the responsibility of the IRB in collaboration with the Institutional Official to report all suspensions or terminations to the appropriate federal authority.

2. Monitoring of Approved Research Studies

The IRB has the authority to:
a. conduct continuing review at intervals determined to be appropriate;
b. attend the consent process with any subject and/or investigator; and
c. observe, or have a third party observe, the consent process and the research.
d. review and approve all consent documents signed by subjects and to ensure that appropriate provisions have been taken to inform any Limited English Proficiency (LEP) patients.

3. Advisory Authority

The IRB may be consulted by the President of the Medical Staff, the Medical Directors, Chief Medical Officer, and/or any other institutional departments to determine if new procedures introduced into the institutions are “new” or “experimental” or if the procedures should, or must, be subjected to further review before acceptance.

The IRB may modify these policies and procedures as needed to reflect the operations of the IRB.

VI. RELEVANT DOCUMENTS

The following are Institutional IRB documents guiding the operation of the IRB.

A. Operating Policies and Procedures

This document is intended to be used for internal guidance of the Institutions and the IRB.

B. Guidelines for Investigators

This is an instructional document intended to assist investigators and their staff in submitting applications.

C. Assurance Statement (Cooperative)

The Institutions maintain a Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP).

D. Protocol Files

Both an electronic and hard copy file will be maintained for each study and will include copies of all research proposals reviewed including the grant application (if federally funded), investigator’s brochure (if applicable), scientific evaluations, if any, that accompany the proposals, approved informed consent document(s)(when applicable), HIPAA privacy document (when applicable), progress reports submitted by investigators, reports of injuries to subjects and all study-related documents/correspondence.

E. IRB Agenda and Minutes

Agenda

The agenda will be sufficiently detailed to show all proposed items submitted for discussion or consideration.
Minutes

The minutes will be written in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving the research; the risk of the research and a written summary of the discussion of controverted issues and the resolution or action of such. Supporting documents that contain information relevant to grammatical/editorial changes to the submitted version of the protocol/informed consent form(s), and other study documents will be kept on file with each study rather than detailed in the minutes.

The minutes will show reports on unanticipated problems reviewed at a convened meeting, continuing review, other informational items discussed at the meeting and all correspondence with investigators since the last meeting.

VII. DUTIES AND RESPONSIBILITIES

A. President of the Medical Staff

1. To appoint members to the IRB.
2. To select the chair from among the membership.

B. IRB Staff

1. Provide the meeting agenda, protocol, background materials, and appendices, if any, to the members at least one week prior to a scheduled meeting.
2. Provide guidance and information as requested by the IRB.
3. Take and transcribe minutes.
4. Maintain records of reviews.
5. Notify approved investigators and IRB members of expiration dates of approved protocols.
6. Communicate in writing the IRB’s findings and actions to the applicants, investigators and institutions as needed.
7. Keep members apprised of unanticipated problem reports received.
8. Notify members of cancellation of meetings.
9. Receive calls or letters from study subjects relating to research issues and causes.
10. Sign IRB correspondence when requested by the chair.

C. IRB Committee

1. Conduct an objective and timely review of each study presented.
2. Use the operating procedures, the criteria for review required by FDA and DHHS, and the ethical principles of the Belmont report and the World Medical Association in considering decisions.
3. Obtain expert advice, as required, if not available among members.
4. Approve, require modification in, or disapprove a study.
5. Determine the date of continuing review.
6. Participate in ongoing education during and between convened meetings as requested by the IRB Chair.

D. Individual Members and Alternate Members of the IRB
1. Attend each meeting in person except for just cause. Just cause is defined as: personal or family illness/vacation or approved leaves.
2. Provide as much possible notice if unable to attend a meeting.
3. Be prepared to discuss each agenda item.
4. Use all of one's area of expertise.
5. Consider the specific approval criteria offered in the regulations and Belmont report.
6. Maintain the confidentiality of any information contained in any review.
7. Shall faithfully discharge his/her duties and refrain from knowingly engaging in matters in which he/she has a financial interest or in matters that are incompatible with the impartial objective and effective performance of his/her duties as an IRB Member. No IRB Member shall realize personal or political gain in any form, which would influence improperly the conduct of his/her duties to the IRB including but not limited to an interest in the publication of the study. When a Member becomes aware that he/she has a potential or actual financial or other interest in a matter before the IRB, he/she shall inform the IRB, in writing, of the conflict and abstain from participating or voting on any protocol where there is such a conflict. If the member informs the IRB verbally of the potential conflicting interest at the meeting, that notice/information shall be included in the records of the IRB.
8. Be familiar with the operating procedures, as specified in these 'Standard Operating Policies and Procedures' of the IRB.
9. Members shall not communicate directly with sponsors.

E. IRB Chair

1. Will be a full member entitled to vote during full committee meetings;
2. Conduct the meeting in an orderly manner;
3. Sign IRB related correspondence;
4. Review responses from study investigators to determine if the response is sufficient to address the IRB’s concern(s) in order to allow approval without being returned to the full IRB (Chair may delegate responsibility to IRB members or staff as appropriate);
5. Appoint an acting chair to serve in his/her absence;
6. Consult with the Medical Director and/or Director of Pharmacy (or designee) regarding reports of emergency use of investigational drugs and devices, where appropriate, and to receive reports of such use within five working days;
7. Conduct expedited review consistent with the requirements, as defined and outlined in provision IX (A)(2) of this policy & procedure.

F. Contractual Review

Institutional policy requires that all research agreements between an investigator and sponsor be reviewed by Hospital Administration and County Counsel after the research has received the approval of the IRB.

G. Principal Investigator

The Principal Investigator is the person ultimately responsible for the conduct of the study and for the actions of all sub-investigators and staff in relation to the conduct of the study. The investigator must:

1. obtain approval of the IRB and Hospital Administration prior to initiating any research or clinical investigation;
2. obtain approval of the IRB prior to making any planned modifications to the approved protocol;
3. report to the IRB:
   a. all deviations from the approved protocol within five (5) working days; and
   b. all unanticipated problems within five (5) working days of notification or receipt of information about such event(s);
   c. any death must be reported within twenty-four (24) hours of principal investigator’s knowledge of such event.
4. understand the IRB imposed expiration date and apply for continuing review prior to that date;
5. present subjects with the current IRB-approved consent form for enrollment in the study;
6. update the consent at the initial approval and subsequent continuing renewals with the expiration date, as provided by the IRB in the study approval letter;
7. determine that each subject is appropriate for the study and that adequate and informed consent has been obtained;
8. maintain a list of all enrolled subjects and maintain that list in a confidential manner so as to protect the privacy of all subjects; and
9. communicate necessary information back to the study sponsor as required.

VIII. IRB COMPOSITION AND MEMBERSHIP

A. Composition

1. The IRB shall have at least five members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the Institutions. The study roster will indicate each member’s role within the committee (scientist, nonscientist and nonaffiliated member). The IRB will be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

2. When the IRB reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, or handicapped or mentally disabled persons, the IRB will include one or more individuals who are knowledgeable about, and experienced in, working with these subjects. If the individuals are not members of the IRB, the individuals will be made a member of the IRB and have voting rights.

3. The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

4. The IRB will include at least one member who is not otherwise affiliated with the Institutions and who is not part of the immediate family of any person who is affiliated with the institution.

5. No member of the IRB may participate in the IRB’s initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB. Such member will be recused from the room during discussion and
voting in Executive Session. Interest, as used in these policies, includes any financial interest, as defined in California Government Code Section 87103, or any interest in the publication of or relating to, a study or protocol, which the member has or will evaluate in his/her role as a member of this IRB.

6. The IRB will, at its discretion, invite consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will not have voting rights.

B. Selection

IRB members are selected by the President of the Medical Staff.

C. Tenure

Individuals appointed to serve as members of the IRB will continue to serve in accordance with the Medical Staff by-laws.

D. Member Confidentiality

Names of IRB members will be released only to: NIH, DHHS, FDA, study-sponsored auditors, and principal investigators upon request.

E. Selection of the Chair

The chair will be selected by the President of the Medical Staff.

IX. PROCEDURES

A. Decisions and Voting

1. Full Board Review

A quorum of a majority of the membership (half plus one, rounding up if the committee has an odd number of members) will be necessary to convene a meeting and conduct business. A quorum must include the following: at least one scientific member, one non-scientific member, one community member, and a member who is not otherwise affiliated with the Institutions and who is not part of the immediate family of a person who is affiliated with the Institutions. If the quorum is lost during the meeting, the items without a quorum vote must be delayed until the committee quorum is met again.

Proxy voting is prohibited.

Action may be taken by a vote of a majority of the members present at a convened meeting.

Members are required to recuse themselves from voting on matters involving studies in which they have a conflicting interest and a reason for recusal. The member may not be counted towards meeting the requirements for action on that item.

2. Expedited Review
Expedited review may be used for minor changes in previously approved research (during the period of one year or less, from the approval date) for which approval is authorized. Investigators should submit a letter with the changes tracked in the protocol and, if applicable, a revised consent form with all changes tracked. Expedited review may also be used for initial and continuing review for research activities that only involve procedures listed in one or more of the categories in FDA/DHHS OHRP’s list of "Research Activities that may be reviewed by the Institutional Review Board (IRB) Through Expedited Review Procedure."

Under the expedited review procedure, the review will be carried out by the IRB chair or by one or more reviewers designated by the chair from among the voting members of the IRB. The timeline for the review is dependent on committee member availability and number of changes being requested. In reviewing the research, the reviewer’s possible actions include approval or approval with contingencies. The reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedure set forth in FDA/DHHS OHRP Regulations which includes referral to the full board for review. Action imposed by the Chair, or designee, may take effect immediately without further review and approval by the IRB.

All expedited actions will be reported to the members at a convened meeting.

B. Circulation of Materials for Review

Each member will receive the following at least one week prior to the scheduled meeting:

1. Agenda

Each member will be provided a list of actions to be considered by the IRB at the convened meeting.

2. New Applications

   a. Each member will be provided a copy of the completed “Application for Review by the IRB” and all study-related materials necessary to provide for an adequate review of the proposed research (i.e., protocol), personnel list, Investigator’s Brochure (when applicable), grant application (when applicable), informed consent form (when applicable), HIPAA (when applicable) and data collection form. At the discretion of the chair of the IRB, only the ‘primary’ and ‘secondary’ reviewers will receive a copy of the Investigator’s Brochure. The Investigator’s Brochure will be made available to all other members upon request.

   b. Each member will be provided a copy of the principal and any sub-investigator(s) curriculum vitae and educational training certificate (unless recently reviewed under a separate application).

3. Amendments (Changes in Project(s) Already Approved by the IRB)

Each member will be provided a copy of the investigator’s written request for consideration of proposed changes and any information necessary to provide for an adequate review by the IRB (i.e., revised protocol and, if applicable, revised informed consent form(s) with all changes tracked).
4. Renewals

Each member will be provided a copy of the completed ‘Renewal Application’ form, status report, and, if applicable, currently approved informed consent form(s), including HIPAA Privacy Consent Document (when applicable). Only the assigned ‘Primary’ and ‘Secondary’ reviewers will be provided a copy of the most recent version of the study protocol and study materials/correspondence necessary to conduct an adequate review. The study protocol will be made available to all other members upon request. All members have access to the study file upon prior notification to the IRB Chair or IRB Administrator.

C. Final Decisions Available to the IRB

1. Approval

a. Approval will be granted when the IRB is satisfied that: 1) the requirements of 21 CFR 50 and 56 or 45 CFR 46 have been met; 2) the principles set forth in the Belmont Report and the World Medical Association are satisfied; 3) and the consent materials have met all requirements of the IRB.

b. Approval Contingent:

The IRB agrees that no serious problems remain in the study but corrections of minor problems are required prior to final approval being granted. The PI is notified via email of the contingencies and a request is made to make the required modifications. The contingency can be removed without an additional meeting by action of the IRB chair or designee. Contingencies must be satisfied by the PI within 60 days of the meeting in which it was reviewed. If the contingencies are not satisfied within that timeframe, the study will not be granted final approval and the PI will need to resubmit the project for approval.

c. Approval with Stipulation, Condition, or Suggestion:

Approval is granted with the stipulation or condition that some stated requirements must be met or includes some suggestions to improve the study further.

2. Disapproval

A research activity may be disapproved only after review in accordance with the non-expedited review procedure set forth in FDA/DHHS OHRP Regulations.

Projects will be disapproved only after it is found that sufficient improvements cannot be made in the study to render it approvable. The reasons shall be clearly stated. Disapproval by the IRB is final and may not be reversed by any institutional official. The IRB may reconsider studies which have addressed the reasons for the original disapproval.

IRB determination letters with all findings, actions and the length of renewal approval will be reported to investigators and the Institutions. Letters will be addressed to the principal investigator and copied to Hospital Administration. The meeting minutes will also reflect all of the actions taken at the meeting and the approval period for the renewal.
D. Modifications of Approved Protocol

Modifications must be approved by the IRB prior to implementation unless the modification is being made to eliminate an immediate hazard to research subjects. In this case, the PI should proceed with making the change and notify the IRB of the protocol deviation as soon as possible but no later than five days after the change is made.

Study modifications must be requested by a letter to the IRB and submitted with all supporting documents with the changes highlighted (redlined and tracked). Depending on the nature of the requested modifications, these may be approved via expedited review or may need to go to a full convened committee meeting.

If a PI leaves the institution or is no longer able to be the PI of a designated study, the PI is required to notify the IRB and seek approval for the change prior to the change being implemented. A letter should be received by both the former PI and the newly identified PI requesting this change.

1. Minor modifications will be reviewed using the Expedited Review Procedure
   a. A modification that reduces risk is considered to be minor.
   b. A modification that increases risk slightly will be reviewed by the chair to determine if the risk is, indeed, appropriately classified as a ‘minor’ risk.

The approval timeline for modifications is dependent on the amount of changes being requested and the availability of a committee member to review the requested modifications.

2. Major Modifications of Approved Protocol

Major modifications will be circulated to all members, reviewed at a convened meeting and may be approved by a majority vote. Materials being modified must be received by the IRB administrator by the meeting submission deadline. The investigator will be informed following the convened meeting whether the modifications were approved.

E. Suspension or Termination of Approval

The IRB has the authority to suspend or terminate research immediately that is not being performed in accordance with the approved protocol or that has been associated with unexpected serious harm to subjects. Any member may request the chair to poll members or to call a meeting concerning such allegations. Action taken under this section will be reported by the IRB chair to the Institutional Official, the Principal Investigator’s Department Chair and Division Chief with a copy to the Principal Investigator. The IRB will report promptly such suspension or termination of approval to the appropriate federal regulatory authority—generally, the OHRP and/or the FDA. Any termination or suspension that occurs outside of an IRB meeting (such as determined by the Department Chair or Institutional Official) must be reported to the IRB.

Apart from institutional reporting obligations, it is the PI’s responsibility to make reports to the sponsor when required.

It will be the responsibility of the PI to notify all study subjects of suspended or terminated studies. If the PI is not able to notify subjects, this responsibility will transfer to the Sub-Investigator.
F. Unanticipated Problems Involving Risks to Subjects or Others

Unanticipated problems involving risks to subjects or others refers to any incident, experience, or outcome that is 1) unexpected; 2) related or possibly related to a subject’s participation in the research and 3) suggests that the research places subjects or others at a greater risk of harm. Unanticipated problems could include, but are not limited to: breaches of confidentiality, errors in dosing of medication, safety monitoring procedures that were not conducted or their results lost or inadvertently destroyed.

An adverse event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. AE’s encompass both physical and psychological harms and should be reported, even if minor. AE’s not deemed to be serious must be reported at the time of continuing renewal or within a final report to the IRB upon closure of the study.

A serious adverse event (SAE) is any untoward physical or psychological occurrence in a human subject participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome. SAE’s must be reported to the IRB within five days of the occurrence. If a SAE takes place at a collaborating site, involving the same protocol, the Institutions’ PI must report this event to the IRB and forward any reports on the event as soon as the information is received.

An unanticipated problem may or may not be an AE and an AE may or may not be an unanticipated problem. Unanticipated problems involving subjects or others must be reported to the IRB within five working days of the investigator becoming aware of the problem(s). Whether serious or not, adverse events that meet all three criteria of unanticipated problems involving subjects or others are reportable by investigators to the IRB within the same timeframe.

Any death must be reported within 24 hours of the investigators knowledge of the event. Reporting is required even after the subject has completed or is withdrawn from the study, or following study closure.

Reports should include: 1) a clear explanation of why the event or series of events has been determined to be an unanticipated problem; 2) whether or not, in the investigator’s opinion, changes in the protocol/informed consent form are warranted; and 3) a description of any corrective actions to be taken by the investigators in response to the unanticipated problem. If investigators are unsure whether an event is an unanticipated problem, the event should still be reported within five working days. The IRB will review the report and make a final determination.

If the report cannot be completed in its entirety within the required time period, a preliminary report should be submitted. The report should be amended once the event is resolved and/or more information becomes available.

External events generally should be reported to the IRB if a monitoring entity or external site investigator has determined that the event constitutes an unanticipated problem.

Reports from independent safety monitoring groups should be provided to the IRB on a regular basis, at least as often as the study undergoes continuing review.
The IRB Chair or designee will review all reports of unanticipated problems and will decide if further action is warranted as a result of the report(s). If the chair/designee decides that review of the report by the full IRB is warranted, the report along with the currently approved version of the protocol and informed consent form will be placed on the agenda for review at the next convened IRB meeting. The IRB has the authority to suspend or terminate IRB approval of protocols that are found to pose unanticipated or heightened risk. Other actions taken by the IRB may include, but are not limited to:

1. Obtaining additional information;
2. Requirement for additional training for investigators and/or research staff;
3. Modification of the research protocol;
4. Modification of the information disclosed during the consent process;
5. Providing additional information to past participants;
6. Notification to current participants when such information might relate to subjects’ willingness to continue to take part in the research;
7. Requirement that the current participants re-consent to participation;
8. Modification of the continuing review schedule;
9. Monitoring of the research;
10. Monitoring of the consent process;
11. Referral to other organizational entities;

The IRB will notify the PI, in writing, of receipt of the report and the determination of the IRB. All reports are filed within the appropriate study file.

The IRB will report promptly such unanticipated problems to the appropriate Institutional Official and federal regulatory authority—generally, the OHRP and/or the FDA.

Apart from institutional reporting obligations, it is the principal investigator’s responsibility to make reports of adverse events and unanticipated problems to the sponsor when required.

G. **Serious or Continuing Noncompliance**

Serious noncompliance is defined as significant failure to comply with institutional policies, local laws or federal regulations. Serious noncompliance involves incidents that have the potential to increase risks/decrease benefits to research participants or affect the rights and welfare of participants.

Continuing non-compliance is defined as a pattern of noncompliance that suggests a future likelihood of reoccurrence or a circumstance in which an investigator shows an unwillingness to comply or cooperate with investigating or correcting noncompliance.

When the IRB finds that research involves serious or continuing noncompliance, the IRB will prepare a report within fifteen days from the date the IRB conducts final review of the serious and/or continuing noncompliance. The report will include identifying information about the PI or about the study if noncompliance was specific to a study; the nature of the event; the findings of the institution or the IRB, including the determination of whether the informed consent needs to be modified and actions taken by the PI, the institutions, and/or the IRB to address the issue. The Institutional Official, in consultation with the IRB Chair will approve the report. IRB staff will send the report to applicable federal agencies — generally, the OHRP and/or the FDA. A copy will be sent to the IRB Chair, Institutional Official, PI, and others as determined by the IRB.

H. **Continuing Review**
1. The purpose of continuing review is understood to be a periodic reassessment of whether the IRB would agree, given the events in the past year that the project should be approved for renewal.

2. The same elements will be considered during continuing review as were considered during initial review. However, at this point, emphasis will be placed on new knowledge in the field, the progress report, the report submitted concerning unanticipated problems, if any, and the reported activity in the study.

3. Upon approval, the IRB will determine a date for continuing review. The date will be determined by the degree of risk involved but in no event will it be greater than one year from the prior approval. The IRB may decide to set a shorter approval period depending on the study. A shorter approval time may be required for high-risk protocols, studies involving vulnerable populations, the projected rate of enrollment and whether the study involves novel therapies. The approval period will be documented in the meeting minutes.

4. Continuing review will be conducted by full board review at a convened meeting or, if eligible, through an expedited review procedure.

5. Following initial IRB approval, research studies in which 1) approval was granted via expedited review; 2) limited review was conducted; 3) all interventions have been completed and are now limited to analyzing data (even if the information is identifiable) or 4) all interventions have been completed and only follow-up clinical data is being accessed are no longer required to complete a continuing review application. However, in accordance with institutional policy, the IRB will require a mandatory annual check in to determine if the study is still active. It is also under the purview of the IRB to require ongoing continuing review should the IRB feel it is necessary to maintain the safety of the participants.

Although continuing review may no longer be required for certain research protocols, the PI is still responsible: 1) for notifying the IRB prior to implementing a change in the protocol, unless they are done to eliminate an immediate hazard to research subjects. In this case, the PI should proceed with making the change and notify the IRB of the protocol deviation as soon as possible; 2) reporting of serious adverse event to the IRB within 5 days, all other adverse events must be reported annually; or 3) study termination.

6. Modifications made to the study, including changes to the protocol or to the informed consent form, will not change the expiration date unless the IRB specifically designates a new date.

7. If the IRB is concerned about possible changes occurring without IRB approval, verification from sources other than the investigator that no material changes have occurred since the previous IRB review will be required. This may be the case if investigators have a history of noncompliance and/or if there is concern based on information within continuing review reports or other sources.

8. If a study is not submitted for continuing review by the expiration date, the study will automatically be closed and the PI notified. The PI will need to submit a new application to re-open the study. No work can be completed on the study during the time the study approval lapses and until it is re-approved.
I. **Study Closure**

Studies should only be closed when all data analysis related to the study has been completed. Once all data analysis is completed, a final report form must be submitted to the committee, along with any manuscripts, articles or other presentation(s) or publication(s) completed with study data.

J. **Emergency Use**

Emergency use is defined in 21 CFR 56.102(d) as: “the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval”. On occasions when an emergency use of a drug or device is warranted in a life threatening situation, the IRB must be notified within five working days. Institutional policy 638.4 *Clinical Research, Emergency Use of an Investigational Drug/Device/Biologic* Product details the requirements for use of the drug or device and provides a consent form for emergency use that would need to be signed by the patient.

It is allowable for the PI to utilize the sponsor’s detailed consent form and protocol during the initial use of the drug/device/biologic; however, it is required that a new protocol be submitted following emergency use in the event the drug/device/biologic protocol is used again. An emergency use treatment cannot be used twice without an active and ongoing protocol.

K. **Investigational New Drug (IND)**

An IND application through the FDA must be completed when either a new drug or an existing drug, being tested for a new use, is being trialed on human subjects for safety and efficacy, prior to being marketed. Following the completion of the FDA application the PI must complete a new submission to the Institutional IRB for use of the drug. Submission requirements also include documentation from the FDA regarding the status of the IND and the investigator qualifications for conducting the trial and this information will be reviewed at a full board meeting. Expedited review is not allowable for investigative drugs.

L. **Investigational Device Exemption (IDE)**

IDE applications must be determined to be either a Significant or Non-Significant Risk device. While sponsors can originally make this determination, both the IRB and FDA must review the risk, with the FDA being the final determining body. Relevant information regarding the risk, any previous investigations and literature on the device must be submitted with the application to the IRB. The risk will be documented in the IRB meeting minutes.

1. **Significant Risk (SR):**

Significant risk devices, as defined by the FDA, are devices:

a). Intended as an implant and present a potential for serious risk to the health, safety, or welfare of a subject;

b). Purported or represented to be used for supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

c). Used for substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
d). That may otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

IDE and IRB applications can be done concurrently; however the study may not commence until both approvals are received.

2. **Non-Significant Risk (NSR)**

Non-Significant Risk devices do not meet the definition of SR devices and once determined to be NSR can proceed without an IDE application to the FDA. The FDA must make the NSR determination, not the sponsor or PI.

Although an IDE application is not needed, an IRB application must be reviewed via a convened meeting. Expedited review is not permissible. To approve a NSR device application, the IRB requires a new application and documentation from the FDA that the device is NSR.

M. **Humanitarian Use Devices (HUD’s)**

The definition of a HUD from the FDA regulations 21 CFR 814.3(m) “means a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year”.

Although a HUD does not meet the definition of research it still requires oversight by the IRB. HUD approval requires the completion of a new application, reporting of any adverse events and continuing review. Initial review of a HUD is done at a convened meeting while continuing review can be completed by either expedited or full board review.

N. **Expanded Access/Compassionate Use**

The FDA provides oversight of the Expanded Access (also known as Compassionate Use) program and defines it as the “use of an investigational drug or biologic, outside of a clinical trial, to treat a patient with a serious disease or condition who does not have comparable or satisfactory alternative therapies to treat the disease or condition”

The PI must submit a new study application, Form 3926 (FDA), the Investigator’s Brochure, FDA approval and HIPAA and informed consent documents for approval. It is permissible to use the sponsor’s consent and HIPAA forms; however if no HIPAA template is provided, use of the Institution’s approved template is required.

Expanded access applications cannot be reviewed via expedited review and must go to the full board for review. Continuing review is required if the treatment of the drug lasts more than one year or if the protocol is applied to subsequent patients. Any adverse events must be reported to the IRB and the FDA. It is the responsibility of the Principal Investigator to comply with all necessary FDA and IRB procedures. If the protocol is applied to subsequent patients, the IRB must receive a Form 3926 for each additional patient. When the protocol is closed, the IRB needs to be in receipt of the summary report to the FDA and the sponsor.

X. **CRITERIA FOR APPROVAL**

Members are required to notify the IRB Chair or to raise an objection at the meeting if they have reason to believe that information submitted is not truthful, accurate, or complete.
A. Review of Local Conditions

The IRB will consider local community attitudes. Members must consider and be sensitive to whether the study presents any issues that might be contrary to a community standard. Issues that might be addressed include:

1. Community Standards

Members recognizing that a protocol does not fit within usual community standards in terms of medical care, ethics, and local values, or any similar issue relevant to Santa Clara County should notify the Chair or IRB Administrator.

2. Investigator Qualifications

Members will determine whether the PI is at least minimally qualified to be responsible for the conduct of the research study, is within their scope of work and that those conducting the procedures are qualified to do so. Participating departments or the Human Resources department may do additional vetting if requested by the IRB Chair.

3. Facility Acceptability

The IRB will determine where the active procedures are to be performed. It must appear that the facility is capable of supporting and willing to support the conduct of the research.

4. Subject Incentives to Participate

The IRB must be able to determine that financial incentives for the subject are not such that the incentives would be coercive or have an undue influence on the judgment of the subject.

In order to accomplish this task, the IRB requires a full statement of payment amounts to the subject for participation as well as the payment schedule to the subjects.

5. Investigator Incentives

The IRB must be able to determine that financial incentives to the investigator are such that they will not cause the investigator to compromise selection or retention of subjects.

B. Protocol Review

In order to approve a study, the IRB must find that all of the following requirements set forth in 21 CFR 50 and 56 and 45 CFR 46 are satisfied. This review is not designed to assure that all state and local laws are satisfied.

1. Risks to subjects are minimized by 1) using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk, and 2) whenever appropriate, using procedures already being performed on the person for diagnostic or therapeutic reasons.
It is commonly accepted that risk may be determined by the skill of the investigator and his or her staff and upon the availability of appropriate equipment, space and staff. Therefore, the IRB will also determine that the investigator attests to the fact that he or she has the minimal qualifications necessary to conduct the study.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research. The IRB will not consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research, the study inclusion and exclusion criteria and the setting in which the research will be conducted.

3. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by, 21 CFR 50 and 45 CFR 46. Waiver of the obligation to gain consent may be approved under 21 CFR 50.23.

4. Informed consent will be appropriately documented in accordance with and to the extent required by 21 CFR 50.27 and 45 CFR 46.116 “Documentation of Informed Consent.”

5. Study advertisements can be construed as recruitment tools. The IRB will review the content of all advertisements to determine that the advertisements are appropriate.

6. Where appropriate, the research plan will make adequate provisions for monitoring the data collected to ensure the safety of subjects.

7. Adequate provisions will be made to protect the privacy of subjects, ensure compliance with applicable laws, including but not limited to HIPAA, and to maintain the confidentiality of files.

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons who are economically or educationally disadvantaged, or prisoners, appropriate additional safeguards will be included in the study to protect the rights and welfare of these subjects.

C. Consent Review

Both, a discussion with the physician/investigator and a document covering the main facts of the proposed medical experiment, are necessary for informed consent. The IRB will look for evidence that both the process and the documentation of the process have been considered. Questions of literacy and language will be considered and the IRB will review those procedures/processes to be used with illiterate or Limited English Proficiency patients. The IRB will require a certified translator transcribe the informed consent for all languages deemed necessary. A certificate of translation will be required for approval.
Basic required elements of informed consent

1. A concise summary is required at the beginning of each consent. The summary must include relevant elements that would help the participant or legally authorized representative determine why they may or may not wish to participate in the research. The information in the summary can be expanded upon later in the consent form.

2. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

3. A description of any reasonably foreseeable risks or discomforts to the subject;

4. A description of any benefits to the subject, or to others, which may reasonably be expected from the research;

5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects;

6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records;

7. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs and, if so, what they consist of, and where further information may be obtained;

8. "Minimal Risk" means that the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests (21 CFR 50.31(k) and 45 CFR 46.102 (j));

9. An explanation of whom to contact for answers to pertinent questions about the research, as well as the research subjects’ rights and whom to contact in the event of a research related injury to the subject;

10. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a subject chooses to withdraw from the study, unless otherwise requested by the participant, the subjects’ data from the time of consent to the date of withdrawal is allowed to be used.

11. If biospecimens are collected, a statement must be added into the consent form specifying whether the samples collected will be used in future research and if so, if the PI will de-identify the samples or use the specimens with identifiable private information.
2. Additional elements required by California law (Division 20, Health and Safety Code, Section 24170).
   
a. If a placebo is administered or dispensed to a subset of the subjects involved in a medical experiment, all subjects of such experiment shall be informed of such fact.

b. An estimate of the expected recovery time of the subject after the experiment.

c. The name, institutional affiliation, if any, and address of the person or persons who are actually performing the study and have the primary responsibility for the conduct of the experiment.

d. The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general guidance the experiment is being conducted.

e. The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

f. Subjects will be provided the Experimental Subject’s Bill of Rights when the research constitutes a medical experiment as defined by section 24174 of California Health & Safety Code. According to this section, medical experiment means:

   (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in section 109920 or 109925 of California Health & Safety Code, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

   (b) The investigational use of a drug or device as provided in Health & Safety Code Sections 111590 and 111595.

   (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

2. FDA’s additional elements of informed consent:

For clinical trials subject to regulation by the FDA, all informed consent documents must contain a statement that a description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

When appropriate, one or more of the following elements of information will also be provided to study subjects:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. Any additional costs to the subject that may result from participation in the research;

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;

f. The proposed number of subjects involved in the study;

XI. EXCEPTIONS TO CONSENT REQUIREMENTS

Consent consists of both an explanation of the risks and benefits and documentation of the explanation. It is expected that every protocol will address both issues. Exceptions to the consent requirement should be rare, and are allowed only by action of the IRB and must be well documented.

The exceptions allowed under 45 CFR 46 and 21 CFR 56 differ significantly.

The DHHS requirements will prevail for NIH funded activities.

The FDA requirements will prevail for all FDA-regulated activities and all other research activities.

A. DHHS Requirements for Alteration of Consent Process (45 CFR 46.116 (f)).

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent, or which waives the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

   a. a public benefit or service program(s);
   b. procedures for obtaining benefits or services under those programs
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

   In addition, the waiver or alteration will not adversely affect the rights and welfare of the subject. The research could not practically be carried out without the waiver or alteration.

2. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or the IRB may waive the requirements to obtain informed consent provided the IRB finds and documents that:
a. the research involves no more than minimal risk to the subjects;
b. the research could not practicably be carried out without the waiver or alteration;
c. if the research involves using identifiable private information of identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
e. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

B. **DHHS/OHRP Requirements for Alteration of Consent Documentation (45 CFR 46.117(c)).**

The IRB may waive the requirement to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which forms are not the community norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

C. **FDA Requirements for Exception from Informed Consent Requirement (21 CFR 50.23).**

In circumstances in which it is not feasible to obtain informed consent, use of any test article is permitted only in the following circumstances:

1. Before administration, both the investigator and a physician who is not otherwise participating in the clinical investigation will certify in writing all of the following:

   a) the human subject is confronted by a life-threatening situation necessitating the use of the test article;

   b) informed consent cannot be obtained from the subject because of an inability to communicate with, or legally obtain consent from, the subject;

   c) time is not sufficient to obtain consent from the subject’s legal representative; or

   d) there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
2. If immediate use of the test article is, in the investigator’s opinion, required to preserve 
the life of the subject, and time is not sufficient to obtain the independent determination 
of a physician not participating in the clinical investigation prior to using the test article, 
the determination of each of the factors in paragraph (1) shall be made by the clinical 
investigator and, within five working days after the use of the article, will be reviewed and 
evaluated in writing by a non-participating physician.

3. The documentation required in paragraph (1) or (2) shall be submitted to the IRB within 
five working days after the use of the test article. The Principal Investigator will be 
required to attend the next meeting to present the case to full IRB.

D. FDA Requirements for Exception from Consent Documentation (21 CFR 56.109 (c)).

The consent form documentation requirement may be waived if the IRB finds that the research 
presents:

1. No more than minimal risk of harm to the subject, and
2. Involves no procedure(s) for which written consent is normally required outside the 
   research context.

In the event the requirement for consent is waived by the IRB, the investigator may still be 
required to provide a written statement to potential subjects.

XII. SPECIAL SUBJECT POPULATIONS

A. Principles Involving Special Subject Populations

Special attention has been paid to several specific sub-groups of the population. Two occasionally 
opposing principles guide this attention:

1. Use of Restricted Population as Study Subjects

Investigators submitting protocols deliberately excluding a sub-group of the general 
population where there is no obvious medical reason for the exclusion will be asked to 
provide written justification for the exclusion.

2. Diminished Capacity for Autonomous Decisions

a) The principle of respect for persons (Belmont Report) requires that individuals be 
treated as autonomous agents capable of making informed choices and that, 
conversely, persons with diminished autonomy be entitled to additional 
protection as needed to compensate for their impaired capacity.

b) Within any subject population, there may be individuals with lessened capacity to 
consider the questions. The IRB may ask questions about the consent process 
with regard to issues of privacy, timing, supplemental information, and assurance 
of comprehension, etc.

c) All of the subjects in certain subject populations may have conditions (emotional, 
developmental, physical, legal, or financial) that impair their decision-making 
abilities. Subjects in these special populations might include children, the
homeless, the chronically or terminally ill, or the mentally impaired. The IRB may require additional support during the consent process in such cases.

d) DHHS has published final regulations regarding involvement of

- the fetus pregnant women and human in vitro fertilization (45 CFR 46.200 Subpart B))
- prisoners (45 CFR 46.300 (Subpart C))
- children (45 CFR 46.400 (Subpart D))

These regulations depend on a “legally authorized representative.” This is an individual, or a judicial or other body authorized under applicable law to consent on behalf of a prospective subject. The applicable law is usually state law. This person/authorized body may also limit what can be approved depending on the risk/benefit evaluation.

e) FDA and OHRP have published final regulations regarding involvement of

prisoners and makes use of the DHHS regulations on children and pregnant

women. The FDA has different guidelines on the testing of drugs in pregnant

women because of the issue of the effect investigational drugs may have on the

fetus.

3. California Law

a. Pursuant to California Health & Safety Code Section 24175, no person shall be

subjected to any medical experiment unless informed consent is obtained either

from such person, a court appointed conservator or guardian, or a person

appointed under Welfare & Institutions Code Section 4655. Consent by a

conservator, guardian, or other appointee may be given only for studies related

to maintaining or improving the health of the subject or for obtaining diagnostic

information.

b. In any research involving administration of experimental drugs, consent may be

given by the parent or guardian of a minor only for drugs, which are related to

maintaining or improving the health of the subject, or are related to obtaining

information about a pathological condition of the subject.

B. Rules Regarding Specific Populations

1. Children

Inclusion of children in research requires the completion of the IRB approved pediatric

checklist. When reviewing clinical studies involving children, the IRB will only approve

research studies falling into one of the following categories:

1. Research not involving greater than minimal risk to the research

   participant.

2. Research greater than minimal risk with the prospect of direct benefit to

   the child, then

   i. the risk has to be justified by the anticipated benefit to the subject;
ii. the relationship of risk to benefit must at least be as favorable as any available alternative approach.

iii. adequate provisions are made for soliciting the assent of the children and permission of their parents of guardians, as set forth in 45 CFR 46.408.

3. Research greater than minimal risk with no prospect of direct benefit to the child then:

i. the risk must be a "minor increase over minimal risk";

ii. the intervention of procedure must be commensurate with those inherent in their actual of expected medical, dental, psychological, social or educational situations;

iii. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition;

iv. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians as set forth in 45 CFR 46.408.

4. Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. When a research study is approvable only under this category, the IRB will request additional review by a panel of experts convened by the Secretary of HHS or the Commissioner of the FDA. Final approval will be contingent upon a finding that the study is approvable by the expert panel.

The category under which the study is approved will be appropriately documented in the minutes of the IRB meeting.

The IRB will only approve studies that satisfy the following requirements for assent and parental permission:

a. Permission of one parent is sufficient for research approved under categories 1 and 2 above.

b. For research approved under categories 3 and 4 above, permission of both parent(s)/guardians is required, unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

The IRB will require that minors between the ages of 7 and 18 years be involved in the consent process and to assent to the process or sign an age-appropriate assent/consent document provided that the investigator determines that the child is capable of assent by evaluating the child's level of maturity, psychosocial and emotional capacity.

The IRB will require developmentally appropriate involvement of children below age 7. At the least, this requires that the child be asked about their willingness to participate in the major (from the child's view) events such as venipuncture and hospitalization.

When minors are involved, the IRB will require submission of a statement about the
process for both minors and adults and submission of developmentally appropriate assent/consent documents.

The IRB may waive the requirements for assent under certain conditions.

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not reasonable (neglected or abused children), permission may be waived if an appropriate mechanism for protecting the children is substituted.

Children who are wards of the State or any other agency, institution, or entity can be included in research only if (i) such research is related to their status as wards; or (ii) the research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. If research is approved under this section, the IRB shall require appointment of an advocate for each child who is a ward.

3. Prisoners
   a. Regardless of any regulations, the IRB will not accept protocols proposing involvement of incarcerated prisoners except where there is the reasonable expectation of direct benefit to the prisoners who are the subject of the study.
   b. The IRB shall include a prisoner, or a prisoner representative with an appropriate background and experience to serve in that capacity whenever considering research involving prisoners.
   c. When reviewing projects involving prisoners, the IRB shall consider the applicable regulations of such research, including but not limited to 45 CFR 46, subpart C.

XIII. RECORDS AND REPORTS

A. Records

1. Ownership of Records

IRB records are the property of the Institutions and the IRB.

2. Confidentiality of Records

All records will be considered confidential and will not be released except with the permission of the applicant or under court order. Inspectors from the FDA and OHRP will be allowed to review and copy files. If subjects’ names are included, all auditors will be requested to erase identifiers and refer to the document solely by use of a code.

3. Retention

All records will be kept locked within the IRB office. Electronic files will be stored on a secured, password protected server. Closed study files will either be kept in the IRB office or in Iron Mountain storage facilities. If in storage, files can be recalled within three days if necessary.

Federal regulations require study records to be kept for three years post completion. However, if the study is sharing data under the HIPAA privacy rule, records must be kept
for six years following the closure of the study. Study files can be sent to Iron Mountain for storage but in the event of an audit, they must be retrievable within three days.

4. IRB Records will include at a minimum:

   a. Study files which include the study protocol, study-related material(s), description of the test article, correspondence, approved informed consent form(s), HIPAA Privacy consent document(s), advertising, adverse events and final reports.
   b. Minutes of all meetings.
   c. List of the IRB members, their degrees and areas of expertise.

B. Reports

1. Minutes

   a. Minutes of the previous meeting will be distributed to the IRB at the next convened meeting.
   b. The Chair will sign the minutes following approval by the IRB.

2. Activity Reports

Suspensions

Suspension of any research must be reported immediately to the Chief Medical Officer of the Institution for action and to the funding agency if applicable.

XIV. EDUCATIONAL REQUIREMENTS

All members of the IRB and all investigators and any study personnel shall comply with the current educational requirements of the IRB prior to serving on the IRB or prior to commencing with the research.

The current educational requirements are included in the study application materials.

XV. RECRUITMENT ONLY PROJECTS

Recruitment only activities are those projects in which a credentialed and privileged member of the medical staff is approached by an outside institution, agency or company to aid in recruiting patients from the Institution to participate in a research study.

Recruitment only activities do not generally require a full IRB application; however in order for a study to truly be recruitment only, no study activities, including consenting or screening, may be done at the Institution.

Any recruitment materials (e.g. flyers, brochures, etc.) that will be provided to patients, posted in common areas or passed out by hospital staff must be reviewed and approved by the IRB Committee. Review by Administration is also required.
SANTA CLARA VALLEY HEALTH AND HOSPITAL SYSTEM
O’CONNOR HOSPITAL
ST. LOUISE REGIONAL HOSPITAL

RESEARCH AND HUMAN SUBJECTS REVIEW COMMITTEE
INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION
OF HUMAN RESEARCH SUBJECTS

Guidelines and Requirements for Review by the
Research and Human Subjects Review Committee

Revised 6.21.2019
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter to Investigator</td>
<td>3-4</td>
</tr>
<tr>
<td>IRB Review Process and Requirements</td>
<td>5-9</td>
</tr>
<tr>
<td>Fee Schedule</td>
<td>10</td>
</tr>
<tr>
<td>Guidelines on Additional Protections</td>
<td>11-12</td>
</tr>
<tr>
<td>Exempt Research</td>
<td>13</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>13</td>
</tr>
<tr>
<td>Privacy and Confidentiality</td>
<td>14</td>
</tr>
<tr>
<td>De-Identification of Data</td>
<td>15</td>
</tr>
<tr>
<td>HIPAA Privacy Rule</td>
<td>16</td>
</tr>
<tr>
<td>HIPAA Limited Data Set</td>
<td>16</td>
</tr>
<tr>
<td>Waiver of HIPAA Authorization</td>
<td>17</td>
</tr>
<tr>
<td>Secure Data Storage</td>
<td>18</td>
</tr>
<tr>
<td>Epidemiologic Studies</td>
<td>19-20</td>
</tr>
<tr>
<td>Advertising Requirements</td>
<td>21-22</td>
</tr>
<tr>
<td>Payment to Research Subjects</td>
<td>23</td>
</tr>
<tr>
<td>Screening Tests Prior to Study Enrollment</td>
<td>24</td>
</tr>
<tr>
<td>Informed Consent Requirements</td>
<td>25-27</td>
</tr>
<tr>
<td>Waiver of Informed Consent</td>
<td>27</td>
</tr>
<tr>
<td>Case Reports</td>
<td>28</td>
</tr>
</tbody>
</table>
Dear Investigator:

To conduct research within the Santa Clara Valley Health & Hospital System, please complete the enclosed forms to apply to the Institution’s Research and Human Subjects Review Committee (a duly constituted Institutional Review Board [IRB]) for consideration of your research request. The Committee is an administrative body that has been established to protect the rights and welfare of humans that are recruited to participate in research activities conducted under the auspices of this Institution. The Committee has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations, California State law, and institutional policy.

Anyone wishing to conduct research using Santa Clara Valley Medical Center’s (SCVMC), O’Connor Hospital’s (OCH) or St. Louise Regional Hospital’s (SLRH) patients/facilities must be a member of the Institution staff. Anyone who does not have staff privileges and credentials must be represented by a member of the Institution staff (e.g., department chair; division chief; physician; etc.) who is willing to serve as the principal investigator and be responsible for overseeing the ethical conduct of the research at SCVMC, OCH or SLRH.

The Committee typically meets on the second Friday every other month beginning at 1:00 p.m. To provide sufficient review time for the Committee members, your application must be submitted to the IRB Office (777 Turner Dr. Building N, Office 2N106) by the submission deadline (generally two weeks before the meeting). All investigators are asked to review carefully the Committee’s submission requirements. Submission of incomplete applications may result in delay of the review and approval process. The meeting dates can be found on the Meeting Schedule or can be requested from the IRB Administrator.

The Committee, which is composed of medical professionals and people whose primary concerns are in nonscientific areas, reviews all research for scientific merit and ethical considerations prior to approval. Inasmuch as the Committee includes faculty, staff, and laypersons, protocols must be written in a language that can be understood by all members of the Committee. A 5th grade level of reading should be considered.

An important requirement is evidence that subjects will have the opportunity to give free and informed consent. Another important consideration is that an appropriate balance is ensured between the potential benefits of the research to society or the subject, and the risks assumed by the subject. By enforcing these requirements, the Committee oversees the protection of subjects’ welfare, dignity and privacy, ensuring that the legitimate search for knowledge is balanced with other human values.

After the proposal is submitted, the project’s principal investigator is required to attend a meeting of the Committee in order to further describe the project and answer any questions which might arise. If you are a student, you are required to have your preceptor/faculty advisor attend the meeting with you. There are no exceptions to this policy.

Once scientific merit has been demonstrated and all questions and concerns have been satisfactorily addressed, the Committee may approve the project or it may vote to give conditional approval pending specific changes. Generally, within two weeks of the meeting, a letter will be forwarded to the principal investigator regarding the outcome of the Committee’s decision.

As principal investigator, it is your responsibility to keep all study-related paperwork on file in a confidential manner. This includes all IRB submission materials and IRB correspondence. In the event that the Committee or a federal agency audits your research, the Committee expects the file to be in order. If applicable, the Committee requires that the principal investigator keep sub-investigators apprised of information related to the research.

In accordance with this Institution’s Federalwide Assurance through the Office for Human Research Protections (OHRP), the Research Committee requires that any person wishing to include patients from SCVMC, OCH or SLRH, as subjects in research, complete an educational program on research ethics and become certified prior to conducting the research. This applies to principal investigators, sub-investigators, study personnel involved in the consent process, and any
person involved in analyzing study data who will have contact with participants and/or access to confidential and identifying information.

ADMINISTRATIVE REVIEW AND APPROVAL PROCESS: Research approved by the Committee requires further review and approval or disapproval by administrative officials of the institution. However, those officials may not approve the research if it has not been approved by the Committee. This approval is conducted by Research Administration. Research Administration looks at the impact the research will have on institution staff and resources and whether the research supports the mission of the hospitals. Please contact Jerry Wright, Director of Research Administration at 408/793-2098 or through email to initiate administrative review. Research Administration is also responsible for initiation and management of research agreements/contracts and management of research study funds.

INSTITUTIONAL POLICY FOR EXTERNAL RESEARCH STAFF: Per hospital policy, external study personnel must go through an on-boarding process for the requisite training and orientation before reviewing any patient identifiable information or interacting with patients. This is required for research staff not already covered by a specific agreement with the county (such as medical students and residents authorized to treat SCVMC, OCH or SLRH patients). The lead principal investigator or coordinator should contact Jerry Wright at 408/793-2098 to arrange for the on-boarding of external research personnel. Institutional clearance will be verified during administrative approval prior to the start of the research.

CLINICAL TRIALS REGISTRATION: Projects under the jurisdiction of the FDA must be registered in a data bank (www.ClinicalTrials.gov) as required by U.S. Law. In addition, many journals require registration in a public trials registry as a condition for publication. Trials must be registered at or before the onset of patient enrollment. Please contact the IRB office for assistance with this.

As of January of 2019 each clinical trial conducted or supported by a Federal department or agency must post an IRB-approved consent form on a “publicly available federal website”. This is the responsibility of the primary awardee. This new regulation is designed to increase transparency and assist with the creation of a more informative informed consent form for clinical trials. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. Currently, the Federal Regulations state either ClinicalTrials.gov or Regulations.gov (Docket ID: HHS-OPHS-2018-0021) can be used to upload the documents.
IRB PROCESS AND REQUIREMENTS

INTRODUCTION
The Institutional Review Board (IRB) established for Santa Clara Valley Health and Hospital System (SCVHHS) operates under the name "Research and Human Subjects Review Committee" hereinafter referred to as "Committee." The Committee operates in compliance with the Common Rule under a Federalwide Assurance Number 00001437 and consists of representatives from a variety of scientific disciplines as well as community members. The primary function of the Committee is to assist investigators in the protection of the rights and welfare of human subjects. Investigators, however, carry primary responsibility for assuring that research protocols measure up to the standards established by Federal Regulations (45 CFR 46; 21 CFR 50; 21 CFR 56) and California State law. The Committee also serves to facilitate valuable human subjects research as well as to protect humans who participate as subjects in research, the investigator, and the Institution through a comprehensive review process.

Whenever the Committee reviews a protocol, an initial question is whether the Committee has jurisdiction over approval of the research. That is, whether the research is subject to Committee review. The first two questions the Committee faces are whether the activity involves research, and second, whether it involves human subjects.

Research is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Activities that are not considered to be research and are excluded include: "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected."; public health surveillance activities authorized by a public health authority to assess onsets of disease outbreaks or conditions of public health importance, and certain criminal justice and intelligence activities.

Human Subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes information or biospecimens; or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes". A clinical trial is considered a type of human subject's research.

Before a project involving humans as subjects in research can be initiated, it must first be reviewed and approved by the Committee and then conducted in full compliance with federal regulations, state law, and Committee policy. There can be no exceptions to this requirement, since violations may result in serious repercussions for the investigator, the Committee, and the Institution. The Committee has the authority to review, approve, disapprove or require changes in research activities involving human subjects. It also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or has been associated with unexpected serious harm to subjects (45 CFR 46.113).

The following description of the Committee's review process reflects the various ethical principles and regulatory requirements that each investigator should consider during the design phase of his/her project.

To approve a research project involving human subjects, the Committee must assure itself that:
1. the prospective subject population is appropriate in terms of characteristics and numbers,
2. the recruitment of subjects is free of coercion or undue influence,
3. the experimental design of the study is sound,
4. any risks associated with the research are minimized to the greatest extent possible,
5). the potential benefits are maximized to the greatest extent possible,
6). the risks to subjects are outweighed or balanced by the potential benefits,
7). the level of subject compensation (if applicable) is fair and non-coercive,
8). the degree to which confidentiality is maintained is acceptable,
9). the method used to obtain informed consent is ethically and legally acceptable, and
10). the investigator has the appropriate qualifications, experience and facilities to conduct the research.

II. SUBMISSION OF RESEARCH APPLICATION
The investigator should carefully review the following information. Questions of interpretation may be directed to the Administrator of the Committee.

III. DEADLINE FOR SUBMISSION
The Committee typically meets on the second Friday of every other month. To provide sufficient review time for Committee members, the application must be submitted to the IRB Office (777 Turner Dr. Building N, Office 2N106) at least two weeks prior to the date of the meeting. There are no exceptions to this policy. Applications are assigned on a "first come, first served" basis. You are encouraged to submit your application as early as possible. Meeting dates are subject to change, please check with the IRB Office for updates prior to submitting your project.

IV. INCOMPLETE APPLICATIONS
The application must be typed, not handwritten. An application is incomplete and will be returned if it is illegible, if it fails to follow the instructions, or the material presented is insufficient to permit an adequate review.
Applications must include the following documents, as applicable:

- Application with Department Chair sign off,
- Complete Study Protocol,
- Data Collection sheet or Data Dictionary,
- Personnel list and associated educational certificates and CV's,
- Clinical Investigators Disclosure and Certification with Department Chair sign off (if the study is funded),
- Draft consent and HIPAA forms (if applicable),
- Pediatric Checklist (if applicable).

Because there is no guarantee that the Committee will consider late applications, it is essential that the application be complete and accurate at the time of submission.

V. PRESENTATION OF PROPOSAL TO COMMITTEE
A review date and time will be assigned following submission of the application, at least one week prior to the scheduled meeting. When a new application is submitted, the Principal Investigator (PI) is required to attend the meeting on the scheduled date to present the study and answer any questions that may arise.

IRB Meetings are held at the Santa Clara County Medical Association (SCCMA) building in the second floor conference room. The SCCMA is located at 700 Empey Way San Jose, CA 95128. If the PI is not available on the date of review, this should be made clear to the Administrator of the Committee at the time of submission. The PI may at his/her discretion have another person present the study; however, that person should be as knowledgeable about the study as the PI. If the study is presented by someone other than the PI, and the person presenting the study is unable to answer the Committee’s questions, consideration of the project will be postponed until all questions have been satisfactorily addressed by the PI. The presentation does not require PowerPoint slides and needs to only be an approximate 10-minute overview of your project.

VI. RESPONSE TO INVESTIGATOR
Within approximately ten (10) working days following the meeting at which the investigator’s application is considered, the investigator will be notified, in writing, of the Committee’s decision. Following the investigator’s presentation to the Committee at the meeting, the investigator may request to know the outcome of the Committee’s decision.

VII. FEES FOR REVIEW

Fees for services provided by the Committee are shown on the Fee Schedule. Payment is due upon receipt of the IRB fee invoice after review of the proposed research. Internal transfers can be arranged. Questions concerning fees should be directed to the IRB Administrator. Justification for deferring payment must be submitted in writing.

VIII. EMERGENCY USE OF A TEST ARTICLE

Emergency use is defined as the use of a test article (i.e., investigational use of a drug/device/biologic) on a human subject in a life-threatening or sight-threatening situation in which no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval.

Institutional Policy 638.4 outlines the process and procedures to be completed for Emergency Use. It is acceptable to use the sponsor’s consent forms in this situation. The IRB must receive all documents related to the Emergency Use no later than 5 days after the test article is used.

Emergency Use can only be employed once per test article, per institution. If the PI anticipates subsequent patients may need the test article, a protocol needs to submitted for IRB approval and ongoing use.

Questions concerning emergency use should be directed to the Chair of the Committee, Dr. Elisabeth Mailhot, at 408/885-6551 or contact the Office of the Director of the Pharmacy at 408/885-2300.

IX. CONTINUING REVIEW

Continuing review is required for studies which are enrolling participants or have in-person, telephone or written contact with human subjects for follow-up visits or interviews and is required annually, or more frequently depending on the risk of the study.

However, with the exception of FDA regulated research, changes implemented in 2019 to the Common Rule now allow that research studies in which all interventions have been completed, or in which the PI has reached the data analysis or manuscript preparation phase no longer require continuing review. FDA regulated studies require ongoing continuing review annually or more often as required. For those studies that do meet this criteria, the PI will still be contacted annually by the IRB Administrator to determine if the study is active and asked to complete a brief online check in form. This check-in form will be sent via DocuSign. All changes, adverse events and study termination must still be reported to the IRB.

Regardless of whether continuing review is required or not, ANY changes, adverse events and study termination are still mandatory reporting requirements.

For studies that require continuing review it is the responsibility of the PI to submit to the Committee a renewal application. Upon receipt of the renewal application, the Committee will review and approve, if appropriate, continuation of the project. It is the PI’s responsibility to be aware of the expiration date; however, as a courtesy reminder, a renewal application will be e-mailed to the PI approximately one month prior to the date of expiration of the project’s approval. Failure to submit a renewal application will result in the project being closed.

Final report forms must be completed for all projects as they conclude, whether an ongoing review is needed or not.
X. **REPORTING CHANGES IN RESEARCH**

Any change in a project must be reviewed and approved by the Committee prior to implementation except where an immediate change is necessary to eliminate a hazard to the subjects. Even if the project is no longer undergoing a continuing review, changes still must be requested and approved, prior to being implemented. If a change is necessary prior to receiving approval, the Committee must be promptly informed of the change following its implementation. Investigators should submit a letter with a request for change in protocol and, if applicable, a revised consent form with all changes tracked.

If a change in the protocol or consent form is relatively minor (e.g., spelling errors), it is not necessary to have the subject sign a revised consent form or an addendum to the consent form. If, however, the change is not minor (e.g., addition of an intervention not addressed in the original consent form, disclosure of a previously unidentified risk) the investigator will be required to have currently enrolled subjects sign a revised consent form or addendum to the consent form, whichever the Committee decides is appropriate.

XI. **SUBMISSION OF A REPORT OF AN ADVERSE EVENT DURING THERAPEUTIC RESEARCH**

If a subject experiences an adverse event that is serious, unexpected, and related or possibly related to participation in the research, the investigator is required to submit a written report to the committee within five (5) working days of being notified of the event. The report must state whether or not, in the investigator’s opinion, revision of the informed consent form is necessary as a result of the event. If revision of the consent form is necessary, ALL changes must be incorporated and highlighted (tracked) prior to submission to the committee. If the investigator feels that revision of the consent form is not warranted as a result of the adverse event, the investigator must explain why he/she feels it is not warranted.

Any death must be reported within 24 hours of the investigators knowledge of the event.

Adverse events that are not considered serious or unexpected should be reported during the continuing review period within the status report or within the final report if the study is not being renewed.

In addition to the Committee’s reporting requirements, the investigator must promptly report to the study sponsor, any adverse event or unanticipated problem that may reasonably be regarded as caused by, or probably caused by the study procedure. If the adverse event or unanticipated problem is serious and/or unexpected, the investigator must report the event to the sponsor who, in turn, will notify the FDA (21 CFR 312.64b). Reporting requirements are usually set forth in the sponsor’s version of the protocol or contract agreement between the sponsor and PI.

XII. **SUBMISSION OF A REPORT OF INJURY DURING NON-THERAPEUTIC RESEARCH**

If a subject experiences an injury (physical, psychological) during non-therapeutic research, the investigator must submit a written report to the Committee within five (5) working days of the PI being notified of the event.

XIII. **REPORTING NON-COMPLIANCE WITH COMMITTEE GUIDELINES**

Any incident of non-compliance should immediately be reported to the Committee. Non-compliance with Committee requirements is a violation of Committee policy, Federal Regulations, and California State law for the protection of human subjects.

XIV. **CERTIFICATION OF APPROVAL/SINGLE PROJECT ASSURANCE FORMS**

This institution holds a Federalwide Assurance (FWA) with the Department of Health & Human Services Office for Human Research Protections (OHRP). The identification number is FWA 00001437. This number is important and will be required in certain forms (e.g., PHS-2590) and for certification of IRB review to funding authorities. All research is conducted in accordance with the Common Rule. Protections for participants do not vary based on the provision of funds and/or support for the study. No human subject research for which this FWA applies may be initiated prior to approval by the Committee. The principal investigator and awardee institution are responsible for ensuring that every collaborating institution engaged in federally conducted or supported
research has appropriately assured compliance with 45 CFR 46 and complied with the IRB requirements prior to its involvement of human subjects. Failure to comply may result in fiscal sanctions by the supporting agency. It is the responsibility of the principal investigator to forward all pertinent documents to the funding agency within the agency's deadline for submission.
INSTITUTIONAL REVIEW BOARD (IRB) FEE SCHEDULE

IRB fees are for administrative expenses associated with the review process by the Research and Human Subjects Review Committee and ongoing oversight by the IRB.

Based on an analysis of the current IRB review costs and what other institutions are now charging, effective January 1, 2010 the fees for review are as follows:

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Full Board Review*</th>
<th>Expedited Review*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review of Application</td>
<td>$2,500.00</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>$1,000.00</td>
<td>$750.00</td>
</tr>
<tr>
<td>Study Modifications/ Amendments</td>
<td>$750.00 (Revised Consent Forms, Recruitment Materials, etc.)</td>
<td>$250.00 (Minor Changes to Protocol, Consent Forms, etc.)</td>
</tr>
<tr>
<td>Reactivation of study that has lapsed in IRB approval</td>
<td>$500 (Requires Full Board Review)</td>
<td></td>
</tr>
</tbody>
</table>

* Review category is determined by the IRB Administrator or Chair.

The following projects will not be charged IRB review fees:
1. Entirely unfunded projects;
2. Research determined to be “exempt” from further IRB review;
3. Applications involving a non-research use of a Humanitarian Use Device;
4. Applications for emergency use of an investigational drug or device;
5. Reporting noncompliance, potential unanticipated problems, adverse events, safety reports or study closures.

Payment is due upon receipt of the IRB fee invoice sent to the principal investigator after review of the proposed research. It is the investigators responsibility to ensure payment is made by the sponsor.

It is expected that investigators or their staff incorporate applicable IRB fees into the study budget during the administrative approval process.

The costs of the review process are still incurred whether or not the IRB approves the study, even if subjects are never enrolled, or if the study is terminated early. The invoice is therefore due and payable upon receipt.

LATE FEES
If payment has not been made within 60 days from receipt of the invoice, 5% of the outstanding balance will also be due. This will increase 5% every following 30 days thereafter.

If payment is not received within 6 months of the invoice date, the study is subject to closure.

Should you have any questions regarding IRB fees, please contact the IRB office at (408) 885-2383.
GUIDELINES ON ADDITIONAL PROTECTIONS AND VULNERABLE POPULATIONS

Provided below is guidance on safeguards needed for inclusion of prisoners, children, fetuses and neonates, persons deemed to be economically and educationally disadvantaged and persons with impaired-decision making ability. If you intend to enroll such individuals, please indicate what protections have been included in the protocol to avoid any coercion or undue influence on prospective enrollees or enrolled subjects.

Children

Federal regulations impose special protections when research involves children as subjects. “Children” are minors who cannot give consent for the treatment involved in the research. Whether the Committee will approve a research study that involves a child depends upon the degree of risk presented to the child and the benefits expected to be gained by the child or with respect to generalizable knowledge about the child’s disorder or condition. The Committee must also determine that adequate provisions are made for securing the child’s assent, when appropriate, and the parent(s) or legally appointed guardian’s consent.

In most cases, parental consent must be obtained if the research involves minors under the age of 18. A written consent form must be used to document informed consent. The Committee may decide that only one parent’s consent is necessary if the study involves minimal risk, or greater than minimal risk but also offers prospects of direct benefits to the subject. In other cases (for example, studies that involve greater than minimal risk but promise generalizable knowledge about the subject’s condition, or studies not otherwise approvable), both parents must consent unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has sole custody or legal custody of the child. The Committee may waive the parent or guardian consent requirement if it is not a reasonable condition (for example, the child who will be a research subject is neglected or abused), but it must assure that an appropriate mechanism for protecting each child is substituted.

Minor subjects 7 years of age or older should be involved in the decision to participate in a research project unless:

1. The subject is incapable, mentally or emotionally, of being reasonably consulted;
2. The Committee specifically waives this requirement.

If an experimental drug will be administered to a minor who is 7 years of age or older, consent must be obtained from the minor as well as from the parent or legally appointed guardian (required in accordance with California State law).

Unless the requirement is waived by the Committee, documentation of assent is required for subjects 7 to 18 years of age. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the Committee for review. The form should include a simplified version of the elements of informed consent (a sample of an assent form is located under the section entitled “Sample Consent Forms”). Note that the child should be given an explanation—at a level appropriate to the child’s age, maturity and condition—of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

A pediatric checklist MUST be completed when conducting research involving minors. This checklist is designed to assist the IRB in determining if your research fulfills all of the requirements of the federal regulations as outlined in 45 CFR 46 Subpart D and 21 CFR Parts 50 and 56 (if FDA regulated) for inclusion of children as research subjects. If your project involves children, please inquire about the checklist with the IRB Administrator.

Prisoners

NO PRISONER MAY BE ENROLLED IN A RESEARCH STUDY WITHOUT THE COMMITTEE’S PRIOR APPROVAL. THIS APPLIES TO ANY PERSON WHO IS CONFined/INCARcerated IN Prison OR kePT IN custody AS A RESULT OF A LEGAL PROCESS. Federal regulations and the State of California have special requirements with which the Committee must comply when reviewing research involving prisoners. Research on prisoners must be reviewed at a convened full board IRB meeting and are not reviewed via expedited review. Some research may be exempt but only if prisoners are included incidentally and the research involves a broader population. The IRB must make the exempt determination.

Pregnant Women, Fetuses and Neonates

IRB Investigator Guidelines: Santa Clara Valley Health and Hospital System, O’Connor Hospital and St. Louise Regional Hospital
Federal regulations have special requirements for research involving pregnant women and fetuses and must be followed. These regulations will be reviewed by the Committee and any questions should be directed to the IRB Office.

**Persons who are Economically Disadvantaged**
Economically disadvantaged persons may be considered vulnerable due to their socioeconomic background. This population may have difficulty providing for food, shelter and basic needs for themselves or their families.

As research studies often provide financial incentives to participation, it is imperative research conducted with this population provides information to the IRB on safeguards enacted to prohibit coercion and undue influence.

**Persons who are Educationally Disadvantaged**
Educationally disadvantaged persons include those people who may have a learning disability or difficulty communicating with researchers, whether due to cognitive, cultural or language barriers.

Enrollment of participants in research that fall under this category will need additional provisions included in the study application on how the PI and study team will present materials in a manner that will allow the participant to have full understanding. The informed consent and HIPAA templates provided by the IRB are currently written at a 5th grade reading level and any additional study-specific information added into the templates, must remain at this level to foster understanding and comprehension.

**Individuals with Impaired-Decision Making Ability**
Persons with cognitive deficits may have a diagnosed or undiagnosed psychiatric disorder, such as depression or schizophrenia; an injury, such as a stroke or traumatic brain injury or a developmental disability, such as autism or mental retardation. Please note, the examples provided above are not to be considered a complete list.

Impaired-decision making ability is a broad term for illnesses, injuries and impairments that affect a person’s judgment and reasoning. PI’s conducting research on participants with cognitive deficits need to be aware of additional safeguards in place for this population. As the basic tenant of research is the right to participate or not, it is possible that this population may not be able to make a purposeful decision whether to enroll in a research study. The PI must also verify the participant understands the risks and benefits of the research and the alternatives to participating.
GUIDELINES FOR EXEMPT RESEARCH
Exempt research are activities that satisfy the definition of research, but are specifically carved out by the Common Rule. Generally, exempt activities are not subject to the Common Rule, except where specifically noted.

Questions relevant to exempt research should be directed to the IRB Office. Research that is thought to be exempt from IRB review must still be submitted to the committee to make the exemption determination. The Office of Human Subjects Protection recommends the investigator should not make the exemption determination. If the committee grants exemption, the project is exempt from further IRB review. However, it may require Administrative Review to determine the staff time and resources allocated to the project. This approval can be done through the Research Administration Director, Jerry Wright.

GUIDELINES FOR EXPEDITED REVIEW
The expedited review procedures apply to research that involve no more than minimal risk, or for research that was previously approved by the IRB but requesting minor changes.
GUIDELINES ON PRIVACY AND CONFIDENTIALITY

The possibility that research may invade the privacy of individuals or result in a breach of confidentiality sometimes arises in biomedical and behavioral research. Under certain circumstances, an invasion of privacy or breach of confidentiality may even present a risk of serious harm to subjects (e.g., as when the research obtains information about subjects that would, if disclosed by the research, jeopardize their jobs or lead to their prosecution for criminal behavior). Under less dramatic circumstances, an invasion of privacy or breach of confidentiality can be morally wrong, or, at least in theory, provide cause for legal action against a researcher or institution. In addition, both the Health Insurance Portability and Accountability Act (HIPAA) and the Federal Policy for the Protection of Human Subjects (known as "Common Rule") provide privacy and confidentiality protections to research participants.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others. Inherent in confidentiality is that information should always be disclosed consistent with what the research participant/patient has authorized.

Privacy and Research

In the context of research, concerns about privacy pertain primarily to the methods used to obtain information about subjects and how that information is then shared with others. Objections to the nature of information sought in research are sometimes couched in the language of privacy (i.e., that it would be an invasion of a subject’s privacy even to inquire about certain matters of a personal nature).

Privacy Issues in the Use of Personally Identifiable Records

Identifying suitable subjects often presents no ethical problems. Physicians studying a particular disease may be able to identify subjects from among their own patients, and the sociologist interested in studying people who have recently been married can identify their subjects through public records. Privacy concerns may arise when potential subjects cannot be identified from public records or from sources that the researcher has identified to which the researcher’s work provides access.

To identify suitable subjects, researchers must sometimes approach institutions (e.g., hospitals or schools) seeking information generally regarded as confidential (e.g., the identity of patients treated for a particular condition or students meeting a particular criterion). In some circumstances, the researcher needs information that would make it possible to contact suitable subjects to obtain further data. In other circumstances, no contact with subjects is contemplated because the information to be obtained from the records is sufficient (or will be combined with data from other sources). In these cases, personal identifiers may not be needed by the researchers, or, if needed and recorded, can be destroyed at some stage of the research. All of these factors are relevant to IRB assessments of privacy and confidentiality issues in research.

When patients give information about themselves to a doctor or hospital for the purpose of facilitating diagnosis or treatment of disease, they do so in a relationship of trust. They generally expect that the information will be shared only as necessary for their health care or reimbursement by their insurance company or other third party payer; patients would not expect information that identifies them to be passed on in casual conversations or made available to journalists, etc. Nor do they necessarily intend that the information will be shared with even their closest family members.
DE-IDENTIFICATION OF DATA

Confidentiality of Research Data
A major set of concerns about confidentiality pertains to the methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.

In most research, assuring confidentiality is only a matter of following some routine practices: substituting codes for identifiers, removing face sheets (containing such items as names and addresses) from survey instruments containing data, properly disposing of computer sheets and other papers, limiting access to identified data, training research staff on importance of confidentiality, and storing research records in locked cabinets. More elaborate procedures may be needed in some studies, either to give subjects the confidence they need to participate and answer questions honestly, or to enable researchers to offer strong, truthful assurances of confidentiality. Such elaborate procedures may be particularly necessary for studies in which data are collected on sensitive matters such as sexual behavior or criminal activities.

In studies where subjects are selected because of a sensitive, stigmatizing, or illegal characteristic (e.g., persons who have sexually abused children, sought treatment in a drug abuse program, or who have tested positive for HIV), keeping the identity of participants confidential may be as or more important than keeping the data obtained about the participants confidential. In such instances, any written record linking subjects to the study can create a threat to confidentiality. Having the subjects of these studies sign consent forms may increase the risk of a breach of confidentiality, because the consent form itself constitutes a record, complete with signature that identifies particular individuals of the group under study. Federal Policy allows for a waiver of the requirement for the investigator to obtain a signed consent form where it will be the only record linking subjects to the research, and where a breach of confidentiality presents the principal risk of harm that might result from the research. FDA regulations allow for a waiver of the requirement to obtain a signed consent form only when the research presents no more than minimal risk and involves procedures that do not normally require consent when performed outside the research context. If both FDA regulations and Federal Policy apply to a protocol, the Committee must meet the requirements of both. In this instance, documentation of informed consent can be waived only if the consent form is the sole record linking subjects to the research, the research involves minimal risk, breach of confidentiality is the principal risk of harm and the procedure involved in the research is one that does not normally require consent when performed outside the research context. (NOTE that the foregoing waiver provisions apply to documentation of informed consent and not waiver of the requirement to obtain informed consent.)

Where data are collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) protection of confidentiality consists of more than preventing accidental disclosures. There have been instances where the identities of subjects or research data about particular subjects have been sought by law enforcement agencies, sometimes under subpoena, and with the threat of incarceration of the uncooperative researcher. Under federal law, researchers can obtain an advance grant of confidentiality called a ‘Certificate of Confidentiality’ that will provide protection even against a subpoena for research data (to obtain further information on this subject, contact the Administrator of the Committee).
HIPAA PRIVACY RULE

HIPAA is the Health Insurance Portability and Accountability Act that was enacted by Congress in 1996. The major purpose of HIPAA is to safeguard patient health information and require that covered entities use PHI responsibly and protect against disclosures to ensure patient privacy. All research is subject to the Health Insurance Portability and Accountability Act (HIPAA), effective on April 14, 2003.

The Privacy Rule establishes the conditions under which Protected Health Information (PHI) may be used or disclosed by covered entities for research purposes. In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

Below is information on creating a limited data set and criteria for waiver of authorization under HIPAA. The HIPAA consent form template approved by the committee can be found in the separate packet for IRB Forms/Templates. If applicable to your study, please complete the HIPAA privacy document in accordance with that which applies to your particular study and submit the document with the research application.

Limited Data Set

A Limited Data Set may be established by removing the following identifiers:

1. Names
2. Postal address information, other than town and city, state, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social Security numbers;
7. Health plan beneficiary numbers;
8. Account numbers;
9. Certificate/license numbers;
10. Vehicle identifiers and serial numbers, including license plate numbers;
11. Device identifiers and serial numbers;
12. Web Universal Resource Locators (URL);
13. Internet Protocol (IP) address numbers;
14. Biometric identifiers, including finger and voice prints; and
15. Full face photographic images and any comparable images.

A Limited Data Set can include the following identifiable information:

- Admission, discharge, and service dates;
- Date of death;
- Age (including age 90 or over); and
- Five digit Zip Code.
WAIVER OF AUTHORIZATION UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

A study qualifies for a waiver of authorization under HIPAA if the following conditions apply. Explain why, in your opinion, you feel that your study meets the following criteria (explain reasoning within the protocol under number 16). NOTE: Include all facts supporting your opinions.

1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals.
   - An adequate plan to protect identifiers from improper use and disclosure has been provided.
   - Adequate written assurance has been provided that the protected health information will not be reused or disclosed to any other person or entity.

2. The research could not practicably be conducted without a waiver of authorization.

3. The research could not practicably be conducted without access to and use of the protected health information.

NOTE: Identifiers must be retained in order to be in compliance with state law regarding genetic testing.
SECURE DATA STORAGE

Storage of research data is critical to protecting patient health information and participant confidentiality. To safeguard study data, the Committee will need to review the data collection sheet or data dictionary you plan to use. A data collection sheet or data dictionary contains the list of data and variables to be collected for the research project and should list all patient demographics, all chart review elements and any prospective data collection to be done. Most commonly, data collection sheets are completed in Microsoft Excel. Sponsors may also provide a data dictionary for collaborative, multi-site trials. Only persons who are on the personnel list are allowed to have access to patient identifiable data.

The IRB Committee has worked in collaboration with the Information Technology (IT) department, the Chief Medical Information Officer (CMIO), County Counsel and the Compliance Department to determine the most secure location for patient data.

H: Drive or Isilon
Currently, the IRB requires use of Isilon, or the HIPAA (H:) Drive. This is the only recommended and approved location for research data to be stored. The PI can request space on the Isilon drive through the Administrator of the Committee. If you do not have access to the H drive from your workstation, it can be provided remotely.

A short form will need to be completed and submitted to the IRB Administrator. The IRB Administrator will work with IS to create the folder for your project. The IRB Administrator can provide additional access to subsequent personnel once they have been approved by the IRB. The Shared (S:) Drive is not a secure location and patient data should not be stored on this drive.

REDCap
If you are the PI of a collaborative study and a requirement of participation is to upload data into the sponsor’s REDCap system, please contact the IRB Administrator. A review will need to be conducted by the IT Security and Compliance teams to determine if the level of security used by the parent site is acceptable.

If you are planning to store PHI on an electronic device, the device must be encrypted and password-protected. If you have a storage request for a system not discussed above where you would like to store data, please contact the IRB Administrator. The system would need to be vetted and approved by the CMIO, the Compliance Department and IT prior to use.
GUIDELINES FOR EPIDEMIOLOGIC STUDIES

Epidemiologic studies present several unique problems because they often use sensitive private documents, such as medical records, and link them with other data, such as employment, insurance, or police records. They also often combine historical research with survey and interview techniques. Epidemiologic studies present significant problems regarding privacy and confidentiality.

In epidemiologic studies, the investigator is attempting to identify risk factors for particular diseases, conditions, or behaviors, or risks that result from particular causes, such as environmental or industrial agents. The research techniques usually employed involve record reviews to identify potential subjects, followed by telephone or in-person surveys or interviews, or mailed questionnaires. Epidemiologic studies may also be limited to reviews of records from various sources (e.g., medical, employment, and police records), which the investigator links together. The validity of epidemiologic studies requires a very high degree of participation (as much as 90 percent) by potential subjects. The behavioral component of the factors often studied in epidemiologic research means that significant rates of nonparticipation are likely to produce biased findings.

When reviewing epidemiologic research, the Committee must ensure that adequate steps are taken to preserve the confidentiality of the data collected. The investigator must specify who will have access to the data, how and at what point in the research personal information will be separated from other data, and whether the data will be retained at the conclusion of the study. The Committee also requires a thorough description of interview instruments and questionnaires.

The primary ethical concerns presented by epidemiologic studies are protection of subjects' privacy (i.e., the right 'to determine what will be known about oneself') and the confidentiality of data (i.e., the determination that information will not be disclosed without permission). Privacy concerns in turn raise questions about the role of informed consent. Even where subjects are not at risk of harm from epidemiologic research, access to records for which individuals have not consented clearly constitutes an invasion of privacy. The Committee expects that the privacy of those records will be maintained, and their contents kept confidential. Access to those records without prior consent for the subject raises concerns about the violation of the ethical principle of respect for persons (sometimes referred to as autonomy).

When a study involves reviews of records without any contact with individuals, it can be argued that the subjects of the research are at no risk of harm, beyond the 'wrong' of invasion of privacy, unless their identity is or can be linked to the research records. Such linkage is often used in epidemiological research, in which case the Committee must ensure that subjects' privacy interests will be adequately protected.

Where the investigator will have personal contact with subjects, a potential for harm does exist. Since they are identified as potential subjects because they either have or are at risk of developing a disease or condition, simple contact with subjects may present a risk of harm, either because of sensitivity to discussing a disease or condition they know they have, or because they may not be aware of their condition.

Consider the case of epidemiologic research into risk factors for HIV infection [human immunodeficiency virus (HIV) is the virus that causes acquired immune deficiency syndrome (AIDS)].

Potential subjects are, by definition, under investigation because of an anticipated relationship to HIV (except for control subjects, who may or may not know which group they are in). Members of known risk groups may face considerable emotional disturbance by being contacted for an HIV study. In cancer studies as well, potential subjects (or their relatives) may be disturbed by the prospect of discussing their medical condition or experience.
With respect to confidentiality, disclosure of information such as that usually collected in epidemiologic studies also presents an ethical concern. All information collected as part of a study is confidential: Data must be stored in a secure manner and must not be shared appropriately. The threat of disclosure of data that can be linked to individuals represents another risk of harm to individuals. In properly designed studies, this risk is insignificant. To maintain confidentiality, researchers must be prepared to resist subpoenas seeking to obtain research data. Guidance on HIV studies from The Office for Protection from Research Risks (OPRR) states that:

Where identifiers are not required by the design of the study, they are not to be recorded. If identifiers are recorded, they should be separated, if possible, from data stored securely, with linkage restored only when necessary to conduct the research. No lists should be retained identifying those who elected not to participate. Participants must be given a fair, clear explanation of how information about them will be handled.

As a general principle, information is not to be disclosed without the subject’s consent. The protocol must clearly state who is entitled to see records with identifiers, both within and outside the project.

Another question is whether and at what point subjects must consent to epidemiologic research: prior to selection but after first contact, before the first contact, or before gaining access to records (through the custodian of the records). In general, wherever possible, potentially eligible subjects should be contacted either by the person to whom they originally gave the information, or by a person with whom they have a trust relationship.

Where identifiers that can be linked to individuals will be used, each subject must provide informed consent prior to participation, except in certain limited circumstances. The federal regulations allow for waiver or alteration of consent requirements under the following conditions: 1) The research involves no more than minimal risk to the subjects; 2) The research could not practicably be carried out without the requested waiver or alteration; 3) If the research involves using identifiable private information of identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; 4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and 5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Further, when the study involves the collection of information of a sensitive nature (e.g., sexual or criminal activity), an investigator may request that the requirement to obtain written consent be waived. The Committee may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: 1) that the only record linking the subjects and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or 2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where informed consent will be obtained, the specific information that the investigator will give a potential subject, both at the time of first contact and in the consent negotiations, must be addressed. If identifiers will be collected and retained, subjects must be so informed, and also be told whether they will be contacted again in the future. The investigator should also provide subjects with a written assurance that any publications that result from the research will present the data only in aggregate form, and in such a manner that individuals cannot be identified. Investigators should inform subjects of what information gained from the study will be passed along to them (e.g., the presence of diseases or conditions they may not have known about).

IRB Investigator Guidelines: Santa Clara Valley Health and Hospital System, O’Connor Hospital and St. Louise Regional Hospital
GUIDELINES FOR ADVERTISING

FDA requires that the Committee review and have authority to approve, require modifications in, or disapprove all research activities covered by IRB regulations [21 CFR 56.109(a)]. The Committee is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, the Committee is expected to review all research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent document, and, for studies conducted under the investigational New Drug (IND) regulations, the investigator’s brochure are examples of documents that the Committee must review. The Committee must also review the methods that investigators propose to use to recruit subjects.

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, is not in and of itself an objectionable recruitment practice. Direct recruiting advertisements are seen as part of the informed consent and subject’s selection processes [21 CFR 50.20, 50.25, 56.111(a)(3) and 812.20(b)(11)]. Committee review is necessary to ensure that the information is not misleading to subjects. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

When direct advertising is to be used, the Committee must review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. The Committee must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the Committee must review the final audio/video tape. The Committee may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate content. The review of a taped message prepared from an IRB approved test may be accomplished through expedited procedures.

No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects but would also be a violation of FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].

Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" implies that all study subjects will be receiving newly marketed products of proven worth.

Advertisements should not promise "free medical treatment," when the intent is only to say that subjects will not be charged for taking part in the investigation. The Committee must consider if the promise of treatment without charge is coercive to financially constrained subjects. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid.

If a clinical investigator decides to begin advertising for subjects after the study has received approval, the advertising may be considered as an amendment to the ongoing study. When such advertisements are easily compared to the consent, the Committee may choose to review and approve the advertisement using expedited review procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement must be reviewed at a convened meeting.
Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. A sample advertisement is included below.

It should be noted, however, that FDA does not require inclusion of all of the following items:

1) The name and address of the clinical investigator and/or research facility;
2) The condition under study and/or the purpose of the research;
3) In summary form, the criteria that will be used to determine eligibility for the study;
4) A brief list of participation benefits, if any (e.g., a no-cost health examination);
5) The time or other commitment required of the subjects; and
6) The location of the research and the person or office to contact for further information.

**SAMPLE ADVERTISEMENT**

**HEALTHY VOLUNTEERS NEEDED FOR BRAIN IMAGING STUDY**

The Department of (Insert Name) at (Insert Name of Institution) is conducting a research study that will involve a series of medication and brain imaging studies. Participants will have PET (positron emission tomography) scans performed. The time commitment for participation in the study involves:

1. An evaluation that will last about 4 hours
2. A neuropsychological testing session that will last about 3 hours
3. A PET scan preparation and session that will last about 5 hours
4. An MRI (Magnetic Resonance Imaging) scan session that will last about 1 hour

Participants must be between the ages of 18 and 70, and have no personal or family history of psychiatric or substance abuse problems. Volunteers will be financially compensated for their time and the inconvenience of traveling to the study center.

For more information, interested individuals should call the research coordinator in the Department of Neurology at 408/000-0000.
PAYMENT TO RESEARCH SUBJECTS

The Committee is required to determine that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)]. It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to a study subject which is excessive in relation to the time spent by the subject or costs, such as transportation, which are incurred by the subject may be considered to present undue influence. Payment to research subjects for participation in studies in not considered a benefit, it is a recruitment incentive. Financial incentives are often used when benefit to subjects is remote or non-existent. The amount and schedule of all payments should be presented to the Committee at the time of initial review. The Committee must review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence [21 CFR 50.20].

Any payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, the Committee may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to the FDA, provided that such incentive is not coercive. The Committee must determine that the amount paid is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent form.
SCREENING TESTS PRIOR TO STUDY ENROLLMENT

For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.

Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent. On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that clinical tests performed solely for determining eligibility for research enrollment are not required for their medical care. Physician-investigators should take extra care to clarify with their patient-subjects why certain tests are being conducted.

Clinical screening procedures for research eligibility are considered part of the subject selection and recruitment process and, therefore, require IRB oversight. If the screening qualifies as a minimal risk procedure [21 CFR 56.102(i)], the IRB may choose to use expedited review procedures [21 CFR 56.110]. The IRB should receive a written outline of the screening procedure to be followed and how consent for screening will be obtained. The IRB may find it appropriate to limit the scope of the screening consent to a description of the screening tests and to the reasons for performing the tests including a brief summary description of the study in which they may be asked to participate. Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a consent document [21 CFR 56.109(c)]. If the screening indicates that the prospective subject is eligible, the informed consent procedures for the study, as approved by the IRB, would then be followed.

Certain clinical tests, such as for HIV infection, may have State requirements regarding (1) the information that must be provided to the participant, (2) which organizations have access to the test results and (3) whether a positive result has to be reported to the health department. Prospective subjects should be informed of any such requirements and how an unfavorable test result could affect employment or insurance before the test is conducted. The IRB may wish to confirm that such tests are required by the protocol of the study.
INFORMED CONSENT REQUIREMENTS

The most common reason for delay of approval of a proposal is an inadequate consent form. Therefore, it is recommended that all investigators review carefully the following information. Submitted consent forms that do not reflect the required format and standards will be returned to the investigator for revision. Existing consent forms, regardless of approval elsewhere, will not be accepted by this Committee. The Committee does not accept consent forms for use in our study population that have been written and approved for use at other institutions.

1. Concise Summary
   A new requirement is the necessity of a concise summary at the beginning of the informed consent. This concise summary requires that key information be conveyed to the participant in an organized manner that will assist the prospective subject or legally authorized representative (LAR) in understanding the reasons why they may or may not want to participate in the research. This summary can be short with additional details provided in the body of the consent form. If you have questions about this new section or would like to see an example of a summary, please contact the IRB Administrator.

2. Readability and Style Requirements
   The informed consent form must be written in the second person throughout (e.g., you are invited to participate, you will be assigned, etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective subject. Utilization of the first person may be interpreted as presumption of subject consent before consent has been legally obtained.

   The font used may be Arial, Tahoma, Helvetica or one that is similar. The font size should be at least a 12 pitch.

   The most common consent form deficiency is an unacceptable level of readability. A prospective subject's ability to understand the elements of informed consent is a function of their intelligence, education, maturity and language skills. It is, therefore, necessary to adapt the language level of the consent form to fit the subject's capabilities.

   The informed consent form must be written in simple enough language so that it is readily understood by the least educated, least sophisticated of the subjects to be utilized. It is recommended that the language consist of short concise sentences arranged in relatively short simplistic paragraphs. It should be remembered that terms which are commonly used by members of a profession become a part of the professional's language. Many people outside that profession, however, do not understand the language. Common words in medicine, such as catheter, intravenous (IV), prognosis, symptomatology, randomly assigned, efficacy, placebo, blinded, etc. are not understood by many laypersons. Terms in the fields of psychology/sociology such as cognitive style, attribution and social sufficiency are equally misunderstood. If there is any doubt that a term may not be understood, a simpler term should be used or a definition should be added, e.g., intravenous (given directly into a vein by way of a needle) or 4 cc (a teaspoonful).

   If the consent form will be used for parents or other legal representatives consenting on behalf of a minor or other legally incompetent subject, the consent form should be written in a style that reflects the fact that it is the minor or other subject who is the participant. The form should be clear that the consenter is agreeing to allow said subject to participate in the study. California law provides guidance on when someone other than the individual can consent to research and who is authorized to consent on behalf of the individual and under what conditions.

IRB Investigator Guidelines: Santa Clara Valley Health and Hospital System; O'Connor Hospital and St. Louise Regional Hospital
Do not use EXCLUDATORY LANGUAGE through which the subject or the subject’s representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

3. **Length**
   The informed consent form should be lengthy enough to explain consent factors adequately, but not so lengthy or detailed as to lose the attention of the subject or to cause confusion.

4. **Format**
   An informed consent form must be structured to fit each project. In order to increase consent form readability, however, the consent form should be written to include the appropriate elements of consent in the same sequence as described in the attached. Each element should be identified by the listed subheading in bold type. Use of a subheading increases readability and helps the prospective subject focus attention on each element of consent. The format suggested may be modified or expanded depending upon the nature of the particular study.

A witness to the consenting process is required in certain circumstances. These circumstances include: 1). When a short form consent is being used; 2). When the subject is unable to read, write talk or is blind but has the capacity to make decisions; 3). When the subject’s guardian or legally authorized representative is unable to read, write, talk or is blind.

In circumstances when a witness is required, the witness must not be involved in the study (cannot be a study staff member) but can be a family member if the person has no stake in the subject’s participation in the study. In addition to the requirements for the signatures of the subject (or representative) and the person obtaining authorization, the witness must also sign the consent certifying that the subject was informed of the research, was given an opportunity to ask questions and signed the consent form voluntarily.

**Short Form Consents**
A short form consent is used when a subject speaks a language, unanticipated by the PI. With prior IRB approval a short form consent can be used. Additional stipulations are required to use the short form. These requirements are:

i. The IRB must approve a written summary of what will be said to the subject or LAR. This summary can be the full English informed consent form.

ii. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. The witness must be fluent in both English and the language of the subject.

iii. At the time of consent, the short form document should be signed by the subject and the summary should be signed by the person obtaining consent as authorized under the protocol. The short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the IRB requires that the translator not serve as the witness.

iv. Use of the short form and summary is required when enrolling subjects using the short form foreign language consent process.

v. The finalized short form version must be used as the template for all foreign language versions. The IRB must receive and approve all certified foreign language translations prior to use.
vi. At the annual renewal, the IRB must be provided with an update on the frequency of each of the languages used.

In addition to these requirements, samples of consent forms are provided in the separate packet for IRB forms/templates.

**WAIVER OF INFORMED CONSENT**

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent if the IRB finds and documents the following. If, as the study investigator, you are requesting a waiver of the requirement to obtain informed consent, explain why, in your opinion, you feel that your study meets the following criteria.

I. The research involves no more than minimal risk to the subjects;

II. The research could not practicably be carried out without the requested waiver or alteration;

III. If the research involves using identifiable private information of identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

IV. The waiver or alteration will not adversely affect the rights and welfare of the subjects: and

V. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Please note the following with regard to the rules about consent waiver:
1) Generally, only completely retrospective studies will meet criterion #2, but investigators are free to request a consent waiver for any study they feel meets these criteria.
2) The source for these criteria is the Federal Regulations governing the operation of all IRBs. They set a minimum standard for consent waiver; however, the investigator should be aware that the law also provides that the IRB can deny the consent waiver based on its internal review of the study even if the study meets these minimum criteria if it finds that a consent waiver is inappropriate.
CASE REPORTS
Data concerning three or fewer individuals collected for the purposes of analyzing and diagnosing the individuals' condition or for instructional purposes, does not involve a testable hypothesis and is not considered research.

Case reports that are prepared for publication in medical journals or presented at professional meetings within or outside of the institution that are unrelated to care of or teaching about the involved patient(s) require IRB review prior to presentation or publication. Case reports presented within the institution at clinical conferences involving faculty, residents, and students, for purposes of education, or as part of the planning and/or evaluation of patient care which are fully de-identified do not require consent or IRB review.

However, case reports often involve reporting on a rare disorder, condition, or course of treatment. In such cases, individuals may be more easily identified as being the subject of a publication than individuals with a more common disease or condition. Also, items such as the patient's age and gender in combination with diagnosis and course of treatment, the name of the treating physician etc. may cause others to be able to identify the patient. In these cases, HIPAA authorization from the patient and IRB review are required.

Protected Health Information and Patient Authorization
As the Institution's IRB also serves as a Privacy Board, any case report that involves any protected health information must be submitted to the IRB for prospective review for approval or exemption. If the report will contain information that directly or indirectly identifies a patient, the author must attain authorization for the use of this identifiable information from the patient. An author may be exempted from obtaining a signed authorization from the patient discussed in the case report if certain identifiers are removed from the case report prior to disclosure (i.e., before the case report is submitted to a journal). The IRB can provide an authorization form to be used in case reports. It is the responsibility of the author to ensure compliance with patient privacy, institutional rules, and federal regulations. It is also the responsibility of the author to ensure that (i) no photos or illustrations that contain identifiable features are included in the case report and (ii) the case(s) described in the report are not so unique or unusual that it might be possible for others to identify the patients in the case reports.

Case Series of More than Three Patients
Records review of more than three patients usually occurs when the clinician/investigator starts asking specific research questions which leads to formal systematic collection of data, moving these activities closer to prospectively designed research. The boundaries between case reporting and formal medical records research may be unclear. Clinicians are advised to consult with the IRB or submit larger case series reports for IRB review when uncertainty exists about whether formal and systematic collection of human subject's research is occurring.
INSTITUTIONAL REVIEW BOARD FORMS/TEMPLATES

INSTRUCTIONS: The IRB requires use of Institution approved forms for research conducted within Santa Clara Valley Medical Center (SCVMC), O’Connor Hospital (OCH) and St. Louise Regional Hospital (SLRH). These forms are divided into three sections. Depending on the nature of your research, some sections will apply while others will not. Please review each section to determine applicability to your research, and include the appropriate forms in your IRB application submission.

Before completing the required forms, please review the separate packet on the investigator guidelines for submission.

To access specific forms, please place your mouse over the document name and press ctrl and click to follow the link to the appropriate page.

Instructions for Submission have been developed to assist you in assembly of your materials.

Once all forms are completed, the IRB requires one single-sided original application and four double-sided copies. Please make sure that all forms are numbered by section (i.e. protocol, informed consent, HIPAA). Do not staple any of the materials; secure only with paper clips or binder clips. Electronic copies of all study documents must also be sent to the IRB Coordinator.

Questions can be directed to the IRB Administrator, Kim Bellon, through e-mail or by phone at (408) 885-2383.

Section 1 - Required Forms

The following forms must be completed for each research submission. Additional forms may be required if applicable to your research.

- Application for Review by Research Committee
- Personnel List
- Protocol
- Clinical Investigators Disclosure and Certification (only required if the study is sponsored)

Section 2 - Informed Consent/Assent

The following sample forms are for use in studies that require obtaining consent from potential study participants. Please also review the Investigator’s Informed Consent Checklist. NOTE: The IRB requires use of the template forms even if the project is part of a multi-center study. The only exception is for sponsored cancer trials. The IRB will accept sponsor consent forms for these studies provided that the page number corresponding to the section within the sponsor consent is listed next to each requirement within the Investigator’s Informed Consent Checklist.

- Sample Standard Informed Consent Form
- Sample Parental Consent Form
- Sample Assent Form (For Children Ages 7-12)
- Sample Assent Form (For Children Ages 13-18)

Updated 1.24.18
Section 3 – HIPAA Authorization
HIPAA (Health Insurance Portability and Accountability Act) might apply if your research involves collecting or using PHI (Protected Health Information). If the HIPAA Privacy Regulation applies to your research, please use the appropriate HIPAA template. NOTE: The IRB Office can provide translated HIPAA templates for certain languages.

HIPAA Privacy Document Template

Pediatric HIPAA Template

NOTE: TO CONDUCT RESEARCH WITHIN THE SYSTEM ALSO REQUIRES ADMINISTRATIVE APPROVAL WHICH IS SEPARATE FROM THE IRB PROCESS. PLEASE CONTACT JERRY WRIGHT, DIRECTOR OF RESEARCH ADMINISTRATION, AT 408/793-2098 TO INITIATE ADMINISTRATIVE REVIEW.
INSTRUCTIONS FOR COORDINATING AND SUBMITTING APPLICATION

Submit all study documents electronically to Kim Bellon, in addition to 1 single-sided hard copy, signed original and 4 double-sided, hard copies of each of the following unless stated otherwise. Hard copy packets must be submitted in the sequence listed below to:

Kim Bellon, IRB Administrator
Research and Human Subjects Review Committee,
Santa Clara Valley Medical Center
Receiving Services Center, Room 2N106,
751 South Bascom Avenue
San Jose, California
95128

(Do not bind or staple any of the materials; secure only with paper clips or binder clips). All pages must be numbered (separately for each section).

*If the proposed research involves a special population (such as children or prisoners), please refer to additional guidelines for coordinating the application within the separate packet of guidelines for submission.

1) Application for Review by Research Committee.

2) Study Personnel List

3) Clinical Investigators Disclosure and Certification Form (for funded studies only).

4) On a separate page, provide a brief summary of the objectives of the proposal using nontechnical language wherever possible.

5) Research protocol written per Committee guidelines. If the study is commercially sponsored, the study sponsor's version of the protocol must also be submitted in addition to addressing the subject matter outlined in the protocol. If the project is funded under a federal grant, a copy of the grant application must also be submitted.

6) Informed Consent Form(s) and/or Assent Form(s) written in the format required by the IRB. Consent forms written in any format other than that required by the IRB Committee will not be accepted with the exception of sponsored cancer trials. Initially, the consent form should be written in English. Once the English version has been approved by the Committee, the consent form(s) should be translated, by a certified translator, into other languages in which your study population is fluent. Once translated, the consent form(s) must be submitted to the Committee for approval prior to use.

A request for a waiver of the requirement to obtain informed consent or signed consent forms must be justified, in writing, under the appropriate section within the protocol.

7) Study sponsor's version or NIH-Approved Sample Informed Consent form, if applicable. If the research is part of a National Institutes of Health (NIH) Multicenter Clinical Trial, NIH requires that the local Committee receive a copy of the NIH-approved sample informed consent form. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent form must be justified in writing by the investigator and approved by the Committee.
8) HIPAA Privacy consent document, if applicable. If, in your opinion, you feel that the proposed research qualifies for waiver of authorization under HIPAA, justification must be provided under the appropriate section within the protocol.

9) Instrument(s) used for data collection (e.g., questionnaire, interview questions or assessment scales), if applicable.

10) Clinical Investigator’s Brochure (applicable when the research involves the use of an investigational drug)

11) Budget (if project has funding).

12) Research ethics training certificates of all study personnel who will be interacting with participants or reviewing identifiable information for purposes of the research.

13) Curriculum Vitae for all study personnel.

14) Data Collection Sheet or Data Dictionary. This if the form used to track the collected data. It is usually in the form of an Excel spreadsheet.
SANTA CLARA VALLEY MEDICAL CENTER
O’CONNOR HOSPITAL
ST. LOUISE REGIONAL HOSPITAL
APPLICATION FOR REVIEW BY RESEARCH COMMITTEE

SECTION 1: APPLICATION DATA

Title of Research Project: ____________________________

SCVMC Principal Investigator: ____________________________

Title of Position: ____________________________

Institution/Division/Department: ____________________________

Mailing Address: _______________________________________

Telephone Number: ___________ Fax: ___________ E-mail: ___________

Sub-Investigator(s): ____________________________
(If more than one sub-investigator, include contact information for each investigator)

Title of Position: ____________________________

Institution/Division/Department: ____________________________

Mailing Address: _______________________________________

Telephone Number: ___________ E-mail: ___________

Projected Starting Date: ____________________________ Projected Completion Date: ____________________________

Source of Funding and Address of Funding Agency: _______________________________________

Sponsor/Third Party Administrator Contact: _______________________________________
(Person Responsible for Payment of IRB Fees – Include Contact Name and E-mail Address)

SECTION 2: CERTIFICATION OF PRINCIPAL INVESTIGATOR

By signing below, you are certifying that all of the investigators involved in the research have reviewed the proposal and agree to conduct the research in compliance with Federal Regulations and California State law governing the use of human subjects in research. It is understood that you will:

1) accept responsibility for the scientific and ethical conduct of the research study;
2) await written approval from the Committee before commencing with the study;
3) obtain approval from the Committee prior to implementing any changes in the study;
4) submit advertisements for the Committee’s review and approval prior to use;
5) report, within five (5) working days, adverse events/unanticipated problems experienced by study subjects;
6) prior to each renewal date, submit completed and signed RENEWAL NOTICE form and, if applicable, RENEWAL APPLICATION form;
7) upon completion of the study, submit a final report.

__________________________________________
Signature of Principal Investigator/Name (Printed)

__________________________________________
Date Signed
SECTION 3: CERTIFICATION OF DEPARTMENTAL REVIEW
The Chair (or his/her designee) of the department(s) involved in the research must sign below acknowledging that the research project has been approved for submission to the Research Committee.

* If more than one department within the Institution will have patients or staff members involved in the research, the signature of each department chair (or his/her designee) is required. This provision is applicable to SCVCMC, OCH and SLRH and non-institutional applicants when use of Institutional facilities is being requested.

** If the person submitting the application is completing the project to meet the requirement of an academic program, the student’s faculty advisor must also sign.

* Signature of Chair/Authorized Designee  
  Date Signed

Name & Title of Position

Signature of Chair/Authorized Designee  
  Date Signed

Name & Title of Position

Signature of Chair/Authorized Designee  
  Date Signed

Name & Title of Position

**Signature of Faculty Advisor (if applicable)  
  Date Signed

Name of Faculty Advisor (Printed)

Title of Faculty Advisor’s Position

MAILING ADDRESS:
Kim Bellon
Santa Clara Valley Medical Center
777 Turner Dr. Room 2N106
San Jose, CA
95128

PLEASE NOTE: Incomplete applications will be returned to the applicant.
**STUDY PERSONNEL LIST**

In the space provided, please list all study personnel involved in the referenced research study by typing in the designated fields. All personnel are required to complete the NIH human research protection training or an equivalent course. This is required of the principal investigator and for all persons with human research study responsibilities (those who interact with research subjects or anyone who analyzes study data/specimens containing subject identifiers). A copy of the educational certificate of completion must be submitted to the IRB Office for the study file.

CV’s/Bio-sketches must also be submitted to the IRB Office for all key study personnel.

**NOTE:** To add or remove personnel to an already approved study, please place a check mark in the appropriate column and submit this form along with relevant revised study documents requesting that the change be approved by the Research & Human Subjects Review Committee.

Completion of a research training for all personnel is mandatory. The IRB offers a [free training](#). CITI training certificates are also accepted.

All research training certificates must be sent electronically to Kimberly.bellon@hhs.sccgov.org

To check a box below, please double-click on the box and then select “Checked” for the default value.

<table>
<thead>
<tr>
<th>Name, Degree</th>
<th>Institution</th>
<th>Study Role</th>
<th>Authorized to Obtain Consent?</th>
<th>Email Address</th>
<th>Phone #</th>
<th>Initial Submission</th>
<th>Addition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Yes ☐ No ☐ N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clinical Investigators Disclosure and Certification

<table>
<thead>
<tr>
<th>To be completed by the Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Research Protocol:</td>
</tr>
<tr>
<td>Name of Principal Investigator:</td>
</tr>
<tr>
<td>Names of Sub-investigators:</td>
</tr>
</tbody>
</table>

**Mark the appropriate box**

*If you mark any questions yes, please explain in the comment section of this form*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you or any of your sub-investigators entered into any financial arrangement with the sponsor of the covered study, whereby the value of the compensation could influence the outcome of the study?</td>
<td></td>
</tr>
<tr>
<td>2. Do you or any of your sub-investigators have any proprietary or significant equity interest in the sponsor's company or in the product being tested in the covered study?</td>
<td></td>
</tr>
<tr>
<td>3. Will the study financially benefit any member of your or your sub-investigators immediate family?</td>
<td></td>
</tr>
<tr>
<td>4. Do you or your sub-investigators have a family or business relationship with the sponsor of the research study?</td>
<td></td>
</tr>
<tr>
<td>5. Are you or your sub-investigators using any unrestricted educational funds, speaking engagement funds or similar remunerations (please explain including the funding source)?</td>
<td></td>
</tr>
</tbody>
</table>

**Comments and Explanations**

*If you answered yes to any of the questions above, please attach details of all financial arrangements and/or interests with a description of steps taken to minimize the potential bias of the clinical study results.*

---

**As the principal investigator, I hereby certify that I and my sub-investigators are familiar with all applicable clinical research regulations and will comply with all of their requirements. Further, I certify I and my sub-investigators will follow all federal and state laws and Institutional policies for research protocols.**

*Signature of Principal Investigator*

**As the principal investigator, I hereby certify that the information given in this questionnaire by me and on behalf of the other investigators, is true and correct.**

*Signature of Principal Investigator*

**As the department chairman, I hereby certify that appropriate steps have been taken in the design and development of the analysis of the studies to minimize bias.**

*Signature of Department Chairman*

**Please note:**

Research projects will be subject to a compliance review. The compliance review is designed to ascertain the level of the compliance with federal, state and local laws and regulations and to provide regulatory expertise when necessary. The compliance review may include participation by outside consultants when appropriate.
PROTOCOL

INSTRUCTIONS: In order to review your proposal, the Committee must have the following information pursuant to its charge by HHS regulations 45 CFR 46 and FDA regulations 21 CFR 50, 56. Each subpart must be titled as shown below and addressed in the sequence listed. Attachment of or referral to applicable sections of any other document is not acceptable as a substitute for completion of each subpart. Please include sufficient information to facilitate an effective review by all members of the Committee including non-specialists in the area of research as well as lay representatives. Responses must be typed into the space following the question.

1. Hypothesis: State your research hypothesis. The hypothesis should consist of a realistic and concise statement of what this research proposal intends to accomplish.

2. Background: Describe pertinent background information and relevant experimental and/or clinical findings.

3. Significance of the Research: Explain the significance and potential importance of the proposed work.

4. Methodology
   a. Describe in detail the research plan, data to be collected and relevant data analysis plans.
   b. Describe the procedures that the human subjects must undergo in the research.
   c. Include an estimate of the probable duration of the study as well as an estimate of the total time required of each subject.

5. Subject Population: Address the following questions in sequence using the listed subheadings:
   a. Age Range: What is the age range of the subjects and the supporting rationale?
   b. Gender: What is the sex/gender of the subjects?
   c. Number: What is the anticipated number of subjects you plan to enroll? Please provide a rationale for the sample size.
   d. Inclusion Criteria: What are the specific inclusion criteria?
   e. Exclusion Criteria: What are the specific exclusion criteria?
   f. Vulnerable Populations: Please check off below which of these vulnerable populations you plan to include.
      - [ ] Economically/educationally disadvantaged persons
      - [ ] Pregnant women
      - [ ] Prisoners
Children (checklist required).
Individuals with impaired decision-making ability
Employees or trainees involved as subjects

If you checked off employees or trainees, how will their interests be protected?

Will subjects be drawn from your own patient base? If your response is no, describe how the subject’s primary care physician will be informed of the patient’s decision to participate. If this notice is not necessary, please explain why.

Do you plan to enroll non-English speaking subjects? If not, please provide a rationale. All documents submitted to the committee should be written in English. Once approved, documents must be transcribed into the language(s) of your subject population. Any document that is transcribed must be a certified transcription and submitted to the committee prior to use.

6. Potential Risks: A risk is a potential harm/injury associated with the research that a reasonable person would be likely to consider injurious. Risks can be generally categorized as physical, psychological, sociological, economic and legal.

a. Risk Classification: Please indicate the overall risk of the study below.

- [ ] Minimal Risk: Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves that those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.
- [ ] Greater than Minimal Risk

b. Potential Risks: What are the potential risks associated with each research-related intervention? If data are available, estimate the probability that a given harm may occur and its potential reversibility.

7. Protection against Risks: For all studies involving greater than minimal risk, describe the procedures utilized to prevent/minimize any potential risks.

8. Potential Benefits to the Subject: Describe the potential therapeutic benefits the subject may receive as a result of participation in the research. Payment(s) to subjects for participation is not a benefit; rather it is considered an offset to inconvenience and cost to the participant.

9. Potential Benefits to Society: Describe the potential societal benefits of the study in terms of the advancement of medical knowledge.

10. Therapeutic Alternatives: Address the following questions in sequence using the listed subheadings. If therapeutic alternatives do not exist, this should be so stated and explained.

a. Therapeutic Alternatives: What are the therapeutic alternatives available to the subjects in the non-research and/or research context, which may be of reasonable benefit to the subject? Alternatives considered to be standard therapy should be distinguished from those judged to be clearly experimental.
b. Risk/Benefit Relationship: What is the relative risk/benefit relationship of the therapeutic alternatives as compared with the research?

11. Financial Obligations: Address the following questions in sequence using the listed sub-headings:
   a. Financial Obligations: What financial obligations will the subject incur as a result of their participation in the study? If none, this should be stated.

   b. Research vs. Standard Treatment Costs: Will the subject incur any financial obligations as a result of the procedures performed solely for research purposes, e.g., additional diagnostic/follow-up tests; administration of drugs/agents that are more expensive than alternatives; longer hospitalization? If so, provide additional detail. If no, this should be stated.

12. Compensation for Participation: State whether subjects will be paid or otherwise compensated for participation, and prerequisite condition(s) that must be fulfilled by subjects in order to receive either full or partial compensation. If subjects will not receive compensation for participation, this should be stated.

13. Confidentiality:
   All storage of PHI must comply with relevant privacy laws and regulations including, but not limited to HIPAA.
   a. Describe the steps taken to assure that participation by subjects will be kept confidential.

   b. What safeguards will be used to protect against identifying, directly or indirectly, any patient in any report of the research project?

   c. Describe provisions for controls over access to documents and data and the safeguards used to protect the information from re-disclosure (i.e., re-disclosure to non-researchers).

   d. If data with subject identifiers will be released, specify the person(s) or agency [e.g., FDA, Company, Organization, NIH] to which this information will be released.

14. Information Purposely Withheld: Address the following questions in sequence using the listed subheadings:
   a. Information Withheld: State any information purposely withheld from the subject and provide justification.

   b. Debriefing: Describe the post-study debriefing of the subject. If no information will be withheld, this should be stated.

15. Informed Consent: Describe the process of obtaining valid informed consent by addressing the following questions in sequence using the listed subheadings. If you are requesting waiver of informed consent, please provide your justification below. NOTE: Attach a copy of all consent/assent forms and ensure that the format, content and readability level is in compliance with the Committee's Guidelines on Informed Consent.
a. **Request for Waiver of Consent:** All requirements must be addressed with justification.

b. **Subject Competency:** Will the subjects be mentally and physically competent to give informed consent? If no, describe the degree of impairment relative to their ability to consent to participate in research? **Substitute consent is limited in the state of California.**

c. **Process of Consent:** Describe the process of informed consent and how it will be structured. This process must be conducive to rational and thoughtful decision-making by the subject/subject’s legally authorized representative without any element of coercion or undue influence.

d. **Subject Comprehension:** How will it be determined that the subject/subject’s legally authorized representative understood the information presented?

e. **Documentation of Consent:** Identify the study investigator(s) and participating personnel who are authorized to certify and document obtaining of informed consent from the subject or the subject’s legally authorized representative?

f. **Assent:** If children ages 7-18 are involved as subjects, how will informed assent be obtained?

16. **Request for Waiver of HIPAA (Health Insurance Portability and Accountability Act of 1996):** All requirements must be addressed with justification.

17. **Conflict of Interest:** Investigators are often involved in clinical trials testing the use of drugs/devices/biologic products. If materials being studied in the protocol will be supplied by commercial entities with which investigators consult or have a financial interest, please explain this arrangement as you respond to the following questions.

a. Do any of the investigators/family members have a separate consulting agreement with the sponsoring company?

b. Do any of the investigators/family members have stock and or stock options with the sponsoring company?

c. Do any of the investigators/family members serve on an advisory board of the sponsoring company?

d. Do any of the investigators/family members have any commercial interest in the study/product(s) used?

e. Will results of the study be made available regardless of outcome? If yes, to whom will the results be made known?
If consultative or financial relationships exist, include the following statement in the consent form:
"One or more of the investigators/family members have a consultative and/or financial relationship with the sponsoring organization(s) involved in this research."

The consent form should disclose what institution(s) (e.g., NIH) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. The following generic disclosure is acceptable:

(name of institution/company) is providing financial support and/or material for this study.

18. Will your research involve any FDA-regulated products (drug(s), device(s) or biologic(s))?  

Drug or biologics must be cleared through the Pharmacy Department Chair.  All devices must be cleared through BioMed at the time of Administrative Approval.

19. Investigational New Drugs: Will an investigational drug(s) be used in the study? If yes, provide the Investigator's Brochure, drug booklet or information sheet supplied by the drug company (sponsor) and the following information:
   a. Name of Drug(s)
   b. IND #
   c. Holder of IND

20. Investigational New Devices: Will an investigational device be used in the study? If yes, provide the following information:
   a. Name of Device
   b. IDE #
   c. Holder of IDE

21. Please state whether you consider the device to be a significant or non-significant risk device.

22. Will your project involve use of a Humanitarian Use Device (HUD)?

23. Facilities Requested or Required (applicable only to projects involving SCVMC, OCH or SLRH facilities). State the location where the study will be conducted. List all facilities needed, including (as appropriate) laboratory space, clinical research wards, office space, equipment, personnel, etc.

Please check the appropriate boxes if your project will involve any of the following:
- Laboratory Tests
- Nursing Time
- Pharmacy Resources
- Radiologic Procedures

24. Submission to Other IRB's: Has the proposed study been submitted to another IRB? If yes, and the project was approved, provide the letter(s) of approval. If not approved, provide the letter(s) of non-approval.

25. Other Relevant Information: Include any other information the Committee should have in order to assist it in fulfilling its responsibilities as indicated below under "Responsibility of the Research Committee."
26. **Bibliography/Literature:** Provide pertinent references and literature. If none exists, this should be stated.
Enclosed Templates

Consents
Sample Standard Informed Consent Form
Sample Parental Consent Form
Sample Assent Form (For Children Ages 7-12)
Sample Assent Form (For Children Ages 13-18)

Investigator's Consent Checklist

HIPAA Consents
HIPAA Privacy Document Template
Pediatric HIPAA Template
INFORMED CONSENT FORM SAMPLE

SANTA CLARA VALLEY MEDICAL CENTER
[The PI must insert the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital]
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF THE RESEARCH STUDY: Comparative Trial of Calcium Channel Blockers XYZ and ABC in Patients with Chronic Exertional Angina Pectoris.

CONCISE SUMMARY
This new section requires “a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research”.

Further guidance for this summary is as follows, “the initial presentation of the key pieces of information can be relatively short. This section of the consent could in appropriate circumstances include a summary of relevant pieces of information that are explained in greater detail later in the consent form and presented in a way that facilitates comprehension”.

You may elaborate on this information later on in the consent form. Please contact the IRB Administrator for examples of concise summaries to review.

(Source: Federal Register: January 19, 2017)

Are you currently participating in any other research studies? ___ Yes ___ No

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS: [The Bill of Rights is only necessary if your research study involves a medical experiment, defined as: The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject”. Remove if not applicable].

You have been asked to participate as a subject in an experimental procedure. California law states that persons who participate in a medical experiment are entitled to certain rights. Before you decide whether you want to participate in the experimental procedure, you have a right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;

IRB Approval Date:
Expiration Date:
IRB Reference #: 
be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;
be given a copy of the signed and dated written consent form; and
be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.

STUDY SPONSOR: [Insert name and location of sponsor]. The sponsor of this study will pay Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital] to participate in this research. [The PI should disclose any potential conflict of interest here].

INVITATION TO PARTICIPATE: You are invited to participate in this research study. The following information is provided to help you make an informed decision about whether or not to participate. PLEASE READ THIS CONSENT FORM CAREFULLY. If you have any questions, please do not hesitate to ask.

Before agreeing to participate in this research study, it is important that you read and understand the information contained in this consent form. This process is called informed consent.

This consent form describes the purpose, procedures, benefits, risks, discomforts and precautions that should be taken during the study. It also describes your right to withdraw from the study at any time and available alternatives.

This consent form may contain words that you do not understand. Please ask the study doctor or a member of the study staff to explain any words or information that you do not clearly understand.

WHY HAVE YOU BEEN SELECTED TO PARTICIPATE? You have been selected to participate because you are an adult and have been experiencing chest pains due to heart disease.

WHY IS THIS STUDY BEING DONE? The purpose of this study is to compare how well two calcium channel blocker drugs, XYZ and ABC, work in the treatment of chest pain due to heart disease. XYZ is an FDA approved drug whereas ABC is an investigational which means that the drug has not been licensed by the Food and Drug Administration (FDA) for general use.

WHAT IS INVOLVED IN THE STUDY? This is a study that is being conducted at several medical centers throughout the United States. Approximately 20 people will participate at this center. This study will take 12 weeks to complete. You will be asked to visit the clinic every two

IRB Approval Date:
Expiration Date:
IRB Reference #: 
weeks for a total of six visits. The following are the procedures you will undergo as a subject in this study.

VISIT 1 will require about 90 minutes. A medical history will be taken and a complete physical examination performed including an electrocardiogram (ECG) which is a recording of your heart's activity. In order to perform an ECG, you will have wires taped to parts of your body and you will be asked to lie down quietly while the test is being performed.

You will then be asked to get up to take an exercise tolerance test. This test measures your heart's ability to respond to exercise. During the test, you will have wires attached to your body for an ECG. You will be asked to walk slowly at 1 mph up a 10% incline on a motor-driven treadmill. Every 3 minutes both the speed and the incline will slightly increase. After 15 minutes, you will be walking at 5 mph up an 18% incline. Your blood pressure, heart rate, heart activity and symptoms will be checked continuously. The test will end after 18 minutes, or sooner if you feel you cannot continue, or if the physician asks you to stop.

Following the exercise tolerance test, you will undergo blood and urine tests. A total of 20 cc (4 teaspoonful's) of blood will be drawn for the blood test. The blood will be obtained by venipuncture which means a small needle will be inserted into a vein in your forearm. You will be asked to provide a small amount of urine for the urine test.

At the end of the previously described tests, you will be randomly assigned (similar to a flip of a coin) to receive either ABC or XYZ. You have a 50:50 chance of receiving either of the two study drugs. Neither you nor the study investigators will know which medication you will be taking.

You will be given a bottle of the study medication and instructed on its use. You will also be given a bottle of nitroglycerin to take if you have any chest pain during the study. Also, you will receive a diary to use so you can write down when you have any chest pain and how much nitroglycerin you take.

VISIT 2 will require about 45 minutes. You will have an ECG and a blood test. You will also be asked to wear a Holter Monitor for 24 hours. A Holter Monitor is like a tape recorder that records each beat of your heart. This allows us to monitor your heart function more closely. It will therefore be necessary for you to wear this monitor continuously for the 24-hour period.

VISIT 3 will require about 90 minutes. You will undergo the exercise tolerance test as well as the blood and urine tests.

VISIT 4 will require about 45 minutes. You will have an ECG, blood test and you will be asked to wear a Holter Monitor for 24 hours.

VISIT 5 will require about 45 minutes. You will undergo an ECG and a blood test.

VISIT 6 will require about 90 minutes. You will undergo the same procedures as performed during your first visit. You will have a history and physical examination, an exercise tolerance test as well as blood and urine tests.

WHAT ARE THE RISKS AND/OR POTENTIAL DISCOMFORTS OF THE STUDY? Below are both the serious and common risks and discomforts you could potentially experience during this study.
**Name of Principal Investigator**  
**Title of Study (title may be abbreviated)**  
**Consent Form, Page X of Y**

**XYZ**: Upset stomach, loss of appetite, diarrhea, dizziness, headache, abnormal heartbeats.

**ABC**: Dizziness, lightheadedness, flushing, headache, swelling of the hands/legs, low blood pressure.

**Nitroglycerin**: Headache, weakness, lightheadedness, low blood pressure.

**Exercise Tolerance Test**: Muscle soreness, chest pain, fainting, shortness of breath, extra heartbeats, heart attack, and sudden death.

**Venipuncture**: Bleeding, bruising, local pain, swelling, fainting, and, rarely, infection at the site of the needle stick. If an infection occurs, it will be treated with antibiotics.

**Pregnancy**: The study drugs may cause serious harm to an unborn child. Therefore, if you plan to be treated with XYZ and ABC, you should not become pregnant. Women who participate in this study must be post-menopausal or surgically sterile, or agree to either refrain from having sexual intercourse or use an effective method of birth control such as oral contraceptives, vaginal contraceptive devices or agents, or IUD’s during the entire study period. If you do become pregnant, you must agree to immediately inform one of the study doctors. You will then be taken off the study and advised of the options available to you.

**Nursing Mothers**: Mothers who are nursing will also not be allowed to participate because the harmful effect of these drugs on breast milk is not known.

**ARE THERE POTENTIAL BENEFITS TO PEOPLE PARTICIPATING IN THE STUDY?** There is scientific data which indicates that both XYZ and ABC may be effective in controlling chest pain that is due to heart disease. It is not known whether one of these drugs is more effective than the other. THEREFORE, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS BY PARTICIPATING IN THIS STUDY.

**ARE THERE POTENTIAL BENEFITS TO SOCIETY FROM THIS STUDY?** The information obtained from this study may help future patients who suffer from chest pain due to heart disease.

**WHAT ALTERNATIVES ARE THERE TO PARTICIPATING IN THIS STUDY?** The alternative to participation in this study is to take other drugs for your chest pain such as X, Y or Z, or therapy that is recommended by your doctor.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?** Any information obtained during this study which could identify you will be kept as confidential as is possible within the law. Representatives of the Office for Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA) may inspect your records during research audits. Your medical records which identify you and the consent form signed by you may also be inspected by the study sponsor, [sponsor name] the Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O’Connor Hospital and St. Louise Regional Hospital and to persons responsible for financial auditing and billing. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

**IRB Approval Date:**  
**Expiration Date:**  
**IRB Reference #:**
The information obtained in this study may be published in scientific journals or presented at scientific meetings, but your name will not be revealed.

[For applicable clinical trials, insert the following paragraph. This information must be included for any trial that will be listed on ClinicalTrials.gov. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.]

ARE THERE ANY COSTS FOR ME? You will not be charged for the study drugs, XYZ and ABC, or any study-related doctor’s visits, examinations, laboratory tests, or procedures that are required by the study.

Certain tests and examinations may need to be done regularly to safely plan the treatment, measure how effective the treatment is, and evaluate any side effects. These tests include laboratory tests and examinations. Costs for these tests and examinations will be billed to you and/or your health care plan. The use of medications or other types of treatment to help control side effects could result in added costs to you and/or your health care plan. Some health insurance plans may not cover these procedures. If you are not covered by insurance and costs would create a financial burden, you should discuss possible alternatives with the study doctor or one of the members of the study staff.

WILL I RECEIVE ANY COMPENSATION FOR PARTICIPATING? To compensate you for your time and the inconvenience of traveling to the study clinic, you will receive $25.00 for each of the 6 visits for a total of $150.00. If you decide to withdraw prior to completing the study, you will receive $25.00 for each visit that you made to the clinic.

WHOM SHOULD I CONTACT IF I HAVE A RESEARCH RELATED EMERGENCY? All forms of medical treatment, whether routine or experimental, involve some risk. In spite of all precautions, you might develop medical complications as a result of your participation in this study. [Insert sponsor name] will pay for short-term medical care for any physical injury resulting from your participation in this research. The sponsor will not pay for long-term medical care or financial compensation for such injuries except as may be provided by law. In the event that you suffer a research-related injury, these medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

CAN I DECLINE TO PARTICIPATE OR WITHDRAW FROM PARTICIPATING? You are free to decide not to participate in this study or to withdraw at any time without adversely affecting your relationship with your physician(s), the study doctor or study staff, or Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital]. Deciding not to participate will not cause you to lose any of the benefits associated with your health care.

WHAT IF NEW INFORMATION BECOMES AVAILABLE? If any information develops or changes occur during the course of this study that may affect your willingness to continue participating, you will be informed immediately.

CAN I BE TERMINATED FROM THE STUDY? You may be removed from the study without your consent for any of the following reasons:

- The study doctors decide that continuing in the study would be harmful to you.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
Name of Principal Investigator
Title of Study (title may be abbreviated)
Consent Form, Page X of Y

- You become pregnant, you plan to become pregnant, or you plan to discontinue contraception.
- You fail to follow the study procedures.
- You participate in other research studies while you are enrolled in this study.
- The company providing the study drug(s) decides to cancel the study.

WILL MY DATA OR SPECIMENS COLLECTED IN THIS STUDY BE USED IN FUTURE RESEARCH?
[The PI should pick one of the below statements that is applicable to their study to be included in the consent:]
Private information and/or biospecimens which are collected during this study might be used without your consent in future research after any information which could identify you has been removed.
OR
Your private information and/or biospecimens will not be used for future research.
OR
Private information which is collected during this study might be used without your consent in future research after any information which could identify you has been removed. Biospecimens are not collected as part of this research study.

WILL MY BIOSPECIMEN OR TISSUE BE USED FOR GENETIC TESTING?
[The PI should determine if this section is applicable and answer accordingly. If yes, will the participant receive results?]

WHO WILL HAVE ACCESS TO RESULTS FROM THE STUDY?
[The PI should determine if the participant and/or their physician would receive results from the study and provide information accordingly].

WILL I HAVE ACCESS TO THE RESULTS OF THE STUDY?
[The PI should determine if this section is applicable and how the participant will receive the results].
The study PI’s anticipate publishing the results of the study when it is complete but this is not guaranteed. No identifying information will be included in any publications.

WHOM DO I CALL IF I HAVE ANY QUESTIONS? If you have any questions, please do not hesitate to ask and they will be answered at this time. If you think of any additional questions later, please feel free to contact one of the study doctors or a member of the study staff at one of the telephone numbers listed at the bottom of this consent form. The Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O’Connor Hospital and St. Louise Regional Hospital has reviewed this study and will review any concerns or complaints you may have regarding your participation in the study or questions you may have about your rights as a research subject. This is a Committee that is concerned with protecting people who volunteer to participate in research studies. The Committee may be reached by calling the office from 9:00 a.m. to 5:00 p.m., Monday through Friday at 408/885-2383 or by writing to the Research Committee, Santa Clara Valley Medical Center, Institutional Review Board Office, 777 Turner Dr. Office 2N106 San Jose, California 95128.

DOCUMENTATION OF INFORMED CONSENT: You are voluntarily making a decision whether or not to participate in this research study. If you would like to participate, please fill in the lines

IRB Approval Date:
Expiration Date:
IRB Reference #: 
Name of Principal Investigator
Title of Study (title may be abbreviated)
Consent Form, Page X of Y

below. Your signature certifies that the content and meaning of the information on this consent form have been fully explained to you and that you have decided to participate having read and understood the information presented. Keep the copy of the consent form that you are given so that you have this information. Thank you for your interest in this study.

Subject’s Name (Printed)                        Subject’s Medical Record Number

Signature of Subject                              Date Signed

In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Printed Name and Signature of Investigator/Designee           Date Signed

IDENTIFICATION OF STUDY INVESTIGATORS

Principal Investigator: Insert Title, Name of Institution, Address, Telephone Number for questions.
Sub-Investigator: Insert Title, Name of Institution, Address, Telephone Number for questions.

24 Hour Emergency Contact Information: If you experience an injury or adverse effect that you feel requires urgent medical attention, call 911 or go to the nearest emergency room or urgent care clinic. Tell the staff in the emergency room or clinic that you are participating in a research study and that they should immediately telephone one of the study doctors (insert names) by calling Santa Clara Valley Medical Center (the PI must insert the correct institution and correct phone number) at 408/885-5000 and asking the operator to page one of the study doctors on call.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
SAMPLE WORDING FOR PARENTAL INFORMED CONSENT FORM

SANTA CLARA VALLEY MEDICAL CENTER
[The PI must insert the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital]
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Is your child participating in any other research studies? ___ Yes ___ No

TITLE OF THE RESEARCH STUDY: Comparison of Dosing Variability of IV Gammaglobulin (IVGG) in Preventing Infections in Allogeneic Bone Marrow Transplant Patients.

CONCISE SUMMARY
This new section requires "a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research".

Further guidance for this summary is as follows, "the initial presentation of the key pieces of information can be relatively short. This section of the consent could in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form and presented in a way that facilitates comprehension".

You may elaborate on this information later on in the consent form. Please contact the IRB Administrator for examples of concise summaries to review.

(Source: Federal Register: January 19, 2017)

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS: [The Bill of Rights is only necessary if your research study involves a medical experiment, defined as: The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject”. Remove if not applicable]. You have been asked to allow your child to participate as a subject in an experimental procedure. California law states that persons who participate in a medical experiment are entitled to certain rights. Before you decide whether to allow your child to participate, you have a right to:

• be informed of the nature and purpose of the experiment;
• be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
• be given a description of any discomforts and risks reasonably to be expected from your child’s participation in the experiment;

IRB Approval Date:
Expiration Date:
IRB Reference #: 
be given an explanation of any benefits reasonably to be expected from your child’s participation in the experiment;

be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to your child, and their relative risks and benefits;

be informed of the avenues of medical treatment, if any, available to your child after the experimental procedure if complications arise;

be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;

be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue your child’s participation in the medical experiment without prejudice;

be given a copy of the signed and dated written consent form; and

be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.

STUDY SPONSOR: [Insert sponsor name and location]. The sponsor of this study will pay Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] to participate in this research. [The PI should disclose any potential conflict of interest here].

INVITATION TO PARTICIPATE: You are invited to permit your child to participate in this research study. The following information is provided to help you make an informed decision about whether or not to allow your child to participate. PLEASE READ THIS CONSENT FORM CAREFULLY. If you have any questions, please do not hesitate to ask.

Before you agree to permit your child to participate, it is important that you read and understand the information contained in this consent form. This process is called informed consent.

This consent form describes the purpose, procedures, benefits, risks, discomforts and precautions that should be taken during the study. It also describes your right to withdraw your child from the study at any time and available alternatives. If you allow your child to participate, you will be given a copy of the signed and dated consent form to keep for your records.

This consent form may contain words that you do not understand. Please ask the study doctor or a member of the study staff to explain any words or information that you do not clearly understand.

WHY HAS MY CHILD BEEN SELECTED TO PARTICIPATE? Since your child will be receiving bone marrow from a donor and he/she does not have an infection, your child is eligible to participate in this study.

WHY IS THIS STUDY BEING DONE? The purpose of this study is to determine how effective an investigational drug called IV Gammaglobulin (IVGG) is in preventing serious infections in patients undergoing allogeneic bone marrow transplantation (bone marrow acquired from a donor, usually a related donor). Investigational means that the drug is not yet licensed by the Food and Drug Administration (FDA) for marketing. The effectiveness and safety of two different doses of IVGG will be compared in this study since we do not know which one works best.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
WHAT IS INVOLVED IN THIS STUDY? The dose of IVGG which your child will receive will be determined by a random assignment (similar to a flip of a coin). IVGG will be given to your child 8 days before their bone marrow transplantation and then once a week for 16 weeks. The drug will be administered to your child intravenously by inserting a needle into a vein in your child's forearm. In order to monitor your child's progress and reaction to the IVGG, blood samples will be drawn via venipuncture by inserting a needle into a vein in the child's arm. Each sample will require two teaspoons of blood. A total of 28 samples of blood will be taken from your child over the 16 weeks of the study. Approximately 20 children will participate at this center.

WHAT ARE THE RISKS AND/OR POTENTIAL DISCOMFORTS OF THE STUDY? The following are the risks and discomforts your child could possibly experience during this study:

**IVGG:** The drug IVGG has a slight chance (less than 5%) of causing an allergic reaction like hives, a fall in blood pressure, sweating, tightness in the chest or wheezing and a small chance (perhaps 1%) of causing kidney damage. It is possible that the higher dose has a greater chance of causing these side effects.

**Venipuncture:** Your child may experience some minor pain from having blood drawn. There is also a chance of bruising in the area where the needle is inserted and a small chance of infection. If your child develops an infection, it will be treated. Rarely, fainting can occur.

ARE THERE POTENTIAL BENEFITS TO PARTICIPATING IN THE STUDY? The use of IVGG may help prevent your child from getting a viral, bacterial, or fungal infection, which can become serious and sometimes fatal in bone marrow transplant patients. HOWEVER, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOUR CHILD WILL RECEIVE ANY BENEFITS BY PARTICIPATING IN THIS STUDY.

ARE THERE POTENTIAL BENEFITS TO SOCIETY FROM THIS STUDY? The information obtained from this study may help us to learn how to prevent infections in future patients undergoing bone marrow transplantation.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATING? The alternative to having your child participate in this research study would be to have your child receive standard supportive care without the administration of IVGG. The standard supportive of care will be explained to you.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL? Any information obtained during this study that could identify your child will be kept as confidential as is possible within the law. Representatives of the Office for Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA) may inspect your child's records during research audits. Your child's medical records, which identify him/her, and the consent form signed by you may be inspected by the study sponsor, [insert sponsor name] the Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital and for purposes of financial auditing and billing. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

The information obtained in this study may be published in scientific journals or presented at scientific meetings, but your child's name will not be revealed.

[For applicable clinical trials, insert the following paragraph]. **This information must be included for any trial that will be listed on ClinicalTrials.gov.** A description of this clinical trial

IRB Approval Date:
Expiration Date:
IRB Reference #: 
will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not
include information that can identify you. At most, the Web site will include a summary of the
results. You can search this Web site at any time.

ARE THERE ANY COSTS FOR MY CHILD AND MYSELF? You will be financially responsible
for the cost of administering IVGG to your child as well as the cost of all laboratory tests that are
deemed necessary for your child during the conduct of this study. You are also financially
responsible for the hospital, physician, and clinic charges generated by your child's participation
in this study.

WILL MY CHILD OR I RECEIVE ANY COMPENSATION FOR PARTICIPATION? You or your
child will not be paid for his/her participation in this study.

WHOM SHOULD I CONTACT IF MY CHILD HAS A RESEARCH-RELATED EMERGENCY? All
forms of medical treatment, whether routine or experimental, involve some risk. In spite of all
precautions, your child might develop medical complications as a result of your child's participation
in this study. [Insert sponsor name] will pay for short-term medical care for any
physical injury resulting from your child's participation in this research. The sponsor will not pay
for long-term medical care or financial compensation for such injuries except as may be
provided by law. In the event that your child suffers a research-related injury, these medical
expenses will be your responsibility or that of your third-party payer, although you are not precluded
from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of
those involved in the research.

CAN I DECLINE TO HAVE MY CHILD PARTICIPATE OR WITHDRAW MY CHILD FROM
PARTICIPATING? You are free to decide not to have your child participate in this study or to
withdraw your child from the study at any time without adversely affecting his/her/your
relationship with the study doctors or Santa Clara Valley Medical [The PI must identify the
correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise
Regional Hospital]. Your decision will not result in any loss of benefits to which your child is
otherwise entitled.

WHAT IF NEW INFORMATION BECOMES AVAILABLE? If any information develops or
changes occur during the course of this study that may affect your willingness to allow your child
to continue participating, you will be informed immediately.

CAN MY CHILD BE TERMINATED FROM THE STUDY Your child may be removed from the
study without your consent for any of the following reasons:

- The study doctors decide that continuing in the study would be harmful to him/her.
- Your child participates in any other research studies while enrolled in this study.
- The company providing the study drug(s) decides to cancel the study.

WILL MY CHILD'S DATA OR SPECIMENS COLLECTED IN THIS STUDY BE USED IN
FUTURE RESEARCH? [The PI should pick ONE of the below statements that is applicable to their study to be
included in the consent]
Your child’s private information and/or biospecimens which are collected during this study might
be used without your consent in future research after any information which could identify your
child has been removed.

OR
Your child’s private information (and/or) biospecimens will not be used for future

IRB Approval Date:
Expiration Date:
IRB Reference #: 
OR
Private information which is collected during this study might be used without your consent in future research after any information which could identify you has been removed. Biospecimens are not collected as part of this research study.

WILL MY CHILD'S BIOSPECIMEN OR TISSUE BE USED FOR GENETIC TESTING? 
[The PI should determine if this section is applicable and answer accordingly. If yes, will the participant receive results?]

WILL MY CHILD AND I HAVE ACCESS TO THE RESULTS OF THE STUDY? 
[The PI should determine if this section is applicable and how the participant will receive the results].
The study PI's anticipate publishing the results of the study when it is complete but this is not guaranteed. No identifying information will be included in any publications. Unless otherwise indicated, the PI will not provide you with the results of the study but they will be available to the public.

WHOM DO I CALL IF I HAVE ANY QUESTIONS? If you have any questions, please do not hesitate to ask and they will be answered at this time. If you think of any additional questions later, please feel free to contact one of the study doctors or a member of the study staff at one of the telephone numbers listed on the last page of this consent form.

The Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital has reviewed this study and will review any concerns or complaints you may have regarding your child's participation in the study or questions you may have about your child's rights as a research subject. This is a Committee that is concerned with protecting people who volunteer to participate in research studies. The Committee may be reached by calling the office from 9:00 a.m. to 5:00 p.m., Monday through Friday at 408/885-2383 or by writing to the Research Committee, Santa Clara Valley Medical Center, Institutional Review Board Office, 777 Turner Dr. Office, 2N106 San Jose, California 95128.

DOCUMENTATION OF INFORMED CONSENT: You are voluntarily making a decision whether or not to allow your child to participate in this research study. If you would like your child to participate, please fill in the lines below. Your signature indicates that the content and meaning of the information on this consent form have been fully explained to you and that you have decided to allow your child to participate having read and understood the information presented to you. You will be given a copy of the signed and dated consent form to keep. Thank you for your interest in this study.

Subject's Name (Printed)  
Subject's Medical Record Number

Signature of Parent(s)/Legal Guardian(s)  
Date Signed

IRB Approval Date:
Expiration Date:
IRB Reference #:  

5
Name of Principal Investigator
Title of Study (title may be abbreviated)
Parental Consent Form, Page X of Y

Name(s) (Printed)

My signature as witness certifies that the parent/legal guardian was informed of the research, was given an opportunity to ask questions and signed this consent form in my presence as his/her voluntary act and deed.

Signature of Witness (if applicable) ____________________ Date Signed __________

In my judgment, the parent(s)/legal guardian(s) are voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent for their child to participate in this research study.

Printed Name/Signature of Investigator/Designee ____________________ Date Signed __________

IDENTIFICATION OF STUDY INVESTIGATORS

Principal Investigator: Insert Title, Name of Institution, Address, and Telephone Number for questions.

Sub-Investigator: Insert Title, Name of Institution, Address, and Telephone Number for questions.

24 Hour Emergency Contact Information: If your child experiences an injury or adverse effect that you feel requires urgent medical attention, call 911 or go to the nearest emergency room or urgent care clinic. Tell the staff in the emergency room or clinic that your child is participating in a research study and that they should immediately telephone one of the study doctors (insert names) by calling Santa Clara Valley Medical Center at 408/885-5000 (the PI must insert the correct institution and correct phone number) and asking the operator to page one of the study doctors on call.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
SAMPLE WORDING FOR ASSENT FORM (FOR CHILDREN AGES 7-12)

SANTA CLARA VALLEY MEDICAL CENTER
[The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital]
ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF THE RESEARCH STUDY: Comparison of Dosing Variability of IV Gammaglobulin (IVGG) in Preventing Infections in Allogeneic Bone Marrow Transplant Patients.

CONCISE SUMMARY
This new section requires “a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research”.

Further guidance for this summary is as follows, “the initial presentation of the key pieces of information can be relatively short. This section of the consent could in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form and presented in a way that facilitates comprehension”.

You may elaborate on this information later on in the consent form. Please contact the IRB Administrator for examples of concise summaries to review.

(Source: Federal Register: January 19, 2017)

1. We would like to invite you to take part in this research study. You are eligible to take part because you will be receiving bone marrow from another person. This is called a bone marrow transplant.

2. Please talk this over with your parent(s) or legal guardian(s) before you decide whether or not to take part in this study. If you decide to take part and then change your mind, this will be O.K. We will also ask your parent(s) or legal guardian(s) to give their permission for you to take part in this study.

3. If you have any questions at any time, please ask.

4. In this study we will try to find out how well a medicine called IVGG can keep you and other people who have bone marrow transplants from getting infections.

5. In this study, you will be given this medicine before and after you get bone marrow from a donor such as your brother or sister. A needle will be used to give you this medicine. It is almost the same as having your blood taken. This medicine will be given to you once a week for 4 months.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
Name of Principal Investigator
Title of Study (title may be abbreviated)
Assent Form, Page X of Y

6. This medicine may give you a rash, cause you to sweat and you may have trouble breathing.
   Having a needle stuck in your arm may hurt and you may have a small bruise.

You are making a decision whether or not to be in this study. If you would like to participate, please
fill in the lines below. Signing this form means that you have decided to participate. You and your
parent(s) or legal guardian(s) will be given a copy of the form to keep. Thank you for your interest in
the study.

Subject’s Name (printed) Subject’s Medical Record Number

Signature of Subject Date Signed

My signature as witness certifies that the subject was informed of the research, was given an
opportunity to ask questions and signed this consent form in my presence as his/her voluntary
act and deed.

Signature of Witness (if applicable) Date Signed

In my judgment, the subject is voluntarily and knowingly giving informed consent to participate in
this research study.

Printed Name/Signature of Investigator/Designee Date Signed

IDENTIFICATION OF STUDY INVESTIGATORS

Principal Investigator: Insert Name, Title, Name of Institution, Address, and Telephone Number
for questions and telephone number where, in the event of an emergency, the investigator can
be reached by a subject on a 24 hour basis.

Sub-Investigator: Insert Title, Name of Institution, Address, and Telephone Number for
questions and 24 hour telephone number for emergencies.
SAMPLE WORDING FOR ASSENT FORM (FOR YOUTH AGES 13-18)

SANTA CLARA VALLEY MEDICAL CENTER

[The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital].

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF THE RESEARCH STUDY: Comparison of Dosing Variability of IV Gammaglobulin (IVGG) in Preventing Infections in Allogeneic Bone Marrow Transplant Patients.

CONCISE SUMMARY
This new section requires “a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research”.

Further guidance for this summary is as follows, “the initial presentation of the key pieces of information can be relatively short. This section of the consent could in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form and presented in a way that facilitates comprehension”.

You may elaborate on this information later on in the consent form. Please contact the IRB Administrator for examples of concise summaries to review.

(Source: Federal Register January 17, 2017)

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS: [The Bill of Rights is only necessary if your research study involves a medical experiment, defined as: The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject]. Remove if not applicable].

You have been asked to participate as a subject in an experimental procedure. California law states that persons who participate in a medical experiment are entitled to certain rights. Before you decide whether you want to participate in the experimental procedure, you have a right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;
- be given an explanation of any benefits reasonably to be expected from your participation in the experiment;

IRB Approval Date:
Expiration Date:
IRB Reference #: 
• be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
• be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
• be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
• be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;
• be given a copy of the signed and dated written consent form; and
• be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.

INVITATION TO PARTICIPATE: You are invited to participate in this research study. The following information is provided to help you decide whether or not to participate. PLEASE READ THIS CONSENT FORM CAREFULLY. If you have any questions, please do not hesitate to ask.

We would like you to talk this over with your parent(s) or legal guardian(s) before you make a decision about whether or not to take part in this study. We will also ask your parent(s) or legal guardian(s) to give their permission for you to take part in this study.

This consent form may contain words that you do not understand. Please ask the study doctor or a member of the study staff to explain any words or information that you do not clearly understand.

WHY HAVE YOU BEEN SELECTED TO PARTICIPATE? You have been selected to participate because you will be receiving bone marrow from a donor who is related to you and because you do not currently have an infection.

WHY IS THIS STUDY BEING DONE? Bone marrow transplant patients often get infections. The purpose of this study is to find out how well a drug called IV Gammaglobulin (IVGG) can prevent infections in patients who have a bone marrow transplant. Two different doses of IVGG will be studied to find out which dose is best.

WHAT IS INVOLVED IN THE STUDY? You will be randomly assigned by chance to receive 1 of 2 doses of IVGG by a method similar to the flip of a coin. The IVGG will be given to you 8 days before your transplantation and then once each week for 16 weeks. The medicine will be given to you through a needle that will be inserted into a vein in your arm.

To find out how you are doing, a small amount of blood (about 2 teaspoons) will need to be taken from you every few days. This will also be done by inserting a needle into a vein in your arm.

WHAT ARE THE RISKS AND/OR POTENTIAL DISCOMFORTS OF THE STUDY? IVGG has a slight chance of causing a rash, a fall in your blood pressure, sweating, a tight feeling in the chest, and difficulty breathing.

The frequent needle sticks to give you IVGG and to draw blood from a vein may cause you some discomfort. There is also a risk of bruising and infection where the needle is inserted. The bruising should go away within a few days. Rarely, people faint from having blood drawn.

IRB Approval Date:
Expiration Date:
IRB Reference #: 
ARE THERE POTENTIAL BENEFITS TO PARTICIPATING IN THE STUDY? The use of IVGG may help prevent you from getting a serious infection, which can sometimes be fatal in bone marrow transplant patients. HOWEVER, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS AS A RESULT OF YOUR PARTICIPATION IN THIS STUDY.

ARE THERE POTENTIAL BENEFITS TO SOCIETY FROM THIS STUDY? Results from this study may help future patients who receive bone marrow transplants.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATING IN THE STUDY? The alternative to this treatment is for you to receive standard care without IVGG during your bone marrow transplant.

WILL MY INFORMATION BE KEPT CONFIDENTIAL? Your right to privacy will be protected. Your identity will be kept confidential to the extent permitted by law.

WHAT ARE THE COSTS FOR ME TO PARTICIPATE? Your parent(s) or legal guardian(s) will be responsible for the cost of the treatment you receive during this study.

WILL I RECEIVE ANY COMPENSATION FOR PARTICIPATING? You or your parent(s) or legal guardian(s) will not be paid or compensated in any way for your participation in this study.

WHOM SHOULD I CONTACT IF I HAVE A RESEARCH-RELATED EMERGENCY? If you experience a problem, either you or your parents(s) or legal guardian(s) should contact one of the study doctors listed at the bottom of this consent form.

CAN I DECLINE TO PARTICIPATE OR WITHDRAW FROM PARTICIPATING? If you decide to participate, you are free to stop participating at any time. This will in no way affect your relationship with any of the doctors who are taking care of you.

WHAT IF NEW INFORMATION BECOMES AVAILABLE? If any information develops or changes occur during the course of this study that may affect your willingness to continue participating, you will be informed immediately.

CAN I BE TERMINATED FROM THE STUDY? You may be removed from the study without your consent for any of the following reasons:
- The study doctors decide that continuing in the study would be harmful to you.
- You fail to follow the study procedures.
- You participate in other research studies while you are enrolled in this study.
- The company providing the study drug(s) decides to cancel the study.

WHO WILL HAVE ACCESS TO RESULTS FROM THE STUDY? [The PI should determine if the participant and/or their physician would receive results from the study and provide information accordingly].

WHOM DO I CALL IF I HAVE ANY QUESTIONS? If you have any questions, please do not hesitate to ask and they will be answered at this time. If you think of any additional questions later, please feel free to contact one of the study doctors listed on the last page of this consent form.
The Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital has reviewed this study and will review any concerns or complaints you may have regarding your participation in the study or questions you or your parent(s) or legal guardian(s) may have about your rights as a research subject. This is a Committee that is concerned with protecting people who volunteer to participate in research studies. The Committee may be reached by calling the office from 9:00 a.m. to 5:00 p.m., Monday through Friday at 408/885-2383 or by writing to the Research Committee, Santa Clara Valley Medical Center, Institutional Review Board Office, 777 Turner Dr. Office 2N106, San Jose, California 95128.

**DOCUMENTATION OF INFORMED CONSENT:** You are voluntarily making a decision about whether or not to participate in this research study. If you would like to participate, please fill in the lines below. Your signature indicates that you have decided to participate having read and understood the information presented. You and your parent(s) or legal guardian(s) will be given a copy of the signed and dated assent form to keep. Thank you for your interest in the study.

Subject's Name (Printed) ____________________________________________________________

Subject's Medical Record Number _______________________________________________________________________

Signature of Subject ____________________________________________________________

Date Signed _______________________________________________________________________

My signature as witness certifies that the subject was informed of the research, was given an opportunity to ask questions and signed this consent form in my presence as his/her voluntary act and deed.

Signature of Witness (if applicable) ____________________________________________________________

Date Signed _______________________________________________________________________

In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Printed Name/Signature of Investigator/Desigee ________________________________________________

Date Signed _______________________________________________________________________

**IDENTIFICATION OF STUDY INVESTIGATORS**

**Principal Investigator:** Insert Name, Title, Name of Institution, Address, and Telephone Number for questions and telephone number where, in the event of an emergency, the study doctor can be reached by a subject on a 24 hour basis.

**Sub-Investigator:** Insert Title, Name of Institution, Address, and Telephone Number for questions and 24-hour telephone number for emergencies.

IRB Approval Date: _______________________________________________________________________

Expiration Date: _______________________________________________________________________

IRB Reference #: ______________________________________________________________________
# INVESTIGATOR’S INFORMED CONSENT CHECKLIST

When applicable, the following must be addressed in the informed consent form document.

- Concise summary of research
- California Experimental Subject’s ‘Bill of Rights’
  (if applicable – only for studies that involve a medical experiment)

### Introduction
- Statement that the study involves research
- Description of study goals
- Name of principal researcher(s)
- Name of sponsor(s)
- Conflict of interest statement if applicable

### Procedures and Subject Involvement
- Expected duration of the subject’s participation
- Approximate number of subjects involved
- Description of procedures (where applicable: description of research vs. clinical procedures)
- If applicable, list the probability for random assignment to each treatment
- Subject’s responsibilities (for clinical studies)

### Possible Risks and Benefits
- List of reasonably foreseeable risks and discomforts
- Statement that some risks may be unforeseeable
- List of reasonably foreseeable benefits (when there is no intended clinical benefit to the subject, the subject should be made aware of this)
- Alternative procedures or treatments

### Costs and Compensation
- Description of all costs to the subject that may result from participation in the study
- Description of any recruitment incentives, medical treatments, or compensation available to subjects
- If applicable, the anticipated prorated payment, if any, to the subject for participating in the trial

### Confidentiality
- Statement that confidentiality will be maintained to the extent allowed by law
- Statement about future research of data or specimens if applicable
- Description of procedures for maintaining confidentiality and protecting subject’s privacy
- Statement that clinical trials will be published in a databank (only if the study product is regulated by FDA)
- When applicable, a statement that indicates whether a specimen will be used for genetic testing.

### Contact Information
- Name and telephone number of person to contact for questions about the research study
- Name and telephone number of person to contact for questions about the subject’s rights as a research subject
- Where applicable: name and phone number of person to contact in case of a medical emergency
**Subject’s Rights as a Research Participant**
- Statement that participation is voluntary
- Statement of right to withdraw at any time without penalty or loss of benefits
- Where applicable: policy on termination of subject participation without subject approval
- Where applicable: policy on disclosure of research findings and clinically relevant information

**General Issues**
- Language used in the informed consent form must be understandable to the subject (consent form should be written in lay language at a fifth grade reading level)
- Subjects must be given the opportunity to ask questions about the study and their participation in the study
- Informed consent materials must be culturally appropriate for the study population
- Individuals with questionable capacity for consent must be excluded.
- A statement, if applicable, about whether the subjects will have access to the results of the study.

If you have questions about specific elements of informed consent, or if you would like to have a consent form reviewed before it is sent to the Committee as part of your formal application, please contact the Administrator of the Committee.
HIPAA Privacy Document Template

Santa Clara Valley Medical Center
[The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital]

Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: (Insert Title of the Research Study)

Principal Investigator: (Insert the Name of the Primary Investigator)
(Insert Institution)
(Insert Address)
(Insert Phone Numbers)

*Sub-Investigator(s): (Insert the Names of the Sub-Investigators)
(Insert Phone Numbers)
(Insert Institution)

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. This authorization form gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] to use your personal health information collected about you for research purposes within our institution. You are also allowing Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] to disclose that personal health information to outside organizations or people involved with the processing of this study.

Date of Approval
Page X of X
What personal health information is collected and used in this study, and might also be shared (disclosed)?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:  
(Modify this list as appropriate - delete or add items as necessary):

- Name;
- Street address, city, county, zip code;
- Telephone numbers, fax numbers, and electronic mail addresses;
- Social security number;
- Medical record number;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs) and Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Family medical history;
- Allergies;
- Full face photographic images and any comparable images;
- Any other unique identifying number, characteristic, or code; <<Please specify>>
- Current and past medications or therapies;
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature;
- Information from <<List all other tests and procedures that will be performed in the study [these tests and procedures should be fully described in the existing ICF along with the associated risks and discomforts of the tests and procedures] >>
- <<[List any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites]>>

Why is your personal health information being used?
Your personal contact information is important for the Santa Clara Valley Medical Center's [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital] research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you. [If collecting social security number for
billing purposes or processing reimbursement to subjects please include a statement to that effect

Which of our personnel may use or disclose your personal health information? The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other Santa Clara Valley Medical Center staff [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital] associated with the study)
- The Research and Human Subjects Review Committee of Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital which is the Institutional Review Board [IRB] of Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital (the Committee charged with overseeing research on human subjects)
- Authorized members of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital] workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital], might receive your personal health information? As part of the study, the Principal Investigator and members of the Principal Investigator's study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following [Modify this list as appropriate- delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information {the examples below are suggestions only}].

- The Office for Human Research Protections and/or the Food and Drug Administration during research audits.
- Other collaborating academic research centers(s) [list all academic centers including those at Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital that may not be within the health system or its associated support offices. This would include collaborators at Stanford, etc., and their roles in project {who are working with the investigators in studying the economic impact of this treatment}].

Date of Approval
Page X of X
- Research data coordinating office and/or their representative: [name that group or company {who will be responsible for collecting results and findings from all the centers}]
- Research data management office and/or their representative: [name that group or company] 
- Pharmaceutical Company and/or their representative: [name that group or company {who will use the results for submissions to the Food and Drug Administration}]
- Government agency and/or their representative: [name that agency {who need to confirm the accuracy of the results submitted to the government or using government funds}]
- Contract Research Organization: [name that company {whose job is to review and correct any mistakes before the results are given to the sponsor or government}]
- Others: [name the other group and why they will receive the results]

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital], the information may no longer be covered by the federal privacy protection regulations.

**Depending on how personal health information will be handled for a specific study, the following notes are some examples of language that might also be included (if applicable):**

- In all disclosures outside of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital], you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

- In records and information disclosed outside of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital], you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

Date of Approval
Page X of X
How long will Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study expires << Specify date of expiration (e.g. 6 years after completion of the study, must be a minimum of 6 years, since the Code of Federal Regulations states that subjects may request from investigators all uses and disclosures of their study information for a period of six years after completion of their participation (45 CFR 164.528))>>. This information may be maintained in a research repository (database). However, Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital], may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care [will or will not] be included in your medical record.

Will you be able to access your records?
You will be able to request access to your medical record at any time. The investigator is not required to release to you research information that is not part of your medical record.

[OR]

You will be able to request access to your medical record when the study is completed. [If applicable, for the majority of blinded studies or other studies where access will be denied:] During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at

Date of Approval
Page X of X
the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

[ONLY USE THE FOLLOWING PARAGRAPH IF APPLICABLE]
If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the Institutional Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document you are permitting Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O'Connor Hospital or St. Louise Regional Hospital] to use and disclose personal health information collected about you for research purposes as described above.

Subject's Name [print]  Subject's Medical Record Number

Subject's Signature  Date Signed

Person obtaining authorization [print]

Person Obtaining Authorization Signature  Date Signed

Date of Approval
Page X of X
Pediatric HIPAA Privacy Document Template

Santa Clara Valley Medical Center
[The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital]
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: (Insert Title of the Research Study)

Principal Investigator: (Insert the Name of the Primary Investigator)
(Insert Institution)
(Insert Address)
(Insert Phone Numbers)

*Sub-Investigators: (Insert the Names of the Sub-Investigators)
(Insert Phone Numbers)
(Insert Institution)

You/your child have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your/your child’s personal health information. This authorization form gives more detailed information about how your/your child’s health information will be protected and includes:

- What personal health information about you/your child will be collected in this study;
- Who will use you/your child’s information within the institution and why;
- Who may disclose your information and to whom;
- Your rights to access research information about you/your child;
- Your right to withdraw your authorization (approval) for any future use of your/your child’s personal health information.

By signing this document you/your child are permitting Santa Clara Valley Medical Center to use your/your child’s personal health information collected about you/your child for research purposes within our institution. You/your child are also allowing Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional

Date of Approval
Page X of X
Hospital] to disclose that personal health information to outside organizations or people involved with the processing of this study.

What personal health information is collected and used in this study, which might also be shared (disclosed)?
The following personal health information will be collected, used for research and may be disclosed or released during your/your child’s involvement with this research study:
- Name;
- Street address, city, county, zip code;
- Telephone numbers, fax numbers, and electronic mail addresses;
- Current and past medications or therapies;
- Current health and history of major illnesses;
- Results of tests.
[The PI should add any other personal health information elements from the adult HIPAA template that apply to your study here.]

Why is your/your child’s personal health information being used?
Your personal contact information is important for the Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] research team to contact you/your child during the study. Your/your child’s health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you/your child.

Which of our personnel may use or disclose your personal health information?
The following individuals and organizations may use or disclose your/your child’s personal health information for this research project:
- The Principal Investigator and the Investigator’s study team (other Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] staff associated with the study);
- The Human Subjects and Research Review Committee of Santa Clara Valley Medical Center, O’Connor Hospital and St. Louise Regional Hospital which is the Institutional Review Board of the Santa Clara Valley Medical Center, O’Connor Hospital and St. Louise Regional Hospital (the committee charged with overseeing research on human subjects);
- Authorized members of the Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] workforce who may need to access your/your child’s information in the performance of their duties (for
example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital], might receive your/your child’s personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your/your child’s personal health information, including the results of the research study tests and procedures to the following:

- The Office for Human Research Protections and/or the Food and Drug Administration during research audits
- Other collaborating academic research centers(s):
- Government agency and/or their representative:
- Others:

The Principal Investigator or study staff will inform you/your child if there are any changes to the list above during your/your child’s active participation in the trial. Once information is disclosed to others outside Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] the information may no longer be covered by the federal privacy protection regulations.

- In all disclosures outside of Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] except as listed above, you/your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

How long will Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] be able to use or disclose your personal health information?

Your authorization for use of your/your child’s personal health information for this specific study expires __________. This information may be maintained in a research repository (database). However, Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] may not re-use or re-disclose your/your child’s personal health information collected in this study for another purpose other than the research described in this document unless you/your child have given written

Date of Approval
Page X of X
permission for the Principal Investigator to do so. Moreover, the Institutional Review Board at Santa Clara Valley Medical Center, O'Connor Hospital and St. Louise Regional Hospital may grant permission to the Principal Investigator or others to use your/your child’s information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures, done solely for this research study and not as part of your/your child’s regular care [will or will not] be included in your/your child’s medical record.

Will you/your child be able to access your records?
You/your child will be able to request access to your/your child’s medical record at any time. The investigator is not required to release to you/your child research information that is not part of your/your child’s medical record.

[OR]

You will be able to request access to your/your child’s medical record when the study is completed.

[If applicable, for the majority of blinded studies or other studies where access will be denied:]
During your/your child’s participation in this study, you/your child will not be able to access your/your child’s medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your/your child’s information will be available should an emergency arise that would require your/your child’s treating physician to know this information to best treat you/your child. You/your child will have access to you/your child’s medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you/your child research information that is not part of your/your child’s medical record.

Can you/your child change you/your child’s decision?
You/your child may withdraw your permission for the use and disclosure of any of your/your child’s personal information for research, but you/your child must do so in writing to the Principal Investigator at the address on the first page. Even if you/your child withdraw your permission, the Principal Investigator for the research study may still use your/your child’s personal information that was collected prior to your/your child’s written request if that information is necessary to the study. If you/your child withdraw your permission to use your/your child’s personal health information that means you/your child will also be withdrawn from the research study.
If you/your child withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you/your child is removed from these specimens.

You/your child will be given a copy of this Research Subject Authorization Form describing your/your child’s confidentiality and privacy rights for this study. You/your child will also be given the Institutional Notice of Privacy Practices that contains more information about the privacy of your/your child’s health information.

By signing this document you are permitting the Santa Clara Valley Medical Center [The PI must identify the correct institution: Santa Clara Valley Medical Center, O’Connor Hospital or St. Louise Regional Hospital] to use and disclose personal health information collected about you/your child for research purposes as described above.

Subject’s Name [Print]  Subject’s Signature  Date Signed
(required if subject is over 7 years of age)

Name of Parent/Legal Guardian  Relationship to Subject
(required if subject is under 18 years of age)

Signature of Parent/Legal Guardian  Date Signed
(required if subject is under 18 years of age)

Person obtaining authorization  Person obtaining authorization  Date Signed
[Print]  [Signature]
SANTA CLARA VALLEY MEDICAL CENTER  
O’CONNOR HOSPITAL  
ST. LOUISE REGIONAL HOSPITAL  
RESEARCH AND HUMAN SUBJECTS REVIEW COMMITTEE

2020 Meeting Schedule

<table>
<thead>
<tr>
<th>IRB MEETING DATES</th>
<th>DEADLINE FOR SUBMISSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 10</td>
<td>December 20*</td>
</tr>
<tr>
<td>March 13</td>
<td>February 28</td>
</tr>
<tr>
<td>May 8</td>
<td>April 24</td>
</tr>
<tr>
<td>July 10</td>
<td>June 26</td>
</tr>
<tr>
<td>September 11</td>
<td>August 28</td>
</tr>
<tr>
<td>November 13</td>
<td>October 30</td>
</tr>
</tbody>
</table>

*Because of the holidays, this submission deadline is 3 weeks prior to the meeting instead of the usual 2 weeks.

Additional meetings may be held in between scheduled meetings if the IRB Office receives multiple submissions that need review for a month not on the schedule.

NOTE: HARD COPIES OF THE APPLICATIONS MUST BE SUBMITTED TO THE IRB OFFICE:

Receiving Building
777 Turner Dr. #2N106

Renewal applications that are not received in time for the meeting will result in the study being closed. Please contact the IRB Administrator at (408) 885-2383 or Kimberly.bellon@hhs.sccgov.org to re-open the study.