SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review IRB

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SUBJECT: CRITERIA FOR APPROVAL OF RESEARCH

1. PURPOSE

   Outline the review process and define the criteria for approval of a research proposal by the Institutional Review Board (IRB).

2. SCOPE

   All research protocols involving investigational drugs or devices, or Investigator-designed projects (e.g., case reviews whether or not intended for publication, chart reviews that are preparatory to research) that may possibly qualify as “research” and involve “human subjects” as defined by the Health and Human Services’ (HHS’) Office of Human Research Subject Protection (OHRP).

3. POLICY

   - All studies that are approved by the IRB must satisfy all of the criteria without exception.

   - Additional criteria may be requested by the IRB prior to approving the study depending on the specifics of the protocol, the qualifications of the Investigator, the risks / benefits to the subjects or as deemed appropriate by the IRB.

   - Approvals are valid for a specified period of time not to exceed a maximum of one (1) year, with a request for renewal required prior to expiration of the approval period.

4. PROCEDURE

4.1. DEFINITIONS

The IRB will review all protocols or project requests in the context of the following definitions set forth in federal regulations at 45 CFR 46 ("The Common Rule"):
Research means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities [45 CFR 46.102 (d)].

Human Subject means a living individual about whom an Investigator (whether professional or student) conducting research obtains:

(1) data through intervention of interaction with the individual, or
(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects [45 CFR 46.102(f)].

4.2. REVIEW PROCESS

A. The Investigator

The Investigator must:

- Submit a SAMC 'Protocol Application' and include all the supporting scientific and ethical documents required by the application, as well as the SAMC 'Financial Disclosure' form;

- Acknowledge by signature his/her awareness and agreement to comply with applicable federal, state and institutional policies and procedures pertinent to the research process and the protection of human subjects [i.e., FDA form 1572 when applicable to drug/biologic/radiation studies, and the "Investigator Commitments" listed on the SAMC Research "Protocol Application";

- Provide documentation of having completed training in "human subjects protections" offered by either the Collaborative Institutional Training Initiative (CITI) at website https://www.citiprogram.org, or .the National Institutes of Health (NIH) at website http://phrp.nihtraining.com/users/login.php. Because SAMC subscribes to the CITI program there is no need to actually print your certificate. It's automatically retained in the database. **To maintain certification, a few refresher modules must be completed every three (3) years.**

B. The IRB Administrative Office

The IRB Administrative Office will receive and present to the IRB Administrative Subcommittee all research protocols for clinical trials and any other projects/requests from physicians or Institutional staff members that meet or appear to meet the definitions of *research* involving *human subjects* as stated above.

D. The IRB Administrative Subcommittee

The Administrative Subcommittee will:

- Determine if the request constitutes *research* for purposes of federal policy and is either exempt or not exempt from the requirements of the "Common Rule". [See IRB SOP R-1224];

- The IRB Administrator, who is both a member of the IRB Administrative Subcommittee and the Research Privacy Board (another subcommittee of the IRB) will determine if the request qualifies for submission to the full 'Research Privacy Board' for purposes of granting an Investigator's request for any waiver or alteration of Authorization to use and disclose private health information (PHI). [See IRB SOPs R-1230 and R-1234]

E. The Convened IRB

The full convened IRB will review and discuss the complete 'Protocol Application' and may vote for approval only when the following criteria have satisfied a majority of the voting members present:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits;
- Selection of subjects is equitable;
- Informed consent is sought from each prospective subject or the subject's legally authorized representative, and appropriately documented in accordance with, and to the extent required by, HHS, FDA and California regulations;

- Appropriate safeguards are induced in order to protect the rights and the welfare of vulnerable populations;
- Adequate provisions to protect the privacy of subjects and maintain confidentiality of data;
- Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence;
- When the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations at subpart B, C, or D, respectively, of the "Common Rule" [45 CFR 46];

4.3 ADDITIONAL REVIEW CRITERIA FOR DEVICES

A. Definitions

FDA regulations state that for studies involving use of an investigational device, the investigator (or Sponsor) must obtain either a "significant risk" Investigational Device Exemption (IDE) from the FDA, or a determination of "non-significant risk" from the IRB. The IRB serves as the FDA's surrogate for review, approval and continuing review of an NSR study.

Significant Risk Device Studies:

A significant risk (SR) device study means an investigational device study that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting for sustaining human life and presents a potential for serious risk to the health, safety or welfare of a subject;
- Is for a use of 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.

Non-Significant Risk Device Studies:

A non-significant (NSR) device study is one that does not meet the definition for an SR device study.

B. IRB REVIEW

If the convened IRB determines that the study is a NSR study, it may approve the study using the criteria outlines in section 4.1 above. The IRB's determine-ation will be documented in the meeting minutes. Neither the Sponsor nor the

IRB has to report the IRB approval of a NSR device study to the FDA. The study may begin without the submission of an IDE.

If the IRB determines that a study, which was presented by the Sponsor (or Investigator) as an investigation involving a NSR device, involves a SR device as defined in 21 CFR 812.3 (m), it shall notify the Sponsor and Investigator according 21 CFR 812.66. To determine if a device involves a significant risk, the IRB must consider the nature of the harm that may result from the use of the device. If a device being investigated might cause significant harm to any of the subjects, the device should be considered "significant risk". Also, if the subject must undergo a procedure as part of the study, such as a surgical procedure to implant the device, the IRB must consider the potential harm caused by the procedure as well as the device. The SR device study **may not begin** until FDA approves an IDE for that device. The IRB's determination will be documented in the meeting minutes. If the FDA has already made the SR or NSR determination, the agency's decision is final.

REGULATORY REFERENCES:

45 CFR 46	Protection of Human Subjects ("The Common Rule")
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 54	Financial Disclosure By Investigators
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemption
21 CFR 814.100	Humanitarian Use Devices
ICH E6	Good Clinical Practice: Consolidated Guidance (April 1996)
FDA Guidance	"Significant Risk and Non-significant Risk Medical Devices", January 2006
FDA Guidance	Frequently Asked Questions About Medical Devices (January 2006)
OHRP Guidance	Engagement of Institutions in Human Subjects Research
CA H&S Code 24170-24179.5	Protection of Human Subjects in Medical Experimentation
CA H&S Code 111515-111545	Experimental Use of a Drug
CAMH RI.2.180	Protection of Research Subjects
45 CFR 160, 162, 164	The Health Insurance Portability and Accountability Act (HIPAA)