SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1231
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SUBJECT: WAIVER OF IRB JURISDICTION

1. PURPOSE

Define the criteria and process by which the Saint Agnes Medical Center (SAMC) IRB waives jurisdiction for research previously approved by another IRB.

2. SCOPE

This SOP applies to research studies in which a local Investigator is conducting a research study that another local institution's IRB or a central IRB (i.e., the proposed IRB of Record) has approved a study for which the local Investigator requests use of SAMC facilities/services for some or all of the research-related procedures.

3. POLICY

- In complying with federal regulations, the SAMC IRB may use joint review, or the review of another qualified IRB, or similar arrangement to avoid duplication of regulatory oversight.

- Denial of a 'Waiver of IRB Jurisdiction' does not automatically imply that the SAMC IRB will assume jurisdiction under federal regulations. It may mean that research will not be permitted in SAMC facilities.

- An 'Institutional Authorization Agreement' will be executed in cases where the SAMC IRB approves the 'Waiver of IRB Jurisdiction' and relies on the oversight and continuing review of an external IRB.

- An "Institutional Authorization Agreement' will not be ordinarily generated for the following types of "research-associated" activities conducted at SAMC and for which SAMC is not considered to be "engaged" in the research:

  (i) Routine medical care or treatment monitoring being carried out incidentally to an external research study (e.g., the need for a research patient to receive

investigational treatment or follow-up close to their home), and the patient has provided the study's Investigator with written informed consent and has also signed a valid authorization to release personal health information (PHI).

(ii) Individual requests for review of medical records sent to SAMC's Health Information Management (HIM) department as part of an external research study funded by a public health agency (e.g., Center for Disease Control or California DPHS) for the purposes of quality assurance or health outcomes, provided the requester has submitted to SAMC a copy of that agency's IRB approval and HIPAA waiver of authorization to disclose PHI (or if applicable the patient's signed HIPAA Authorization).

(iii) Individual requests for review of medical records sent to HIM as part of an insurance carrier's research on a cohort of their covered patients provided the requester has submitted to SAMC a copy of that study's IRB approval and HIPAA waiver of authorization to disclose PHI (or if applicable the patient's signed HIPAA Authorization).

(iv) Individual requests to the SAMC Pathology Department for biospecimens (e.g., tumor blocks/slides and corresponding pathology report) for purposes of research conducted externally, provided the requester has submitted to SAMC's Pathology Department a copy of the study's IRB approval letter and the patient's signed HIPAA Authorization.

4. PROCEDURE

- The Investigator must complete the 'Application for Waiver of Jurisdiction' and provide the SAMC IRB copies of the following:

  - Study protocol;
  - Investigator's Brochure;
  - Approval letter from the 'IRB of Record';
  - 'IRB of Record's' stamped informed consent;
  - The California Experimental Patient's Bill of Rights;
  - Valid Authorization (under HIPAA) to disclose protected health information (PHI).

- Depending on study specifics, an application for a 'Waiver of IRB Jurisdiction' may be eligible for expedited IRB review or may require Full Board review as follows:

  Criteria for SAMC IRB Expedited Review

  In addition to providing the required documents mentioned above, and depending on whether or not the research involves a drug or medical device, all of the following criteria must be met to qualify for expedited review:

  (1) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(2) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling;

(3) The proposed IRB of Record must have a Federalwide Assurance (FWA);

(4) No employee of SAMC is directly involved in the management of the study or the consenting of a research subject but is merely executing a service at the direction of the Investigator which is consistent with their job description;

(5) Risks related to the tests and/or procedures are reasonable in relation to the knowledge and or benefit that may be expected to result from their participation.

Criteria for Full Board Review:

In addition to providing the required documents mentioned above, and depending on whether the research involves a drug or medical device, Full Board review is required when any one of the criteria for expedited review above is not met. (Note: If the proposed IRB of Record does not have a FWA, the waiver will be denied).

- If the waiver is approved by the SAMC IRB, the Chair of the SAMC IRB will execute an Institutional Authorization Agreement between the IRB of Record and the SAMC IRB confirming the authority of the IRB of Record to assume oversight and continuing review, and that the Investigator assumes responsibility for the conduct of the study. This Institutional Authorization Agreement will also be signed by SAMC's Chief Medical Officer (CMO) acknowledging Institutional approval.

- Subsequent to the approval of the waiver, the Director of Clinical Research will ensure that the Investigator complies with our SOPs for research study billing (if applicable) in order to avoid inappropriate billing of third party payers or Medicare (CMS).

- The Investigator and the IRB of Record jointly assume responsibility of informing the SAMC IRB if an audit of any source documents located in SAMC's Health Information Management system is to be conducted by an authorized representative from the study's Sponsor or any state or federal agency.

REGULATORY REFERENCES

21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
21 CFR 50	Protection of Human Subjects
21 CFR 56.114	Cooperative Research
45 CFR 46.114	Cooperative Research

Federal Register Notice Vol 63, No. 216, 11/9/98	Protection of Human Subjects: Categories of Research that May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure
OHRP Guidance	Engagement of Institutions in Human Subjects Research