SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1210
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SUBJECT: INVESTIGATOR RESPONSIBILITIES

1. PURPOSE

   Outline the role and primary responsibilities of research Investigators conducting human subject research under the oversight of the SAMC IRB.

2. SCOPE

   An Investigator is defined as an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The term “Principal Investigator” is used to designate the lead investigator conducting a clinical investigation where there is more than one investigator (i.e., “Sub-investigator(s)”).

3. POLICY

   - The Investigator is responsible for ensuring that an investigation is conducted according to the research protocol and the signed Statement of the Investigator for drug studies (i.e., FDA Form 1572), or the “Investigational Plan” (or protocol) for devices studies, and all applicable regulations [see Regulatory references below] for protecting the rights and welfare of subjects under the Investigator’s care.

   - The Investigator will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

   - 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.

4. PROCEDURE

4.1 The Investigator must provide documentation of having completed training in "human subjects protections". Because SAMC subscribes to the CITI program mentioned above, there is no need to actually print the certificate. It's automatically retained in the database. **Note: To maintain certification, a few refresher modules must be completed every three (3) years.**

4.2 The Principal Investigator will submit a Protocol Application [SOP R-1207] to the IRB for review before initiating any research study.

4.3 Each Investigator will obtain the written informed consent of each human subject to whom the investigational drug/device is to be administered or implanted, or on whom only an investigational test or intervention is to be performed. The exception to the required subject's signature is when the subject is not able to participate in the consent process, and the study has been approved for: surrogate consent [SOP R-1221], waiver of consent [SOP R-1218]; or consent under emergent conditions [SOP R-1220]. When possible, the investigator will obtain the assent of a minor [SOP R-1232] who has been asked to participate in a clinical investigation.

4.4 The Investigator will ensure that the Informed Consent document is appropriately signed and dated by the subject, the person administering the consent, the Principal Investigator, and the witness (if circumstances require it) in order to be valid. Although the Principal Investigator may delegate consenting of the subject to a qualified research staff member, the Investigator must be available before the research candidate signs the consent to discuss the study and answer any questions the research candidate has. The subject's signed informed consent will be retained in the subject's study records

4.5 The Investigator will ensure that a HIPAA-compliant authorization allowing disclosure of personal health information and the California Patient's Bill of Rights was presented and signed by the research subject. These documents will be retained in the subject's study records.

4.6 The Investigator shall administer drug/device only to subjects under the Investigator's personal supervision or under the supervision of a Sub-investigator responsible to the Investigator.

4.7 The Investigator will ensure that adequate records of the disposition of the drug/device will be maintained (dates, quantity and use by subjects) from the time of receipt from the Sponsor through its distribution to the subject and its return to the Sponsor, or otherwise its destruction on site (if unused).

4.8 The Investigator will ensure that adequate and accurate case histories are prepared and maintained for each subject to whom the investigational drug/device is to be administered or implanted, or on whom an investigational test or intervention is to be performed, or who were employed as a control in the study. These case histories include the case report forms (CRFs) and supporting data contained in source documents (e.g., lab reports, radiology imaging and interpretation, physical assessments, histories, diaries, questionnaires, etc), the signed and dated consent form, drug disposition records and physician and nurse progress notes.

4.9 Notify the IRB and the Sponsor immediately (within 24 hours) of any serious and unexpected adverse event, or any unanticipated problem that places subjects or others at a greater risk of harm than was previously known or recognized [SOP R-1215].

4.10 The Investigator will furnish the following reports to:

(a) *The Sponsor*: individual subject case reports, safety reports (i.e., all adverse events, serious and non-serious), progress reports, a final report, and financial disclosure reports;

(b) *The IRB*: annual study status reports, interim study status reports (documenting any protocol or informed consent amendments, protocol deviations, patient recruitment numbers, etc), safety reports (serious and unexpected adverse events only), final report, financial disclosure reports, and reports of all unanticipated problems involving risk to human subjects or others.

4.11 The Investigator will retain (i.e., archive) or request that the Institution retain (if SAMC's Clinical Research Department project managed the study) the completed study records for the prescribed length of time:

(a) *Under an Investigational New Drug Application (IND)* - the Investigator is required to maintain study records for a period of 2 years following the date a marketing application is approved for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

(b) *Under International Conference of Harmonization (ICH) Guidelines* - the Investigator is required to maintain study records for at least 2 years after the last approval of a marketing application in an ICH region (i.e., European Union, Japan and the United States).

Note: It is the responsibility of the Sponsor to notify the Investigator/Institution of how long they wish the records be retained for their registration purposes.

(c) *Under Trinity Health policy* – the Institution is required to maintain study records for at least 7 years.

4.12 The Investigator shall, upon request and at reasonable times, permit an authorized officer or employee of the FDA to have access to, and copy and verify, any records or reports made by the Investigator and his or her study staff. Unless required by law to divulge a study subject's identity, all such access will comply with the federal Health Insurance Portability and Accountability Act (HIPPA) to protect the privacy of individually identifiable health information.

4.13 The Investigator shall, upon request and at reasonable times, permit an authorized representative of the Sponsor, to have access to study records or reports made by the Investigator or his/her study staff for purposes of verifying compliance with the study protocol and applicable federal regulations.

REGULATORY REFERENCES

45 CFR 46	Protection of Human Subjects ("The Common Rule")
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure By Investigators
21 CFR 312.60 to 312.69	Responsibilities of Investigators
21 CFR 812.100 to 110, 812.140 to 812.150	Responsibilities of Investigators
ICH E6	Good Clinical Practice: Consolidated Guidance (April 1996)
FDA Guidance	"Adverse Event Reporting to IRBs – Improving Human Subject Protection" (January 2009)
FDA Guidance	Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects
OHRP Guidance	"Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or others and Adverse Events" (January 15, 2007)
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)