



INSTITUTIONAL REVIEW BOARD INVESTIGATOR'S GUIDELINES

In order to participate in human subject research, an investigator must agree to fulfill certain obligations. Requirements are set forth by the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). NorthBay Healthcare Institutional Review Board (IRB) has given their assurance that these requirements will be enforced.

No research protocols involving human subjects can be conducted at NorthBay Healthcare System facilities without prior review and approval by the NorthBay Healthcare IRB. No subject accrual can occur during any time period in which IRB approval has lapsed (e.g. lapse in annual review).

Federal regulations require that the investigator submit proposed research to an IRB that will assume responsibility for the initial and continuing review of the study. The NorthBay Healthcare's IRB has jurisdiction for all research conducted at NorthBay Healthcare System facilities, for all research conducted by members of the NorthBay Healthcare medical staff, and for certain research conducted in the community.

Application and Study Presentation:

The investigator, or a qualified representative, must attend that portion of an IRB meeting in which their research is being discussed for initial review to present a brief overview and to respond to any questions or concerns of the Board members. At the discretion of the IRB, the investigator / representative may be asked to leave the meeting room during the voting procedure. Subsequent review regarding protocol activities (including revisions/amendments/adverse events) and annual review may not require the investigator's / representative's attendance at the IRB meeting. A Progress Report is required of the principal investigator at intervals appropriate to the degree of risk of the study, but not less than once a year. If there are questions regarding either protocol activity or information on the annual review, approval will be delayed until these questions are answered to the satisfaction of the IRB.

Submission Requirements:

The investigator will ensure that the following documents are given to the IRB at least ten days prior to the IRB meeting:

- Research Application
- Protocol Summary (or Sponsor Summary)
- Informed Consent
- Complete Protocol
- Investigator's Brochure (for all studies involving pharmaceutical agents or a memo if no Investigator's Brochure is available.)

The investigator will ensure that the Progress/Annual Report form is submitted to the IRB at least 10 days prior to the IRB meeting date on the month it expires (at least annually).

Supervision:

Investigators shall administer research only to subjects under their personal supervision or under the supervision of investigators responsible to them (“co-investigators”). The principal investigator is responsible for submitting documentation on all co-investigators to the IRB; for ensuring that any co-investigators are following the most current IRB approved protocol; are using the most current consent document; and that co-investigators are adhering to all IRB requirements.

Adherence to Protocol:

The investigators shall adhere to the protocol approved by the IRB. Any deviation from or change to the protocol must receive prior approval by the IRB. An exception is allowed when the changes are necessary to protect the safety and welfare of the subject. In that case, the IRB must be notified of the deviation in writing as soon as possible, but no later than 5 working days after the action.

Informed Consent:

Written informed consent must be obtained from each subject before research is initiated, unless written consent has been waived by the IRB. The consent document used must be the latest version approved by the IRB. The investigator acknowledges that the consent document is a memorialization of an active process of discussion with the proposed research subject regarding the nature of the research including the risks, benefits, alternatives, costs, etc. The subject must be provided with a copy of the consent document as well as a copy of the Research Subject’s Bill of Rights (Attachment D) at the time the consent is obtained. Any protocol actions that affect the informed consent must be reviewed and approved by the IRB.

Advertising for Study Subjects:

Advertising is an extension of the informed consent process. Examples of advertising include newspaper, radio, television, flyers and posting on the Internet. The IRB must approve all advertisements prior to their publication or distribution.

Data Collection:

The principal investigator shall remain responsible for the maintenance and submission of accurate data pertinent to the investigation, including forms designed to record observations, adverse reactions, control of test articles and other data.

Adverse Event Reporting:

The investigator shall promptly notify the IRB of any protocol related serious or unexpected adverse events. Initial notification of serious events may be made by telephone or fax within 5 working days of the investigator’s knowledge of the incident, with written follow-up within 5 additional working days. Any hospitalization of a NorthBay Healthcare research subject must be reported within 5 working days of the investigator’s knowledge of the hospitalization, whether or not it is related to the research. All deaths of research subjects during or within 30 days after participation in a research protocol must be reported to the IRB, in the same manner as other adverse events.

Audits:

It is the responsibility of the investigator to notify the IRB of the findings of any audit of approved research. In addition it is the responsibility of the principal investigator to notify the IRB of any sanctions or disqualification of an approved investigator.

Records and their Retention:

Research activities, including obtaining of informed consent, dates and observations of interval visits, notation of trial completion, results and adverse events must be documented in the subject's medical chart. All records pertaining to research must be maintained for the period specified in the federal regulations.

IRB Administrator (Recording Secretary):

The IRB Administrator is available to assist investigators with questions or concerns regarding IRB regulations, submissions and documentation. The Administrator maintains the official IRB files as well as resource materials for IRB members and investigators. For assistance, phone (707) 624-7001.

Signature: *By signing below the investigator agrees to adhere to these requirements.*

Return a signed copy of these Guidelines to the NBH IRB.

Investigator's Signature

Date Signed

Investigator's Name (please print)