



## **INSTITUTIONAL REVIEW BOARD INVESTIGATOR'S GUIDELINES FOR CONDUCTING QUALITY IMPROVEMENT OR EVIDENCE-BASED PRACTICE PROJECTS AT NORTHBAY HEALTHCARE.**

In order to participate in a Quality Improvement (QI) or Evidence-Based Practice (EBP) project at NorthBay Healthcare, an investigator must agree to fulfill certain obligations.

No Quality Improvement or Evidence-Based Practice project that is done through a bachelors, masters, or doctorate program 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).

NorthBay Healthcare's IRB has jurisdiction for all, QI and EBP projects conducted at NorthBay Healthcare System facilities, for all projects conducted by employees, student staff members, students of affiliated medical schools and of the NorthBay Healthcare medical staff.

### **Application and Study Presentation:**

The investigator, accompanied by their NB preceptor, must attend that portion of an IRB meeting in which their project is being discussed for initial review to present a brief overview and to respond to any questions or concerns of the Board members. The investigator will not be in 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 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 project 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 provided to the IRB according to the Submission Timeline Guidance Sheet:

- IRB Application
- Protocol Summary
- Informed Consent (if applicable)
- Complete Protocol

The investigator will complete a Progress Report (or Final Report) and submit it to the IRB the month before the expiration date of the study.

### **Supervision:**

Investigators shall administer any process or practice change only to subjects under the supervision of their NB preceptor or faculty advisor. 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; 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.

**Advertising for Study Subjects:**

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, security 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 project/protocol related serious or unexpected adverse events. Initial notification of serious events may be made by telephone or email 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 QI or EBP subject must be reported within 5 working days of the investigator’s knowledge of the hospitalization, whether or not it is related to the project. All deaths of project 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 their approved project. 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:**

All records pertaining to the project must be maintained for the period specified in the federal regulations.

**IRB Administrator:**

The IRB Human Protections 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)