OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

GUIDANCE ON IRB APPROVAL OF CHANGES IN STUDY TEAM MEMBERS

Date: February 8, 2013
This guidance supercedes ORD and ORO's June 7, 2010 guidance entitled:
ORD and ORO Guidance on IRB Approval of Changes in Protocol Study Teams

SCOPE: Proposed changes to an approved, on-going research activity must be reviewed and approved by the IRB in accordance with the Common Rule (38 CFR Part 16 and VHA Handbook 1200.05). This document describes ORD's current guidance on when an IRB must review and approve changes in study team membership. ORD offers guidance on the following topics:

1. Changes in the study team member named within a protocol and/or informed consent form.
2. Replacement of a study team member identified by title in the protocol and/or informed consent form.
3. Changes in key research staff listed on IRB application forms.
4. Changes in Principal Investigator, Co-Principal Investigator, Local Site Investigator, or Investigator

1. CHANGES IN THE STUDY TEAM MEMBER NAMED WITHIN A PROTOCOL AND/OR INFORMED CONSENT FORM.

In a protocol or informed consent form, study team members are generally identified by name or by title. If a study team member is identified by name in the IRB-approved protocol and/or informed consent form, a replacement or termination of that member's role constitutes a change in the protocol and/or informed consent form. Therefore, such a change requires IRB review and approval. For example, if an IRB-approved protocol specifically identified the name of a medical monitor and later another individual was identified to replace him or her, the protocol would require an amendment reflecting the change in the name of the medical monitor. This protocol change would require IRB review and approval prior to initiation of the change unless it was necessary to eliminate apparent immediate hazards to the subjects.

2. REPLACEMENT OF A STUDY TEAM MEMBER IDENTIFIED BY TITLE IN THE PROTOCOL AND/OR INFORMED CONSENT FORM.

If a study team member is replaced by another individual AND the IRB approved protocol and/or informed consent form identify the person by title and not name, a replacement by another individual with the same title is not a protocol or informed consent change. Therefore, no IRB review and approval is required. For example, if a Principal Investigator (PI) appointed a new research study coordinator to replace the original research study coordinator in an IRB-

approved protocol when neither is mentioned by name, the replacement in personnel does not require review and approval by the IRB because the protocol remains unchanged.

3. CHANGES IN KEY RESEARCH STAFF NAMED ON IRB APPLICATION FORMS.

IRB application forms are typically designed to assist an IRB in the review of a protocol. IRB application forms usually require the PI to include the names of the study team members associated with the protocol, often referred to as "key research staff" or "key personnel". Changes in the status of key research staff or key personnel listed on an IRB application form do not require IRB review and approval unless

a. They are one of the following:
   - Principal Investigator (PI),
   - Local Site Investigator (LSI),
   - Co-PI or Co-LSI, or
   - Investigator; or

b. The local IRB requires it of other staff or personnel.

4. CHANGES IN PRINCIPAL INVESTIGATOR, CO-PRINCIPAL INVESTIGATOR, LOCAL SITE INVESTIGATOR, OR INVESTIGATOR

Changes in the PI, LSI, Co-PI, Co-LSI, or investigator of an IRB-approved protocol should be reviewed and approved by the IRB to ensure that the new individual meets criteria described in 38 CFR 16.111.

REGULATORY AND VHA POLICY REFERENCES:

38 CFR § 16.103(b), Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:…(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

VHA Handbook 1200.05, Paragraph 9(c) (1-3), (1) If a study team member is identified by name in the IRB-approved protocol, a replacement or termination of their role constitutes a change in the protocol. Such a change requires IRB approval (e.g., if an IRB-approved protocol specifically identified the name of a medical monitor and later another individual was identified to replace the medical monitor, the protocol would require an amendment reflecting the change in the name of the medical monitor. This protocol change would require IRB approval prior to initiation of the change, unless it was necessary to eliminate apparent immediate hazards to the subjects).

(2) If a study team member is replaced by another individual and the IRB-approved protocol identifies the person by title and not name, a replacement by another individual with the same title is not a protocol change. No IRB approval is required (e.g., if a PI appointed a new research study coordinator to replace the original research study coordinator in an IRB-approved protocol when neither is mentioned by name, the replacement in personnel does not require approval by IRB because the protocol remains unchanged).

(3) IRB may also require a specific individual(s) by name to be part of the study team as a condition for IRB approval of the research. In that case, a proposed change in that specific individual would require IRB approval.