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## **ORD and ORO Guidance on IRB Approval of Changes in Protocol Study Teams**

Proposed changes to an approved, on-going research activity must be approved by the IRB in accordance with the Common Rule (38 CFR Part 16 and VHA Handbook 1200.05). Approval must be granted prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects (38 CFR 16.103(b)(4)(iii)). The following provides guidance on changes in the study team.

**Changes in the study team described within a protocol.** In a protocol, study team members are generally identified by name or by title.

**Change in person named in protocol.** 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. Therefore, such a change requires IRB 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 approval prior to initiation of the change unless it was necessary to eliminate apparent immediate hazards to the subjects.

**Replacement of a study team member.** 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. Therefore, no IRB 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 approval by the IRB because the protocol remains unchanged.

**Changes in key research staff listed on IRB application forms.** IRB application forms are 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". IRB application forms are not the protocol nor considered as part of the protocol. 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 they are one of the following:

- Principal Investigator (PI)
- Local Site Investigator (LSI)
- Co-PI or Co-LSI.

**Changes in PI, LSI, Co-PI, or Co-LSI.** Changes in the PI, LSI, Co-PI, or Co-LSI of an IRB-approved project must be evaluated and approved by the IRB to ensure that the new individual meets criteria described in 38 CFR 16.111.

The 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.