SUBJECT: VA Ann Arbor Healthcare System (VAAAHS) Local Requirements for Approval of Changes in Study Team Members

1. PURPOSE:

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. This guidance outlines the local requirements for review and approval of changes in Study Team Members.

2. SCOPE:

SCOPE: Proposed changes to an approved, on-going research activity must be reviewed and approved by the appropriate oversight committee in accordance with the Common Rule (38 CFR Part 16 and VHA Directive 1200.05).

3. DEFINITIONS:

Research: Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalized knowledge.

VA Research: VA research is research conducted by VA investigators while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

VA Investigator: A VA investigator is an individual who conducts research approved by the VA Research & Development committee (RDC) while acting under a VA appointment, including full and part-time (VA Paid) employees. VA investigators must uphold professional and ethical standards and practices and must comply with all applicable VA and VHA and federal regulations and policies.

Principal Investigator (PI): The PI is an investigator in charge of a research project or program. The PI must hold a current paid VA appointment with a set tour of duty (i.e., not an intermittent VA employee, WOC employee, fee-basis physician, or contracted employee). Trainees can serve as a co-investigator but must have a VA PI sufficiently experienced in the area of the trainee's research interest to serve as PI. The PI oversees scientific and technical aspects of a grant or protocol and the day-to-day management of the research. For an investigation conducted by a team of individuals, the PI is the responsible leader of that team. Research projects must have a single PI as point of contact. Studies funded by the VA Office of Research and Development (VA- ORD) in which a "Multiple PI" form was filed and accepted by VA-ORD may name both PIs. Exceptions to the guidelines listed here for PI roles may be granted by the ACOS on an individual basis except in cases where approval would constitute deviation from published VHA Handbooks or Directives.

Study Team Member: Any person associated or listed on a Study Team Roster either in the Project or in the Protocol.

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. 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. 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. Such a change requires IRB approval prior to initiation of the change, unless it was a necessary apparent immediate hazard to the subjects.

5. CHANGES IN THE STUDY TEAM MEMBER NAMED WITHIN A PROJECT:

All members of a study project must be reviewed and approved by the Reseach & Development (R&D) coordinator. To add new study team members or remove currently approved study team members requires Reseach & Developmnet Committee (RDC) review and approval with the exception of the PI. To change a study team member, submission of a Project Staff Change is required in AAROW. To change the Principal Investigator (PI), submission of an RDC Project Amendment Form is required.

a) Instructions for completing a Project Staff Change form in AAROW:

   i) From the AAROW home page, select My Work Space – select Project Assistant – select View My Projects – Click to open (Project) – select Project Staff Change Form – select Add a New Form. Complete form and submit for PI to sign.
   ii) Once signed by the PI, the request will be reviewed by the R&D Coordinator and the study contacts listed on the project will receive a decision letter via email. New study team members are not permitted to begin working on the project until RDC and all other relevant committees have given approval.

b) Instructions for RDC Project Amendment Form in AAROW:

   i) From the AAROW home page, select My Work Space – select Project Assistant – select View My Projects – Click to open (Project) – select (RDC Project Amendment Form) – select Add a New Form. Complete form and submit to current PI for signature.
   ii) Once signed by the current PI, the request will go to full committee for review. Study contacts and the new PI will receive a decision letter via email. The current PI must continue acting as PI until the request is approved.
   iii) Sometimes there are additional requirements for PI changes to the sponsor. Contact the RDC Coordinator to discuss any additional requirements for your sponsor or grant.

6. CHANGES IN THE STUDY TEAM MEMBER NAMED WITHIN AN IRB 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.

7. REPLACEMENT OF A STUDY TEAM MEMBER IDENTIFIED BY TITLE IN THE IRB 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.

8. 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 they are the Principal Investigator of the study.

An IRB Staff/PI Change Form must be submitted in ARROW to transfer a PI, add or remove study team members. While multiple study team members can be added with one form or removed with one form, please submit separate forms for additions and removals. PI transfers also must be completed on a separate form.

a) Instructions for IRB Staff/PI Change Form to Transfer in PI On the AAROW Protocol:

   i) From the AAROW home page, select My Work Space – select Protocol Assistant – select View My Protocol – Click to open (Protocol) –select IRB Staff/PI Change Form - select Add a New Form. Complete form, attach the PI Transfer Form (see below) and submit for PI to sign.
   ii) A PI Transfer Form must also be submitted. The PI Transfer form is a word document in ARROW under the Help tab in the upper right corner. The form is labeled Transfer_PI_Form_120718 under IRB Documents under the Help section. Fill out this form and attach it to the IRB Staff/PI Change Form before submitting.
   iii) **NOTE:** Research Personnel being added as a Principal Investigator or Co-Investigator should have current Human Subject Citi Training, Scope of Practice, and a Conflict of Interest.

b) Instructions for IRB Staff/PI Change Form to Add or Remove Study Team Members in

AAROW:

i) From the AAROW home page, select My Work Space – select Protocol Assistant – select View My Protocol – Click to open (Protocol) –select IRB Staff/PI Change Form - select Add a New Form. Complete form and submit for PI to sign.
ii) **NOTE:** All Research Personnel being added to an IRB Protocol should have current Human Subjct CITI Training and a current Scope of Practice.

c) For more information about Study Team Member Assigments & Roles in AAROW as well as step-by-step images for navigating AAROW, refer to the AAROW 'Help' Section and read through the 'Making Changes to Existing Staff and Their Roles' document. Contact the IRB coordinatos for additional support.

9. CHANGES IN THE STUDY TEAM MEMBER NAMED WITHIN AN IACUC PROTOCOL:

Until the IACUC module is live in AAROW, please contact the IACUC Coordinator to report changes and for information.

10. CHANGES IN THE STUDY TEAM MEMBER NAMED WITHIN A SAFETY PROTOCOL:

Until the Safety module is fully live in AAROW, please contact the Safety Coordinator to report changes and for information.

11. CONTACTS:

Projects:	Sam McVean, RDC Coordinator at 734-845-5602
Protocols:	Cathy Kaczmarek, IRB Coordinator at 734-845-3439 Sheena Hatcher, IRB Coordinator at 734-845-5901
Safety & IACUC:	Carolyn Slusher, Safety & IACUC Coordinator at 734-222-7981

12. REFERENCE:

VHA Directive 1200.01

VHA Directive 1200.05

VHA Handbook 1200.06

VHA Directive 1200.08

13. FOLLOW-UP RESPONSIBILITY: Research Committee Coordinators