

VAMHCS RESEARCH & DEVELOPMENT SERVICE  
R&D Committee Process Module

PM-RDC-034

Effective Date: 9/15/14

R&D Committee Submission Worksheets

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Applicable Regulatory Context:

[VAMHCS Policy 512-151/RD-100]

**d RDC Responsibilities Related to the Evaluation of Research Activities.**

(1) The RDC is responsible for establishing policy to ensure that all research has been reviewed and approved for scientific quality, ethical use of human subjects, animals and biohazards and for appropriateness for the VAMHCS. This review must promote:

- (a) *Maintenance of high standards of protocol review*, and relevance to the mission of VA;
- (b) *Protection of human subjects* (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel;
- (c) *Welfare and appropriate use of animals in research*;
- (d) *Safety of personnel engaged in research and of the research environment* (through compliance with VHA Handbook 1200.08, "Safety of Personnel Engaged in Research");
- (e) *Security of research laboratories* where hazardous agents are stored or utilized;
- (f) *Security of VA data*, VA protected information (VAPI), and VA sensitive information;
- (g) *Required review of "just-in-time" submissions.*

(2) For protocols not meeting criteria for assignment to any subcommittee, the RDC is the review and approving committee of record.

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1. All transactions to the R&D Committee (RDC) for human research projects must be accompanied by a completed "Worksheet for Submitting a Transaction for a Human Research Subjects Research Project" and all required documents.
  - a. The Worksheet prompts the Investigator to provide documentation to meet RDC requirements.
  - b. Worksheet covers new protocols, annual reviews, and modifications. There is a separate worksheet for study closure/completion.
  - c. Worksheet currently applies to human protocols. Animal and laboratory worksheets are under development.
  
2. RDC staff review the Worksheet and initiate applicable actions:
  - a. ISO-PO Checklist:
    - i. New protocols: initiate the process for ISO-PO review concurrently with IRB administrative review.
    - ii. Modifications: send to ISO or PO if the mod involves change to information security or privacy practices.

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- b. Collaborative Studies template:
    - i. Not needed if “VA-only”
    - ii. If needed (does involve work at the UM or other non-VA entity) ensure that it has been submitted.
    - iii. If there are questions, contact the Collaborative Studies Working Group for guidance.
  - c. Investigational drugs: notify VAMHCS Investigational Drug Service
  - d. Research Protocol Safety Survey (RPSS): send to SRS coordinator
  - e. PI credentials: Check with VAMHCS Medical Staff Office
  - f. Conflict of Interest
    - i. Ensure there are VA FCOI forms for any investigators
    - ii. If there are “YES” answers to any questions in Section 1, send the form to the Research FCOI Officer
  - g. Team member List
    - i. All team members listed in CICERO should be listed. Add any additional members who are engaged in the human research at VAMHCS.
    - ii. Each individual must have a category of “VA paid staff”, “WOC”, or “UM/non-VA only”. *“UM/non-VA only” means that no work is done by the individual at the VA or by accessing identifiable VA data; i.e. the individual is totally engaged at the UM or other non-VA entity.*
    - iii. If the individual is a WOC, date of WOC appointment must be provided.
    - iv. Hold up the transaction if a WOC appointment cannot be confirmed.
  - h. Required trainings
    - i. Ensure that dates of last trainings are provided.
    - ii. Hold up the transaction if a team member is not current on trainings
  - i. Scope of Practice
    - i. PI or Team Member SoP must be on file.
    - ii. If necessary, the team member/PI completes a SoP (See PM-RDS-028)
    - iii. Hold up the transaction if a team member/PI is not current on SoP.
3. RDC coordinators track the progress of the transaction by initialing the right column of the Worksheet.
  4. When all requirements have been fulfilled, the transaction is placed on the agenda for the next RDC meeting.