

## Institutional Review Board (IRB)

The *Institutional Review Board (IRB)* is an independent committee responsible for oversight of human research to assure the safety and protection of research participants. If there is any element of research in any activity involving human subjects - including identifiable biological specimens and private medical data – the project must undergo IRB review before any study activities can begin. If you are unsure whether IRB is required for your project, submit an abstract of what you propose to do and request a determination from the IRB of Record.

In order to approve research, the IRB must determine that all applicable requirements are satisfied:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent will be sought and appropriately documented.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Additional safeguards have been included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence.

### Initial IRB Review

Minneapolis VA IRB forms are available on the MVAHC IRB's SharePoint site within the MVAHCS intranet. Most forms are also on the Minneapolis VA's internet website.

- The ***Investigator Data*** form is completed by the Principal Investigator only if s/he has not been a PI at MVAHCS before.
- A ***Request to Review Research Protocol*** form is completed for each new project.
- The ***Initial Review Application*** provides instructions for preparing your submission and lists the additional documents that must accompany the application.

All required components of the application packet should be submitted to the IRB Office at least three weeks before the IRB-A meeting, which is generally held on the first Monday of each month. The Research & Development Committee will not approve the research until final approval has been obtained from the IRB and all other applicable subcommittees. To avoid a delay in the review process, ensure that information is consistent among the consent form, HIPAA authorization, protocol, and application prior to submitting the materials.

Before any research activities are conducted, the Principal Investigator must receive an ***Authorization to Conduct Research (ACR)*** from the Associate Chief of Staff for Research (ACOS/R). Be sure to read the IRB approval letter, which contains important information about your responsibilities and specific procedural requirements.

### Continuing Review (CR)

The IRB must conduct an annual review of all approved human studies protocols at least every 365 days. Minneapolis VA IRB forms are available on the MVAHC IRB's SharePoint site within the MVAHCS intranet. Most forms are also on the Minneapolis VA's internet website.

Generally, the CR paperwork should be submitted at least six weeks before the IRB approval's expiration date to ensure that all administrative and review processes are completed in time. If approval lapses, all research procedures (including data analysis) must cease. Prolonged lapse may result in sequestration of data and prevention of study resumption.

## Ongoing IRB Reporting Requirements

### Amendments

The IRB must approve all research study revisions prior to implementation.

- An **Amendment Request for IRB Review** is used for changes to the protocol, consent, recruitment materials and changes to a PI. Except when necessary to eliminate apparent immediate hazards to the subjects, all modifications to the research protocol or consent form must be approved by the IRB prior to implementing the changes.
- A **Personnel Amendment** is submitted for new additions to the study team. New study personnel cannot start interacting with participants or identifiable data until they are approved by the IRB.

### Notifications

A **Notification** is any information given to the IRB that doesn't change the protocol or require IRB approval; that is, you are *telling* the IRB – not asking the IRB for permission. Examples include:

- Communications from the study's Data & Safety Monitoring Board
- Scheduled monitor visits and follow-up reports
- Removal of personnel from the study team

### Unanticipated Events, Problems, and Incidents

- Local unanticipated serious adverse events
- Unanticipated problems involving risks to subjects or others
- Privacy or information security incidents related to VA research, including:
  - Any inappropriate access, loss, or theft of PHI
  - Noncompliant storage, transmission, removal, or destruction of PHI
  - Theft, loss, or noncompliant destruction of equipment containing PHI
  - Any termination or suspension of research by PI or study sponsor

The IRB reviews serious adverse events, patient complaints, and allegations of non-compliance and takes all actions necessary to ensure the protection of human participants in research.

## Study Closure / Completion of IRB Oversight

Prepare and submit an updated abstract and a **Request for Closure** form to the IRB. The VA's Research Compliance Officer may also conduct a final review of study documents prior to closure.

*[NOTE: Annual IRB reviews are still required if identifiable data can still be accessed by the PI. The study must remain open with the R&D Committee until all analyses and manuscripts have been completed.]*

## References:

1. VHA Handbook 1200.05