

HawkIRB Guidance - IRB-03 (VA) Studies

When completing a HawkIRB New Project application, there are additional considerations for research involving patients and/or resources from the Veterans Administration Health Care System (VAHCS) in Iowa City. The IRB-03 HawkIRB New Project application includes additional questions about study design, research team members, subject populations and Principal Investigator (PI) oversight. This guidance sheet is a resource to assist you with preparing a HawkIRB application for IRB-03.

Research studies involving both the Iowa City VAHCS and the University of Iowa will have to submit two separate IRB applications for the correct IRB to review the activity at each location. IRB-03 will review research activity that involves the VAHCS only. Any research activity that involves the University of Iowa or UIHC, must be reviewed under IRB-01.

Section II: Principal Investigator and Research Team Members

All members of the research team must have an appointment with the Iowa City VAHCS. The University of Iowa IRB 03 will only provide oversight to team members who have an affiliation with the VAHCS. In some circumstances the VA Research Office may allow a without compensation (WOC) appointment to the Iowa City VAHCS, but this will need to be discussed with the VA Research Office. Additionally, all team members will also need a HawkID. If a HawkID is not assigned to a VA faculty, staff, or student contact Nadine Miller in the VA research office at VA ext. 3595 / e-mail: nadine-miller@uiowa.edu . [From a UI phone dial 158 and the extension. From outside the UI dial 338-0581 and enter the extension.]

PI's of an 03 study will need to be either Faculty or Staff. For VA research team members, the VA investigator will be asked to provide the person's HawkID and whether or not the individual will be a contact person for the project. Trainees and University of Iowa students are not permitted to be listed as PI on IRB 03 (VA) research applications.

Section III: Funding

III.4- Conflict of Interest-

All team members on the research study should review the VA Conflict of Interest Policy and determine whether they have a financial interest in the study. Any IRB applications in which a significant financial interest has been disclosed will not undergo IRB review until the Conflict of Interest Officer has reviewed the financial interest and either determined that no conflict exists

or the IRB receives a management plan for the conflict.

Researchers with questions about conflicts of interest should contact Mark Yorek (VA ext. 7696 / e-mail: mark-yorek@uiowa.edu) or Kari Points (VA ext. 7678 / e-mail: kari.points@va.gov) for further information about this process. [From a UI phone dial 158 and the extension. From outside the UI dial 338-0581 and enter the extension.]

Section VI: Subjects

VI.13.a- Enrolling non-veterans

For all IRB-03 studies enrolling non-veteran subjects, the Principal Investigator must describe those subjects in Section VI.13 and present a compelling argument for their inclusion in Section VI.13.b (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members). To comply with the VA research regulations, the research must relate to the care of Veterans or active duty military personnel. Non-veterans may only be entered into VA-approved research if there are no enough Veteran patients or for the types of subject populations stated above.

VI.36- Enrolling Subjects Who Lack Decision-Making Capacity

There are specific rules that VA researchers must follow in order to enroll individuals who lack decision-making capacity.

The IRB will need to determine that the proposed research entails:

(a) No greater than minimal risk to the subject;

or

(b) Presents a greater probability of direct benefit to the subject than harm to the subject;

or

(c) Greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

Additionally, the IRB will also need to determine that:

(a) The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects' lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke);

or

(b) The subject of the research is not directly related to the subjects' lack of decision making capacity but the VA investigator has presented a compelling argument for including such subjects (e.g., transmission of methicillin-resistant staphylococcus aureus infections in a nursing home where both individuals with and without decision-making capacity are affected).

VI.46-VI.48- Enrolling subjects with PTSD

Any IRB-03 study that involves research on post-traumatic stress disorder will require additional review. Researchers will also need to make sure that their study has adequate sensitivity to the needs of individuals with PTSD (as discussed in VI.47). Additionally, safeguards need to be put into place to consider any medication that the research participants will be taking to treat their PTSD (VI.48a-c).

Section VII.D- Project Description

VII.D.6- Storage of Data

Research records that are collected under IRB 03 must be stored indefinitely. Describe your plan to retain research records until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule.

VII.D.18- Waivers of Documentation of Consent: Collecting Protected Health Information

This question only applies to researchers seeking a waiver of documentation of consent. If a researcher plans to collect information from subjects that include protected health information,

they would need to discuss in the application why the use of this involves minimal privacy risks to the subjects, and why the research cannot be conducted without use of the protected health information.

HawkIRB Attachments Page

HIPAA Authorization Form

As of February, 2019, the VA HIPAA Authorization form is included in the Informed Consent Document template for research conducted at VAHCS. Fill in the information that can be completed in advance and add the document in the proper attachment category on the Attachment page.

There is a form on the Other Committee Review page in the HawkIRB form (in the "VAMC" tab) that the Principal Investigator can provide to a subject who wishes to revoke their HIPAA authorization.

Informed Consent Document Template

The VA has a separate Informed Consent Document (ICD) template that includes a VA-specific header and footer. Replace the bold/bracketed text with content that is specific to the study.

Medical Radiation Protection Committee Form

VAHCS research radiation review will occur through an agreement with the University of Iowa.

Specific information about this process is located on the [HSO website](#). Generate the appropriate short or long form and/or the MRPC Lasers form and attach them in the proper attachment category on the Other Committee Review page in the HawkIRB application (in the MRPC tab).

For questions, contact the VA Radiation Safety Officer at 335-8503 or gordon-axt@uiowa.edu.

Pharmacy & Therapeutics Form

VAHCS has its own Pharmacy & Therapeutics Committee (P&T Committee). Generate the appropriate form and attach it in the proper attachment category on Other Committee Review page in the HawkIRB form (in the P&T tab).

VA Checklist

All VA researchers must complete and attach the VA Checklist for Reviewing Privacy,

Confidentiality and Information Security in Research. This checklist is available on the Other Committee Review page in HawkIRB (in the VAMC tab).

Attach the completed checklist on this page.

For questions regarding completion of the VA Checklist, contact the VA Privacy Officer, Makenzie Johnson at VA ext. 6092 / email: Makenzie.Johnson@va.gov or VA Information Security Officer Randall

Smith at VA ext. 6266 / email: Randall.Smith@va.gov . [From a UI landline, dial 158 and the extension. From outside the UI or using Skype for Business, dial 338-0581 and enter the extension.]