Human Research Protections Program (HRPP) Investigator Handbook

Harry S. Truman Memorial Veterans' Hospital
Research and Development
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Overview of HRPP

Letter from the Human Research Compliance Officer (HRCO)

Welcome to the Research and Development's (R&D) Human Research Protection Program (HRPP) Handbook! Here at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH), we strive to be on the forefront for the advancement of protections for human participants in research. We have an excellent record of compliance with human research protection rules, regulations, and policies, and we are working to continually improve in this area. This Handbook has been prepared to aid you in your work as a researcher. It should be a reference that will help fulfill your obligations regarding human participant protections. This Handbook is a testament of R&D's strong commitment to develop a community of researchers that are exceptional with regard to implementing human research protections. Please know that the R&D staff is here to assist you when needed. Thank you for your commitment to research and to the protection of human participants.

Karen Smarr, Ph.D.
Human Research Compliance Officer
Harry S. Truman Memorial Veterans' Hospital

What is HRPP?

The continual pursuit of knowledge that can help not only VA patients, but also other healthcare consumers is highly valued and supported throughout the VA system, and at the HSTMVH. One of the most important qualities of a researcher is the "intention to do careful, ethical work" (Parker & Katz, 1998*). Protecting the welfare of our patients who accept, or decline, to participate in research must be the primary concern of every research protocol involving human participants. All health science professions have ethical principles and guidelines that guide the behavior of those practicing in that profession. There are also principles (like those in the Belmont Report) and regulations (such as the Common Rule) that guide the ethical behavior of those conducting human participants research.

At the national level, the Veterans Health Administration (VHA) is committed to being at the forefront of strategies for the protection of human participants in research programs. One of the responsibilities of the R&D Committee is ensuring the welfare of all human subjects. Therefore, the Research Office at the HSTMVH has designated a Human Research Compliance Officer (HRCO), who oversees all aspects of the VA human research portfolio. HRCO oversight includes ensuring proper credentialing, educational verification, and training for human researchers. There also is a major emphasis on close interaction with the Health Sciences-Institutional Review Board (HS-IRB) and on the formulation of Research Office policies regarding human research.

*Parker, J.C., & Katz, R.T. (1998). Strategies for an academic career. In J.K. Silver (Ed.), The Business of Medicine (pp. 279-291). Philadelphia: Hanley & Belfus.

Who are the staff responsible for the HRPP?

Sallie Houser-Hanfelder, FACHE, HSTMVH Director

Ms. Houser-Hanfelder is the Institutional Officer for the HRPP. She is ultimately responsible for the overall conduct of the Research and Development (R&D) program, including the welfare of human participants. She is responsible for ensuring that adequate resources and facilities are provided for the HRPP. Ms. Houser-Hanfelder is advised and assisted by the R&D Committee and the Associate Chief of Staff for Research & Development (ACOS/R&D).

Associate Chief of Staff/R&D (ACOS/R&D)
Phone: (573) 814-6550
Fax: (573) 814-6551

The ACOS/R&D is responsible for the daily operations of the Research Service providing administrative support, and implementing the decisions of the R&D Committee and the HS-IRB. He provides assistance to investigators on scientific and administrative matters including research involving human participants. He also is responsible for ensuring that decisions of the R&D Committee are communicated to investigators and that proper records are maintained.

Lawrence Propp, Administrative Officer/R&D (AO/R&D)
Phone: (573) 814-6553
Fax: (573) 814-6551
Email: Lawrence.Propp@va.gov

Mr. Propp supervises the day-to-day operations of the Research Office. He is responsible for the deployment of resources, as required, to maintain compliance with HRPP activities. He advises the ACOS/R&D, the HS-IRB, and investigators concerning relevant regulations, and their interpretation, for conducting VA human studies research.

Karen Smarr, Ph.D., Human Research Compliance Officer
Phone: (573) 814-6560
Fax: (573) 814-6561
Email: Karen.Smarr@va.gov

Dr. Smarr is responsible for the development and review of HRPP policies and procedures. She monitors compliance with HS-IRB policies, and is the Hospital's liaison to the HS-IRB. She also develops and implements the quality assurance/improvement program for HRPP, which includes ensuring that training requirements are met by all research administrative staff, investigators, and research team members.

Nancy Dietz, Ph.D., R.Ph., Research Pharmacist
Phone: (573) 814-3538
Fax: (573) 814-6535
Email: Nancy.Dietz@va.gov

Dr. Dietz is responsible for ensuring that all relevant Pharmacy staff are trained in the procedures for the dispensing and storage of investigational drugs and devices, and that all related recordkeeping practices are followed and consistent with hospital policies. She also dispenses investigational drugs and devices when feasible.

Karen Watson, Research Secretary
Phone: (573) 814-6550
Fax: (573) 814-6551
Email: Karen.Watson2@va.gov

Ms. Watson initiates the process for new research applications. She coordinates the process of research staff appointments and two-year reappointments. She also oversees staff compliance with training requirements, credentialing, and primary source verification (e.g., verifying the education, certification, and/or licensure of new staff appointments).

What are the responsibilities of the PI in relation to the HRPP?

The PI maintains the responsibility for ensuring the protection of all human participants involved in VA-approved research, and is expected to abide by the highest ethical standards. The PI's responsibilities in relation to protecting human participants include:

1. Developing and executing research that incorporates the principles of the Belmont Report.

2. Conducting research in accordance with an approved protocol.

3. Overseeing all aspects of the research, including supervision of the research team members, residents, and other staff involved in conducting human research.

4. Ensuring that the informed consent process approved by the HS-IRB is followed.

5. Establishing and maintaining open lines of communication with his/her research participants throughout their research participation.

6. Complying with institutional policies and administrative requirements, including requirements of the HS-IRB (e.g., submitting documentation for amendments, annual reviews, and adverse events) for conducting research.

7. Acknowledging contributions of the VA when presenting results of studies in publications, presentations, media interviews, and other public activities as outlined in VHA Handbook 1200.9.

How Can HRPP Questions, Suggestions, or Concerns be Addressed?

Any person listed as a staff member responsible for the HRPP is available to answer questions, accept suggestions, or consider concerns voiced by investigators or their team members. In addition, the HS-IRB administrator (Ms. Michele Kennett, 573-882-3181) is available as a point of contact for members of any human research team. Questions, suggestions, or expressions of concern of any type are welcomed and encouraged.

R&D Application

What are the steps in the application process?

Completion of this packet is required for review of research projects by the Research and Development (R&D) Committee. Applications must be received at a minimum of four (4) weeks prior to the R&D Committee meeting. Final approval will not be given until all required subcommittees of the R&D Committee (MU Health Sciences IRB, Subcommittee on Animal Studies, and Subcommittee on Research Safety) have also approved the protocol. Routing to the required subcommittees (except MU Health Sciences IRB) will be handled internally by the Research Office.

Application Parts
Part I: Research and Development Committee
Part II: Subcommittee on Research Safety
Part III: Human Studies/Health Sciences IRB
Part IV: Subcommittee on Animal Studies
Part V: Abstract, Full Proposal (to be attached), and Data Security Plan
Part VI: Conflict of Interest Statement(s)

Steps
1. Complete Part I (R&D Committee) through Part VI (Conflict of Interest) for all projects.

2. All project staff who will access VA patients and/or data, or who will access VA space for research activities are required to hold VA appointments (Paid or Without Compensation [WOC]). Detailed information on the forms and procedures can be obtained in the Research Staff Section of the HRPP Handbook.

3. If projects involve either ionizing, or non-ionizing radiation, a separate application must be made to the Radiation Safety Committee (573-814-6000 Ext. 52590).

4. Obtain a concurrence signature from the Director(s) of participating VA Service Line(s) (i.e. Primary Care, Specialty Care, Behavioral Health, Clinical Support, Information Management, Facilities Management, or Business Office) whose approval will be required for the project.

5. Include the following supplemental materials: (a) copy of Abstract on a disk or CD, and (b) CVs for the PI and Co-PIs.

6. Submit the entire packet (including hardcopy of HS-IRB application and HS-IRB approval letter) to the VA Research Secretary, Room B044, HSTMVH (Phone: 573-814-6550).

Why must I also apply to the HS-IRB?

The HS-IRB reviews all VA protocols involving human subject participants prior to initiation; and continually monitors ongoing research through periodic reviews, including the review of adverse events and amendments to the protocol. The HS-IRB is charged with the responsibility of protecting the rights and welfare of all research participants in VA-approved research as required by the Common Rule and the Federal-Wide Assurance (FWA).

What if my project appears to be Exempt?

All research involving human participants must be submitted to the HS-IRB. Decisions regarding Exempt status can only be made by the HS-IRB.

How do I apply to the HS-IRB?

Part III of the Application to Conduct Research is the HS-IRB application. The process of applying for HS-IRB approval is electronic and completed on the e-IRB website. Once you have electronically submitted your HS-IRB application, send three (3) copies of the application, signature page, and all supporting documents to the HS-IRB Office at the following address:

125 Folk Hall
One Hospital Drive
Columbia, MO 65212

Internal DC mailing code: DC 074.00

Attach one copy of the HS-IRB application to Part III of the "Application to Conduct Research."

Tips for Using the e-IRB Website

Log-in
In order to use the system, an account must first be created by selecting the appropriate link on the log-in page. To log onto the e-IRB system, enter your username and password. If you are MU faculty, staff, or a student, your username is your MU Paw Print, and your password is your Paw Print password (this is the username and password used for your MU email account). If you are external to the University system, enter the username and password you supplied when your e-IRB account was created. Once you log in, you will see the “Main Menu.”

HS-IRB Forms
To begin a new application, select “IRB Forms” from the Main Menu. Three types of applications are displayed at the top of the “Health Sciences IRB Forms” page. Select the appropriate link for the application you wish to submit (Behavioral Science, Exempt, or Medical).

Document Storage
The IRB application process is completely electronic. All supporting documentation (such as consent forms, debriefing statements, surveys, scripts) is electronically attached to the application as computer files. You can also attach files to the application such as those created in word processing programs, documents that are scanned, etc. in the "Submit/Print" portion of the application, there is a link to "Document Storage." Selecting this option will enable you to upload the appropriate supporting documentation. You can also access this feature by clicking on "Document Storage" from the "Main Menu." From this link you can upload and view supporting documentation.

Saving your work
The e-IRB system automatically saves each section of the application when you select the "Save and Continue" button at the bottom of each section. You can also begin an application and return at a later time to finish your work.

Submission
When you have completed all required information, submit the application. From the "Print/Submit" page, a copy of your application can be printed before you officially submit it to the HS-IRB. You can also print the "Signature" page that is needed to submit with the application. You will not be able to submit the application if any required information is missing. Missing information will be listed in red on the "Print/Submit" page.

Log-out
Remember to log out of the system. After two hours of inactivity, the system will automatically log you out.

Technical Support/Help with Application
When you are logged into the e-IRB system, each page has links at the bottom that will link to information to contact the HS-IRB and Technical Support. You will be able to send questions, feedback, and technical problems by completing the forms that are available through those links. The HS-IRB contact information is also available on the e-IRB website. PLEASE NOTE THAT THE E-IRB WEBSITE WORKS BEST WITH VERSION 5 OR GREATER OF INTERNET EXPLORER FOR PC AND VERSION 7 OR GREATER OF NETSCAPE FOR MAC.

Dates for Submission
HS-IRB meeting dates and application deadlines for each meeting are available on the HS-IRB website.

What is a Conflict of Interest (COI)?

A Conflict of Interest is defined as any financial arrangement, personal obligation, or action of the investigator that exerts, or is perceived to exert, inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings.

Conflicts of interest arise because of:

1. Intellectual property involved in research and partnerships between industry and academia.

2. Financial incentives by pharmaceutical or biotech companies for investigators conducting clinical trials or enrolling participants into a clinical trial.

3. A particular role or relationship an investigator has within the administrative structure(s) of the institutions(s) with whom they are affiliated.

How do I disclose a COI?

Investigators must submit COI documentation with their R&D application. This includes completion of the "Conflict of Interest Statement (VA Form 1313-9)" for each investigator (including PIs, co-PIs, and other investigators/collaborators) with 5% or more effort on the protocol; and completion of Part VI of the R&D application ("Conflict of Interest"), which lists the proposed study's investigators, their role, and the percentage of effort on the protocol.

The ACOS/R&D is the designated COI Administrator. He/she reviews all financial disclosure statements and determines if there will be a negative impact on the research. Findings from these reviews are made available to the R&D Committee and the HS-IRB.

The HS-IRB (with monitoring by the HRCO) will review COI issues in the review of the protocol. The HS-IRB considers any issues that raise the possibility of coercion or undue influence on the informed consent process. Necessary actions to minimize risks to subjects will be assessed. The HS-IRB and the R&D Committee will initiate remedies to manage or eliminate COI through modifications in the protocol, change in consent to reflect the COI, and/or monitoring of the research by an independent reviewer. If a COI is not remedied through this process, a non-biased third party may be authorized to obtain informed consent from participants.

The HSTMVH Director is informed of any inability to resolve a significant COI, and any investigator that fails to comply with the COI policy/remedies. He/she may impose remedies and/or restrictions including, but not limited to:

1. Termination of the research study.

2. Removal of the investigator from the research project.

3. Revocation of the privilege to conduct research.

4. Sanctions, which may include prohibition from submitting proposals to the IRB and/or R&D Committee.

THE INVESTIGATOR IS RESPONSIBLE FOR DISCLOSING ANY COI. IF A COI DEVELOPS AFTER HS-IRB APPROVAL, IT MUST BE REPORTED IMMEDIATELY. CONFLICTS OF INTEREST INVOLVING THE INVESTIGATOR'S SPOUSE OR DEPENDENT CHILDREN THAT REASONABLY APPEARS TO AFFECT THE RESEARCH MUST ALSO BE REPORTED.

IT IS THE INVESTIGATOR'S ETHICAL OBLIGATION TO CONSIDER THE POTENTIAL EFFECT THAT A FINANCIAL RELATIONSHIP OF ANY KIND MIGHT HAVE ON THEIR STUDY, INCLUDING INTERACTIONS WITH RESEARCH PARTICIPANTS.

Some examples of financial conflicts of interest:

1. Salary or payments for services (such as consulting fees or honoraria).

2. Compensation to the investigator(s) that is affected by the outcome of the study.

3. Stocks, stock options, or other ownership interests.

4. Patents, copyrights, or other intellectual property rights and any royalties from such rights.

See Conflict of Interest in Research Policy (HPM 589A4-339), or VHA Handbook 1200.13 for more details.

Staff Appointments

Who must acquire a VA staff appointment?

For the HSTMVH to ensure that each member of the research team has the credentials, competencies, and qualifications to perform their assigned duties, all project staff who will access VA patients, and/or data, or who will access VA space for research activities must hold a VA appointment (Paid or Without Compensation [WOC]).

What are the procedures to receive a VA appointment?

1. Notify the Research Secretary at least one week in advance of the processing date.

2. The Principal Investigator(s) should complete the Request for Staff Appointment (HSTMVH).

3. The Principal Investigator should submit a Request for Functional Statement of Research Duties and Responsibilities. Note. Physicians and health care providers will have additional appointment requirements (e.g., submitting copies of licenses/certificates and/or following hospital credentialing requirements, as may apply).

4. The following documents should be submitted by the applicant: (a) Application for Federal Employment (OF612), (b) Questionnaire for Non-Sensitive Positions (SF85), (c) Declaration for Federal Employment (OF306), (d) VA Benefits Letter, and (f) Documentation of HIPAA Functional Classification. Note. The Questionnaire for Non-Sensitive Positions (SF-85) is not required for appointments of less than six (6) months duration.

5. If the new Research staff member is not a U.S. citizen, submit a copy of the Visa.

6. Complete all required training activities; deliver certificates to Research Secretary.

7. Obtain key card for Research space after all required training is completed.

What trainings need to be completed?

1. **General Research Orientation:** This orientation is required for all new Research staff who request an Access Key Card to enter Research Laboratories.

2. **Human Research Training:** Completion of web-based modules is required for staff involved in human research protocols:

   a. "Overview of Good Clinical Practice and Human Subjects Protection" **https://www.citiprogram.org/default.asp**; this training must be renewed annually.

b. **VA & WOC staff** must complete the VHA HIPAA training located at **http://www.ees-learning.net**; this training must be renewed annually.

3. **Animal Care and Welfare Training:** Completion of two web-based modules is required for staff involved in animal protocols: "Working With the VA IACUC" **http://www.researchtraining.org** and University of Missouri, Office of Animal Resources "Basic Animal Care and Use" **https://www.research.missouri.edu/acqa/index.htm.**

4. **Radiation Safety Training:** This training is required for all staff whose duties will involve access to Research laboratory space. Appointment must be scheduled with the Radiation Safety Officer at Ext. 52590; the RSO will deliver the required training and provide the certificate to the Research Secretary; this training must be renewed on an annual basis.

5. **VA Research Data Security & Privacy**: Completion of the web-based module is required for all research staff. http://www.vcampus.com/vcekpvalo/? Password Tip: When entering your password while registering on VALO the first time, only enter the first 20 characters of your username in the Password box. Make sure your full username is entered following the correct format in the username box. Use link at the bottom of that page to get to the VALO login page and enter your username and password to log into VALO.

6. **Laboratory Safety Training:** This training is required for all staff involved in laboratory-related activities and will be provided and documented (via checklist) by the responsible PI.

7. **Hospital-wide Safety Training:** A paper and pencil training module must be completed by all Research employees; this training must be renewed on an annual basis.

What does the HS-IRB require for members of my research staff?

The HS-IRB requires that PIs and their research staff complete the University of Missouri-Columbia's Human Subjects Training, and HIPAA Training. HS-IRB applications will not be reviewed if PI(s) have not completed the compliance training.

These training modules are accessible through the e-IRB website. After logging-in, click on "Compliance Training." On this page under the heading "Quiz/Survey Name", the "Educational Training Quiz" and the "Health Sciences HIPAA Training Quiz" must be completed. The next column to your right entitled "Reference Materials" has links to the educational/instructional material covered in the training. The next column informs you of when the training was last completed, and when it should be renewed. The human participants training must be renewed every three (3) years. In the next column, there are links to access Certificates of Completion once the training has been completed. The last column will direct you to links to training quizzes.

What trainings will need to be completed annually after initial appointments?

Overview of Good Clinical Practices and Human Subjects Protection
VA Research Data Security & Privacy Training
VHA Privacy Training

Informed Consent

How do I document informed consent?

The PI develops written informed consent documentation for participants to sign which must be approved by the HS-IRB prior to enrolling patients in a study. The VA Research Consent Form template, available on the HS-IRB website, must be used to produce informed consent documentation.

When informed consent is obtained, it is best practice to have the participant sign and date three (3) copies. One original should be placed in the participant's research file maintained by the PI. The other should be scanned into the participant's electronic medical record (see the CPRS Section of this Handbook for more information) and then placed in the participant's paper medical record. The participant must receive a signed and dated copy of the consent document. Informed consent documents are required to be retained for seven (7) years.

How do I document that a participant understands their rights in relation to the Health Insurance Portability and Accountability Act (HIPAA)?

Research participants must sign a "HIPAA Authorization." The HIPAA Authorization template is available on the HS-IRB website. PIs can add their study's information to this template.

As with the informed consent document, it is best practice to have the participant sign and date three (3) copies of the HIPAA Form. One original should be placed in the participant's research file maintained by the PI; one should be scanned into participant's electronic medical record (see the CPRS Section of this Handbook for more information) and then placed in the participant's paper medical record; and one (signed and dated copy) provided to the participant.

When do I disclose conflict of interest?

Conflict of interest disclosure must be made to the HS-IRB and the R&D Committee during the application process. If the application receives approval, conflict of interest also must be disclosed to the participant during the consent process (prior to obtaining written consent).

Computerized Patient Records System (CPRS)

How do I gain access to CPRS for me and my staff?

Indicate on an appointee's "Request for Functional Statement of Research Duties and Responsibilities" that he/she requires access to VISTA/CPRS. The PI should also send an email to the Research Secretary with a list of the staff who will require access to CPRS. At that time, the Research Secretary will respond with instructions for CPRS-specific training requirements.

Once an individual has been authorized to use CPRS, they can access CPRS from the physicians' workstations in Medical Records (if computers are not available for them to use at other stations).

What is the documentation that will be required and how is it entered into CPRS?

Informed Consent
The informed consent process is documented in the VA patient's electronic medical record using the CO-RESEARCH PARTICIPANT NOTE.

1. Log onto CPRS
2. Choose patient
3. Select the "Notes" tab and then select the "New Note" button
4. In the "Location of Current Activities" box, there is a place to type labeled "Encounter Location." In that text box , type CO-A/S RESEARCH CLINIC. Then click "OK"
5. In the "Progress Not Properties" box, type CO-RESEARCH PARTICIPANT. Then click "OK"
6. The text for the note appears on the screen. Complete any information that is missing
7. When the note is complete, sign it

You will only need to complete this note one time. After it is entered, you can view it by selecting the "Postings" button on the upper right hand side of the patient's cover sheet in CPRS. The notes title will be listed in the "Crisis Notes, Warning Notes, Directives" box. Just select the title to view the note.

Scanning Consent and HIPAA Forms into electronic record
Original signed consent forms are taken to Medical Records (E002) for scanning into CPRS and placement in the patient's medical file.

Once the forms are scanned, they can be viewed in CPRS. When you are in the patient's record, select "Tools" in the menu at the top of the CPRS window. Select "VISTA Imaging Display." You will be asked to log on with your CPRS/VISTA access and

verify codes. Scroll down the “Image Listing” box to find the document you wish to view. Click on it to view.

Other CPRS documentation

For other research documentation that should be included in the electronic record, you may simply choose a generic, blank progress note from the “Progress Note Properties” Box. If you would like to produce a template that is specific to your study, contact the HRCO for assistance.

Pharmacy

What information is maintained in the pharmacy regarding my research study?

The Pharmacy maintains a protocol file for each study, which includes:

1. A copy of the HS-IRB-approved Consent Form (VA Form 10-1086, VA Research Consent Form) that has been signed by the participant

2. A copy of the Investigational Drug Information Record (VA Form 10-9012)

3. A copy of the Report of Subcommittee on Human Studies (VA Form 10-1223)

4. A copy of the approved research protocol and any amendments

5. A copy of the Investigator Brochure for the study

6. A valid and updated Investigational Drug/ Device Dispensing Log for the protocol

What information must be obtained for my study's Investigational Drug/Device Dispensing Log?

The following information is included in an *Investigational Drug Dispensing Log*:

Participant's name
Social Security number
Name of drug
Dosage form
Strength
Source of the drug (manufacturer, sponsor)
HS-IRB number and approval/review dates
Inventory notes
Amount and date of drug received
Expiration date of prescription
Lot/control number
Date of authority to use
Serial number and date of prescription dispensed
Pharmacist's verification signature
Inventory balance
Name of prescriber
Initials of dispensing pharmacist

The following information is included in an *Investigational Device Log*:

Name and identification number of the patient
Device name
Serial number

Model number
Manufacturer
Name of issuer
Inventory balances
Other relevant details specific to the appropriate use and dispensing of the device

Continuing Review

What is continuing review?

The process of continuing review helps R&D and the HS-IRB ensure that MU and VA policies and procedures are being followed for each research study, and that each study is conducted according to the protocol approved by the HS-IRB.

What if I need to make a change in a component of the study?

To make changes to a study, follow HS-IRB policies and procedures for closing a study. For additional information see http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

What problems and events do I have to promptly report to the IRB?

Investigators must comply with the requirements of the HS-IRB for the problems that require prompt reporting to the HS-IRB. See http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf for a list of problems that require reporting and the time frame for reporting.

The HSTMVH defers to the HS-IRB policies and procedures for the review of these problems and the handling of problems determined by the HS-IRB to be unanticipated problems involving risks to participants or others.

How is my study continually monitored by the R&D Committee and the HS-IRB?

Both the R&D Committee and the HS-IRB require documentation to be completed for the continuing review process.

The R&D Committee reviews all studies annually. When it is time for a study's annual review, the PI is sent a brief protocol survey that should be completed and returned to the Research Office. The HRCO may also perform periodic, random protocol audits.

The HS-IRB reviews all studies annually, but could require review more often. For additional information about continuing review procedures see http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

FAILURE TO SUBMIT CONTINUING REVIEW REPORTS IN A TIMELY FASHION WILL RESULT IN EXPIRATION OF THE STUDY. A NEW HS-IRB APPLICATION MAY HAVE TO BE SUBMITTED AND THE STUDY WOULD START OVER. BE AWARE THAT R&D REVIEW IS A SEPARATE PROCEDURE FROM HS-IRB REVIEW AND MAY HAVE DIFFERENT TIMELINES.

What if there is a failure to follow the protocol or approved procedures for a study?

Failure to follow HS-IRB-approved protocol procedures must be reported to the HS-IRB in accordance with HS-IRB polices and procedures. For additional information see http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

What is required when I complete a study?

When all data analysis and patient interaction is complete, follow HS-IRB policies and procedures for closing a study. For additional information see http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

What if an investigator does not comply or there is an allegation of non-compliance with HS-IRB and VA policies or approved research protocol?

All complaints, or allegations of non-compliance are handled according to HS-IRB policies and procedures. For additional information see http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

Possible consequences of noncompliance include:

- Termination of protocol(s)
- Restrictions on privileges to conduct research
- Potential disciplinary action

Accreditation

What is the Association for the Accreditation of Human Research Protections Programs, Inc. (AAHRPP) and how is it related to the HSTMVH's HRPP?

AAHRPP is a not-for-profit organization, and its mission is to protect the rights and welfare of research participants. The U.S. Department of Veterans Affairs (VA) has awarded a contract to AAHRPP to operate an accreditation program to ensure that VA medical centers are in compliance with VA and other relevant federal regulations designed to protect human research participants.

References and Resources for More Information

Human Subjects Research Policies

Assurance of Compliance and Quality Improvement for Human Research Protection Program (HPM 589A4-340)

Conflict of Interest in Research (HPM 589A4-339) [PDF (46 KB) or Word (138 KB)]

Credentialing of Individuals Involved in Human Subjects Research (HPM 589A4-342) [HTML or PDF (18 KB)]

Human Research Protection Program (HPM 589A4-321) [HTML or PDF (29 KB)]

Institutional Conflict of Interest in Research (HPM 589A4-365)

Investigational Devices (HPM 589A4-338)

Outreach Program for Human Research Participants (HPM 589A4-366)

Required Education and Training for Research Activities (HPM 589A4-337) [HTML or PDF (18 KB)]

Research Informed Consent (HPM 589A4-341) [HTML or PDF (15 KB)]

Research Misconduct (HMP 589A4-362)

Review of Research Proposals (HPM589A4-042)

Sponsored Research (HPM 589A4-364)

University of Missouri-Columbia HS-IRB Policies

http://www.research.missouri.edu/policies/files/hsirb_SOP_Binder2.pdf

VHA Handbooks Relevant to Research Activities

Research Misconduct (1058.2)
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1259

Financial Conflicts of Interest in Research (1200.13)
http://www1.va.gov/VISNS/visn02/Research/forms/alb/IRB/Guidelines/VHA_Handbook_1200.13.pdf#search='vha%20handbook%201200.13'

Reporting Adverse Events in Research to the Office of Research Oversight (1058.1)
http://www1.va.gov/oro/docs/1058.1_111904.pdf#search='vha%20handbook%201058.1'

Requirements for the Protection of Human Subjects in Research (1200.5)
http://www1.va.gov/oro/docs/VHA_HB_1200.5.pdf#search='vha%20handbook%201200.5'

Presentation of Research Results Handbook (1200.19)
http://www.va.gov/portlandrd/pdf/publications/va_research_handbook.pdf#search='vha%20handbook%201200.19'

Inclusion of Women and Minorities in Research Handbook (1200.9)
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=359

Other Websites

HS-IRB Website

Belmont Report

Declaration of Helsinki