

**VAMHCS RESEARCH SERVICE
STANDARD OPERATING PROCEDURE**

SOP #HRP 01.09

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**CONDUCTING HUMAN PARTICIPANTS RESEARCH AT THE VAMHCS:
THE RELATIONSHIP OF VAMHCS RESEARCH STANDARD OPERATING PROCEDURES
TO THE POLICIES AND PROCEDURES OF THE UMB HUMAN RESEARCH PROTECTIONS
OFFICE (HRPO)**

OBJECTIVE:

- To describe the expectations for VAMHCS human subjects researchers and staff with regard to University of Maryland Baltimore Human Research Protections Program and Institutional Review Board Policies and Procedures (UMB HRPP and IRB P&P).
- To specify when VA or VAMHCS policies should be followed by VAMHCS researchers and staff and when UMB HRPP and IRB P&P should be followed.
- To describe the working relationship between the VAMHCS Research Service, VAMHCS Office of Research Compliance, and the UMB Human Research Protections Office (HRPO)

BACKGROUND:

The University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) is an IRB of record for VAMHCS human subjects research. The UMB Human Research Protections Office (HRPO) is the office that administers the IRB and the protocol review process, and develops and publishes policies and procedures for the conduct of human subjects research (the “UMB HRPP and IRB P&P”).

The UMB HRPP and IRB P&P apply to HRPO staff, IRB members, UMB researchers and research staff *as well as VAMHCS researchers and staff*. VAMHCS researchers and staff are expected to follow UMB HRPP and IRB P&P except where explicitly indicated in the policy or procedure.

UMB HRPP and IRB P&P must harmonize with VA regulations and VAMHCS requirements with IRB and HRPP policies and procedures. VA regulations and VAMHCS requirements are included and cited in UMB HRPP and IRB P&P where necessary.

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This SOP lists specific policies and procedures of both institutions that must be followed by VAMHCS researchers and staff. All current UMB HRPP and IRB P&P and Research Service SOPs are available at the websites:

<http://www.hrpo.umaryland.edu/policies.asp>

http://www.maryland.research.va.gov/research/human/human_subject_sops.asp

For ease of reading, SOPs will only be referred through their numbers, not full titles. The numbering format of UMB IRB policies and procedures (IRB P&P) is currently under revision; VAMHCS SOPs can be recognized through this format: “HRP [2-place digit].[2-place digit]”.

POLICY:

VAMHCS investigators, research committee members and research staff are expected to comply with all applicable IRB P&P. In areas where the VA has specific requirements, the IRB has stated in its policies and procedures, specific procedures for VA studies. Where an additional Research Service SOP exists, VAMHCS investigators and staff are expected to comply with those as well.

RESPONSIBILITIES:

- The Research Service, Office of Research Compliance and the UMB HRPO are responsible for preparing SOPs that are concordant with applicable rules and regulations for conducting human subjects research.
- VAMHCS research staff (investigators, coordinators, research assistants) and research committee members (R&D Committee and its subcommittees) are responsible for knowing and complying with all applicable VAMHCS Research Service SOPs and UMB HRPP and IRB P&P.

DEFINITIONS

Engaged in Research, Person [IRB Definition]:

- Person who intervenes with living individuals by performing invasive or noninvasive procedures for research purposes (e.g., drawing blood; collecting other biological samples; dispensing drugs; administering other treatments; employing medical technologies; utilizing physical sensors; utilizing other measurement procedures).
- Person who intervenes with living individuals by manipulating the environment for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; orchestrating environmental events or social interactions; making voice, digital, or image recordings).
- Person who interacts with living individuals for research purposes (e.g., engaging in protocol-dictated communication or interpersonal contact; conducting research interviews; obtaining informed consent).
- Person who releases, obtains, receives, or possesses private information that is individually identifiable (either directly or indirectly through coding systems) for research purposes (e.g., obtaining private information from medical records and/or research records in an individually identifiable form).

Engaged in Research, Performance Site(s) [IRB Definition]: A performance site becomes “engaged” in human participants’ research when its employees or agents 1) intervene or interact

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with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human participants' research when it receives a direct Federal award to support the research.

Engaged in Research, VA [VA Definition]: A VA facility is **engaged** in human subject research (and needs an Assurance) whenever its **employees** or **agents**:

- Intervene or interact with living individuals for research purposes, *or*
- Obtain, release, or access individually-identifiable private information (or individually-identifiable specimens) for research purposes. [38 CFR 16.102(f)]

Protocol Deviation (PD) - Any difference in study conduct from the criteria or procedures prescribed in the approved protocol, which may or may not affect the participants' rights, safety, welfare, and/or the integrity of the study and resultant data. Deviations may result from the action of the participant, investigator, or staff.

Protocol Exception (PE): A deviation approved by the IRB prior to implementation

Protocol Violation (PV): A deviation that affects the participant's rights, safety, welfare, and/or the integrity of the resultant data

UMB HRPP and IRB P&P. The body of policies and procedures published by the UMB Human Research Protections Office.

Unanticipated Problems Involving Risks to Research Participants or Others (UPR): An event (including on-site and off-site adverse event reports, injuries, side effects, breaches of confidentiality, deaths, or other problems) that occurs any time during or after the research study, which in the opinion of the PI:

1. ***Involves harm*** to one or more participants or others, ***or placed one or more participants or others at increased risk of harm AND***
2. ***is Unexpected AND***
3. ***is Related*** to the research procedures.

VAMHCS Research. A study is VAMHCS research if:

- the research will be conducted completely or partially in VA facilities or at VA approved off-site locations or otherwise utilizes VA resources,
- the research will be conducted by researchers with VA appointments while on official VA duty (including those with WOC status),
- the VAMHCS or its satellites will be recruitment sites for the research project,
- the research is VA-funded, or
- the research involves VAMHCS medical records or VAMHCS databases, or otherwise derives data from intervention or interaction with VAMHCS subjects or tissues.

PROCEDURE:

1. VAMHCS investigators and staff must familiarize themselves with all applicable institutional policies and procedures (both VAMHCS and UMB).
 - 1.1. IRB Investigator Manual and P&P describe investigator responsibilities and required procedures.
 - 1.2. VAMHCS investigators and staff must complete all human subjects protections trainings required by the IRB and the VA. These trainings are summarized with links to training

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sites on the Research Service website: www.maryland.research.va.gov. [HRP04.02, IRB P&P]

2. Protocol Submissions and Approvals: Investigators and Research Staff

- 2.1. The Investigator must obtain IRB approval of new protocols, exempt protocols, amendments, and continuing review prior to submitting to the VAMHCS R&D Committee for review and approval. Investigators must follow HRPO policies and procedures for this. This includes completing all sections of CICERO, including :
- 2.1.1. Indicating on the IRB application:
- 2.1.1.1. that the VAMHCS will be a performance site “**engaged**” in research;
 - 2.1.1.2. use of the VAMHCS Informed Consent Form (ICF) template (VA Form 10-1086) with the appropriate participant injury language, HIPAA language, and VAMHCS contact information (name and number);
 - 2.1.1.3. For studies involving the use of investigational drugs, supplying the IND# to be validated by the IRB analysts; [IRB P&P]
 - 2.1.1.3.1. obtaining the approval of the VAMHCS Investigational Drug Pharmacist and making arrangements for study drug delivery, accountability and dispensing; [HRP 05.01]
 - 2.1.1.3.2. Informing the IDP when IRB AND RDC approvals have been obtained. [IRB P&P; HRP 05.01]
 - 2.1.1.4. For studies involving the use of investigational devices, supplying the IDE# to be validated by the IRB analysts; [IRB P&P]
 - 2.1.1.4.1. The IRB makes the determination for “significant risk” or “not significant risk” categories (investigators MAY NOT make this determination).
 - 2.1.1.4.2. when applicable, obtaining the approval of the VAMHCS Investigational Drug Pharmacist and making arrangements for study device delivery, accountability and dispensing; [HRP 06.01]
 - 2.1.1.4.3. when applicable, informing the IDP when IRB AND RDC approvals have been obtained. [IRB P&P; HRP 06.01]
- 2.1.2. Obtaining Departmental or Service approvals on scientific merit, availability of resources and feasibility. [IRB P&P; HRP 01.03]
- 2.1.3. Submitting research proposals for a determination **by the IRB** as to whether the proposal meets criteria for human participant research (investigators MAY NOT make this determination); [IRB P&P; IRB]
- 2.1.4. Submitting research proposals for a determination **by the IRB** as to whether the proposal meets the exempt criteria as defined by the Federal regulations (investigators MAY NOT make this determination.) [IRB P&P]
- 2.1.5. Submitting research proposals for a determination **by the IRB** as to whether the proposal meets criteria for expedited review or full board review (investigators MAY NOT make this determination).
- 2.1.6. applying for a HIPAA waiver or a HIPAA waiver for recruitment purposes (the IRB will make a determination based on the justifications provided by the investigator);
- 2.1.7. If staff other than the Investigator will obtain informed consent, this must be stated in CICERO. Designated staff must be qualified by training and knowledge of the study. It is suggested that designated staff be referred to by “role” rather than by given names.

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- 2.2. The Investigator may not initiate any VA research activities without first receiving VAMHCS R&D Committee (RDC) approval and notification from the ACOS/R&D that the study may be initiated. [IRB P&P; HRP 01.03]
 - 2.2.1. The investigator ensures that a copy of the VA initiation letter is uploaded into CICERO as a permanent record at the IRB.
 - 2.3. Investigators must submit all protocols for RDC approval according to HRP 01.03.
 - 2.3.1. The Investigator must submit the following documents to the RDC:
 - 2.3.1.1. The UMB IRB final approval letter,
 - 2.3.1.2. The UMB IRB approved VAMHCS Informed Consent Form (VA Form 10-1086) stamped with the Date of IRB Approval and Date of IRB Expiration; and
 - 2.3.1.3. ISO/PO Checklist
 - 2.3.1.4. Additional requirements as outlined in the VA R&D Committee SOP. [HRP 01.03 and RDC Worksheet]
 - 2.4. The PI must also indicate in CICERO the funding source and contract organization utilized, if applicable. The PI will be responsible for any applicable fees associated with industry-supported research conducted at VAMHCS including but not limited to initial IRB review fee, continuing review fees, pharmacy fees (VAMHCS IDS and UMB pharmacy), and reimbursements to the VAMHCS for services/resources used.
 - 2.5. Requests for modifications to research projects must be submitted to the IRB. Notice of the IRB approval of modifications must be sent to the RDC for notification. [IRB P&P; HRP 01.03]
 - 2.5.1. If applicable, modification requests must be reviewed by the Radiation Safety Officer, the Privacy Officer, the Information Security Officer, the Investigational Drug Pharmacist, or others.
 - 2.5.2. Modifications may not be implemented until IRB approval is received, **unless** the modification is to reduce the risk of immediate harm to participants.
3. Protocol Submissions and Approvals: HRPO & IRB Analysts
- 3.1. For studies involving investigational drugs or devices, the IRB analyst will confirm IND and IDE numbers according to IRB P&P.
 - 3.2. The IRB Analyst will compare the VAMHCS Informed Consent Document (ICD) and the UMB IRB ICD to assure that no discrepancies exist. In addition, the IRB Analyst will assure that the VA specific contact information, participant injury language, and HIPAA language are present in the VAMHCS ICD, as applicable.
 - 3.3. For research that requires review at the fully convened IRB Meeting, the IRB Analyst will assign reviewers in accordance with RB policies and procedures.
 - 3.3.1. Scientific and feasibility review occurs according to IRB P&P.
 - 3.4. The IRB Analyst will assure that one VAMHCS voting-representative is present at each convened IRB meeting at which VA research is discussed.
 - 3.4.1. The IRB Analyst will identify the VA representatives at the IRB meeting in the IRB minutes.
 - 3.4.2. All IRB members are required to have an initial orientation as well as continuing education requirements [IRB P&P].
 - 3.4.3. Representatives from the VAMHCS Office of Research Compliance or the VAMHCS Human and Animal Research Protections Officer may also be present to confirm VA representation and conduct of the discussion of VA issues.
 - 3.5. The IRB Analyst will assure that the UMB IRB final approval letter contains a statement that, prior to initiation of VA research, VAMHCS R&D approval is required.

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- 3.6. The IRB Analyst will verify that each page of the VAMHCS ICF (VA Form 10-1086) has been stamped with the IRB approval and expiration date.
- 3.7. The IRB Analyst will ensure that meeting minutes document VA-specific requirements as applicable (see 4.7 below).
- 3.8. The Chair, UMB IRB will notify the VAMHCS Medical Center Director of any determination of serious or continuing noncompliance.

4. Protocol Approvals: IRB

- 4.1. The IRB Committee, Chair, or designated Committee Member will conduct all reviews of VA human research in accordance with UMB IRB and VA R&D policies and procedures.
- 4.2. The IRB Reviewers will review the VAMHCS ICF (VA Form 10-1086) for inclusion of all the elements of informed consent.
- 4.3. For research reviewed by the full, convened IRB, approval for VAMHCS may not be granted unless there is a VAMHCS voting representative present for the discussion and vote.
- 4.4. For VAMHCS research, the IRB must approve entering non-veterans into VAMHCS research unless there are insufficient veterans available to complete the research.
- 4.5. For FDA regulated research, a licensed physician must be included in the IRB quorum.
- 4.6. The IRB meeting minutes, reviewer worksheets, and/or correspondence will document VA-regulated special requirements (such as deliberations on subjects with impaired decision-making capacity) when applicable.

5. Research & Development Committee (RDC) [HRP 01.03]

- 5.1. The VAMHCS R&D Committee receives IRB minutes outlining all approvals for new submissions, exempted protocols, expedited reviews, amendments, continuing reviews, and adverse events or unanticipated problems involving risks to participants or others for review and approval.
- 5.2. The VAMHCS R&D Committee will not consider a research proposal for final approval until the proposal has been approved by the IRB* and the applicable RDC subcommittees and institutional approvals (Subcommittee for Research Safety, Privacy Officer, and Information Security Officer).
- 5.3. For initial reviews, the RDC administrative staff evaluates the required materials by using the RDC Submission Worksheet to ensure that all required documents are present and whether further review is necessary.
 - 5.3.1. When all items are in order, the study is placed on a list of protocols to be approved at the next scheduled RDC meeting.
- 5.4. The VAMHCS RDC considers protocol modifications:
 - 5.4.1. All approved modifications must be sent to the RDC upon IRB approval. Modifications are then reviewed by the RDC administrative staff to determine if additional reviews are necessary.
 - 5.4.2. Modifications that are clerical or administrative in nature or are minor clarifications may receive expedited approval from the RDC Chair or designee as long as the following have been reviewed:

* For grant proposals, the RDC does evaluate the proposal and gives approval for the grant to be submitted to the granting agency. If a favorable decision is obtained, the protocol enters the "Just-in-Time" (JIT) process in which the proposal then begins the IRB/RDC submission process. As above, research cannot begin until both IRB and final RDC approvals are obtained.)

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- 5.4.2.1. If the modification involves addition of staff, the new staff are found to be compliant with mandatory VA training requirements.
 - 5.4.2.2. If the modification involves the addition of procedures that involve ionizing radiation or other safety issues, the Radiation Safety Officer or Subcommittee on Research Safety review and approve the modification where necessary.
 - 5.4.2.3. If the modification involves a change in HIPAA authorizations, HIPAA waivers, or other procedures that could affect the privacy of participants, the VAMHCS Privacy Officer must review and approve the modifications.
 - 5.4.2.4. If the modification involves a change in data management, security, transfer, or transmission, or other procedures that could affect the security of VA data, the VAMHCS Information Security Officer must review and approve the modifications.
- 5.5. Committee and subcommittee members must be current in VA mandatory human protections trainings.
- 5.6. R&D Continuing Review
- 5.6.1. The IRB reviews and renews approval of protocols at least annually. The IRB Request for Continuing Review contains VA-required queries. [IRB P&P]
 - 5.6.2. Annual updates generated from the VA ePROMISE system must be completed by Investigators annually.
6. Mandatory Trainings and Scope of Practice
- 6.1. Investigators and staff must complete all VAMHCS and UMB mandatory trainings and must be able to produce corroboration for the trainings. The PI must also ensure that his/her staff is current on mandatory trainings and be able to produce corroboration. [HRP 04.02; IRB P&P]
 - 6.2. Investigators and staff must work within their research scopes of practice;
 - 6.3. The PI must ensure that he/she does not assign research staff to perform procedures outside their scopes of practice;
 - 6.4. VA credentialing in VetPro is required for all licensed research staff and all research staff who do not hold, but may be or are eligible for, licensure, registration, or certification that would be required for clinical practice in the health care.
7. Recruitment of Participants
- 7.1. VA recruitment may not occur through a “cold call process”. An RDC-approved recruitment letter must precede any phone calls and social security numbers may not be requested over the phone.
 - 7.1.1. The VAMHCS logo must appear on the letters and there must be a clear description of the VAMHCS-University of Maryland relationship.
 - 7.2. The IRB must approve a HIPAA waiver for recruitment purposes before contact information can be accessed or letters mailed to potential participants.

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8. For VAMHCS research that lapsed approval due to failure to gain continuing approval:
 - 8.1. The investigator is required to immediately submit to the IRB Chair a list of participants for whom suspension of the research would cause harm, and for the IRB Chair, with appropriate consultation with the VA Chief of Staff, to determine which participants could continue in the research because it was in their best interest.
 - 8.2. Lapses in gaining continuing approval must be reported to the sponsoring agency, private sponsor, ORD, ORO, and other federal agencies as appropriate.
 - 8.3. The investigator must comply with IRB P&P.

9. Emergency use of a test article
 - 9.1. An investigator who undertakes emergency use of a test article at the VAMHCS must comply with IRB P&P and VAMHCS procedures delineated in HRP 05.01, procedure #13.
 - 9.1.1. The investigator must follow the procedures listed in both IRB P&P and HRP 05.01.
 - 9.1.2. Informed consent must be obtained.
 - 9.1.3. The investigator must notify the IRB and the VAMHCS RDC Chair when an emergency use has occurred.
 - 9.1.4. Data may not be collected for research purposes.
 - 9.2. *The VA does not allow planned emergency research under any circumstances.*
 - 9.3. The investigator must obtain IRB approval for any subsequent use of the test article.

10. Conflict of Interest
 - 10.1. The PI and research staff must follow HRPO P&Ps regarding conflict of interest (COI).
 - 10.2. The IRB has final authority for COI determinations and for approvals of COI management plans.
 - 10.3. RDC members and RDC subcommittee members must follow HRP 01.03.
 - 10.4. VA representatives on the IRB must comply with UMB policies for committee members.
 - 10.5. The ACOS/R&D or designee notifies the University when a CRADA has been negotiated for a VAMHCS research project. [HRP 01.15]

11. Decisionally Impaired Participants and Surrogate (LAR) Consent
 - 11.1. The VA has specific criteria for the use of decisionally impaired participants in research and for the hierarchy of LAR for surrogate consent[†]. The IRB has specific requirements outlined in their policies and procedures. These are summarized in Research Service SOP 03.01G: "Informed Consent Guidebook"
 - 11.2. At the time of protocol submission to the IRB, Investigators must justify the inclusion of decisionally impaired participants for VA research.
 - 11.3. When decisionally impaired participants are identified for recruitment into VA research, assessment and documentation by medical staff of the individual's decision-making capacity must take place. [HRP 03.01G, HRP 03.03]
 - 11.4. The VA differs from Maryland state law regarding surrogate consent (legally authorized representatives [LAR]). IRB P&P specifies this difference and states that for VA research and for participants recruited at the VAMHCS, the VA requirements apply. [IRB P&P and VAMHCS HRP 03.01G, 03.03]

[†] (VHA Handbook 1200.05, Par 49)

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- 11.4.1. The surrogates permitted to serve as LAR for VA research are in order of priority:
- 11.4.1.1. the spouse,
 - 11.4.1.2. adult son or daughter,
 - 11.4.1.3. parent,
 - 11.4.1.4. adult sibling,
 - 11.4.1.5. grandparent or adult grandchild of the research participant,
 - 11.4.1.6. close friend.

A grandparent or grandchild must meet the (Health Care Decisions Act (HCDA) special requirements for close friends or other relatives in order to act as a surrogate and LAR. An “adult” is a person of 18 years or older.

12. During the conduct of the study:

- 12.1. Whenever the research is performed at the VAMHCS or a participant is recruited at the VAMHCS, the VAMHCS version of the informed consent form must be used. In most cases[‡], the participant must also be registered in CPRS to enable research notes, Research Subject Clinical Warnings (RSCW), scanning of consent forms, and pre-registration of the participant in the case of unanticipated events requiring treatment.
- 12.2. A “Research Subject Clinical Warning” must be placed in the subject’s electronic medical chart (CPRS) if the participant’s participation in the study involves:
- 12.2.1. Any invasive research procedure;
 - 12.2.2. Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
 - 12.2.3. Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive; or
 - 12.2.4. The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault).
- In other situations, the IRB determines if flagging is necessary.
- 12.3. The PI must provide a copy of the VAMHCS version of the signed informed consent document to the participant or the participant’s representative and will keep the original signed informed consent document as part of the research file.
- 12.4. For studies in which the Investigational Drug Service is responsible for the accountability and dispensing of study drugs or devices, the PI must provide a copy of the VAMHCS version of the signed informed consent document to the Investigational Drug Pharmacist or designee prior to dispensing of the drug or device.
- 12.5. The IRB or the Research Compliance Office has the authority to observe or have a third party observe the informed consent process or conduct of the research [IRB P&P; HRP 02.01, 03.01G, HRP 03.03]
- 12.6. Investigators must keep a master list of all participants from whom consent has been obtained whether the IRB granted a waiver of documentation of informed consent. The master list must be secured according to the approved information security plan described in the CICERO application.

[‡] All research participants, whether veterans or nonveterans, should be registered in CPRS (health record created or updated) if their involvement in the research involves admission to VA facilities as in-patients, treatment as outpatients at VA facilities, or use of procedures or interventions in the medical care of the participant at a VA facility or at facilities contracted by the VA to provide services to Veterans.

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- 12.7. “Reportable New Information”, including “Unanticipated problems involving risks to participants or others” (UPR), and local unanticipated serious adverse events must be reported to the IRB as in IRB P&P.
- 12.7.1. In addition, investigators/staff must report any serious UPR or local unanticipated serious adverse event in their VA research in writing to the VAMHCS ACOS/R&D within 5 days of becoming aware of the event.
- 12.7.1.1. Other reporting requirements to Sponsors and other entities also apply.
- 12.7.1.2. Unfounded classification of a serious adverse event a ‘anticipated’ is considered serious noncompliance. [HRP 01.08]
- 12.7.2. Protocol Exceptions can be requested through IRB P&P. For VAMHCS studies, the PI must notify the RDC of IRB approvals of PEs.
- 12.7.2.1. Unapproved PEs may result in protocol deviations or violations and possible grounds for findings of noncompliance.
13. Complaints, suggestions and allegations of non-compliance
- 13.1. The policies and procedures of the Research Service and the HRPO regarding complaints and allegations of noncompliance have been developed collaboratively so that notifications, investigation and reporting occur with the knowledge and cooperation of both entities when VA research is in question. [IRB P&P; HRP 01.07]
- 13.2. The PI must attempt to resolve complaints from participants and families by handling them internally and in a fair and open way. If necessary, the PI should refer the participant/family to the VAMHCS Human and Animal Research Protections Officer or the HRPO according to HRP 01.07 and IRB P&P.
- 13.3. The PI must report any allegation of noncompliance to the VAMHCS ORC or the HRPO according to IRB P&P and RCO P&P.
- 13.4. The PI must report unresolved complaints to the Human and Animal research protections officer (HARPO) and inform participants of how to contact the HAARPO for complaints or allegations.
- 13.5. Complaints may be reported to the IRB at Continuing Review unless they involve potential risks to participants or others. [IRB P&P]
14. Reports of Complaints, Allegations of Noncompliance, UPR and SAEs
- 14.1. The RCO investigates allegations of noncompliance from research participants, families and staff. These are processed according to RCO SOPs. The RCO notifies the HRPO of investigations or audits related to allegations of noncompliance or significant complaints. The HRPO proceeds according to IRB P&P.
- 14.2. The Human and Animal Research Protections Officer (HAARPO) follows through on complaints from research participants, families and staff according to HRP 01.07.
- 14.3. Reporting of initial and final findings related to complaints, allegations of noncompliance, and SAE are reported through the channels delineated in IRB P&P, HRP 01.07 and RCO SOPs.
15. Quality Assurance and Quality Improvement
- 15.1. The VAMHCS requires investigators to develop and periodically assess the effectiveness of their own “internal” quality management programs. [HRP 02.04]
- 15.1.1. Investigators are subject to for-cause or routine audits by the HRPO Quality Improvement Specialist team (QIS) or by the VAMHCS Office of Research Compliance. [IRB P&P; RCO SOPs].

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- 15.1.2. Research Service Guidelines HRP 07.02G, 07.03G, 07.05G, 07.06G and 07.07G as well as assorted tools are available at the Research Service website: www.maryland.research.va.gov. The HRPO also offers tools at its website: <http://medschool.umaryland.edu/ORAGS/hrpo/toolkit.asp>.
- 15.1.3. The IRB and Research Service offer consultation with a Quality Improvement Specialist at any point before, during, or at the close out of the research study. These consultations will focus on assisting the Investigator with developing a study implementation plan including mechanisms to enhance compliance with research conduct, reporting, and recording requirements of *Good Clinical Practice's*. Investigators are encouraged to use this service early in the start up phase of their study. [HRP 02.01, 02.02, 02.03, 07.02.G, 07.03.G, 07.05G, 07.06G, 07.07G]
- 15.1.4. The PI and staff must cooperate with audits and investigations conducted by the ORC or HRPO.
- 15.1.5. The ORC and representatives of the HRPO may observe the consent process to evaluate investigators'/staff's practices.
- 15.2. The VAMHCS Office of Research Compliance or designees of the RDC periodically conduct audits of the IRB and the VAMHCS Human Research Protections Program in order to evaluate the effectiveness and make improvements where indicated.
- 15.3. Audit findings that require reporting will follow IRB P&P and RCO SOPs.