



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 1 of 18

Written/Revised By:

Author	Author	Author
Print Name: Annette Anderson, MS, CIP	Print Name: N/A	Print Name: N/A
Signature: Signature on File	Signature: N/A	Signature: N/A
Date: 7/23/2014	Date: N/A	Date: N/A

Approved By:

Program Manager	Director, PRIDE
Print Name: Annette Anderson, MS, CIP	Print Name: Holly Birdsall, MD
Signature: Signature on File	Signature: Signature on File
Date: 7/23/2014	Date: 7/24/2014

Issued By:

Quality Manager	Designee Title (if applicable):
Print Name: Avis Bullard, M.S., CQA(ASQ)	Print Name: N/A
Signature: Signature on File	Signature: N/A
Date: 7/24/2014	Date: N/A



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 2 of 18

1 SCOPE AND APPLICABILITY

- 1.1 This Standard Operating Procedure (SOP) sets forth the authority and responsibilities of the VA Central Institutional Review Board (IRB). It also contains procedures for identifying and reporting any instances of individuals attempting to exert undue influence on the VA Central IRB or any of its members.
- 1.2 This SOP applies to all research that is submitted to the VA Central IRB for review. It pertains to investigators, VA Central IRB members, VA Central IRB administrative staff, and local VA facilities that have entered into a Memorandum of Understanding (MOU) with the Veterans Health Administration Central Office (VHACO) listing the VA Central IRB as an IRB of record for the facility.
- 1.3 It is the policy of the VHACO Human Research Protections Program (HRPP) that the VA Central IRB operates as an independent authority to carry out all the responsibilities required of an IRB in accordance with VA and other requirements, and that any attempt to exert undue influence on the VA Central IRB or any VA Central IRB member individually is promptly identified and reported (see paragraph 4.9.1.)
- 1.4 It is the policy of the VHACO HRPP that the VA Central IRB oversees certain specified multi-site human subject research as designated for review by the VA Office of Research and Development (ORD). Commercial IRBs are not currently used for approval of VA research.
- 1.5 ORD designated research is submitted to the VA Central IRB by investigators from VA facilities that have an MOU with the VHACO HRPP for the VA Central IRB to serve as an IRB of record. The VA Central IRB may not oversee research for any VA facility until that facility has listed the VA Central IRB on its Federal Wide Assurance (FWA) and entered into an MOU with VHACO.
- 1.6 It is the policy of the VHA Central Office HRPP that the VA Central IRB may not serve as the IRB of record for any non-VA entity. The only exception is that it may serve as the IRB of record for a VA non-profit Education and Research Foundation only in relation to a specific project for which the associated VA facility will have VA investigators involved in the conduct of the research at the facility.

2 DEFINITIONS

- 2.1 **Assurance** - . A written commitment by the institution to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16 (VHA Handbook 1058.03). For the purposes of these SOPs, "assurance" and a "Federal wide Assurance" (FWA) are synonymous.
- 2.2 **Human Protections Administrator** - The individual named in an FWA as a primary contact responsible for directing, or having in-depth knowledge of, the daily operations of an Institution's program for protecting human research subjects (VHA Handbook 1058.03).



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 3 of 18

- 2.3 **Institutional Official** - The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to external agencies and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. The Principal Deputy Under Secretary for Health is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities. (VHA Handbook 1200.05).
- 2.4 **IRB of Record** - The IRB(s) designated under a VA facility's FWA for review and oversight of the facility's human subject research (VHA Handbook 1058.03, paragraph 4m).
- 2.5 **Memorandum of Understanding (MOU)** - A written agreement between two VA facilities or between a VA facility and a non-VA Institution documenting their relationship and defining their respective roles and responsibilities within that relationship (VHA Handbook 1058.03, paragraph 4n).
- 2.6 **Suspension of IRB Approval** - A determination by an IRB Chair, a qualified IRB voting member designated by the IRB Co-Chair, or the convened IRB to temporarily interrupt some or all previously approved research activities. The suspended activities could include, but not be limited to, recruiting of new subjects for the research. Suspended studies remain open and require continuing review. (VHA Handbook 1200.05)
- 2.7 **Termination of IRB Approval** - A termination of IRB approval is a determination by the convened IRB to permanently halt some or all previously approved research activities including, but not limited to, enrollment of new subjects in research. (VHA Handbook 1200.05)
- 2.8 **VA Institution** - Any entity operated by the VA, including but not limited to: VA hospitals, medical centers, clinics, and healthcare systems; space owned, leased, or rented by VA; and space that is "shared" with a non-VA entity (unless the VA space is leased to a non-VA entity and specifically designated in writing not be used by VA or VA employees for research). A VA facility may include multiple campuses and satellite components. The terms "facility" and "VA facility" are synonymous (VHA Handbook 1058.01 and VHA Handbook 1200.05).

3 RESPONSIBILITY

- 3.1 Institutional Official – See SOP VA Central IRB SOP 100, Veterans Health Administration Central Office (VHACO) Human Research Protection Program (HRPP) Overview, Structure, and Responsibilities.
- 3.2 Chief Research and Development Officer (CRADO) – See SOP VA Central IRB SOP 100, Veterans Health Administration Central Office (VHACO) Human Research Protection Program (HRPP) Overview, Structure, and Responsibilities.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 4 of 18

- 3.3 Director, Program for Research Integrity Development and Education (PRIDE) – See SOP VA Central IRB SOP 100, Veterans Health Administration Central Office (VHACO) Human Research Protection Program (HRPP) Overview, Structure, and Responsibilities.
- 3.4 Local VA Facility IO – The local facility IO is the Signatory Official for the institution when entering into an MOU with the VHACO Central Office designating the VA Central IRB as an IRB of record on its FWA. The local facility IO is responsible for ensuring that the facility meets all the obligations as set forth in the MOU and that no research submitted to the VA Central IRB is otherwise approved or begun at the facility until it is approved by the VA Central IRB and by the local facility in accordance with VHA Handbook 1200.01. In VA facilities, the IO is the Medical Center Director.
- 3.5 VA Central IRB – The VA Central IRB is responsible for fulfilling all responsibilities and for performing all functions of an IRB in accordance with 38 CFR 16 and VHA Handbook 1200.05, including but not limited to the authority to:
- 3.5.1 Approve, require modifications to secure approval, or disapprove research activities brought before it in order to assure that the rights and welfare of human research participants are being protected.
 - 3.5.2 Suspend or terminate approval of research not being conducted in accordance with VA Central IRB's requirements or due to concerns regarding the safety, rights, or welfare of human research participants, research project staff, or others.
 - 3.5.3 Observe or have a third party observe, the informed consent process and the conduct of the research.
- 3.6 VA Central IRB Administrator – The VA Central IRB Administrator is responsible for overseeing the daily administrative activities of the VA Central IRB. This includes ensuring that all local VA sites participating in a VA-funded, multi-site project submitted to the VA Central IRB for review, have an approved MOU on file and that the VA Central IRB has been designated as an IRB of record on the local site's FWA. If the site does not have an approved MOU in place, and/or is not designated as an IRB of record on the facility's FWA, the VA Central IRB Administrator works with the local facilities in getting these documents submitted and processed. The VA Central IRB Administrator also ensures a database is maintained and kept up-to-date of all local VA facilities with approved MOUs and their renewal dates.
- 3.7 VA Central IRB Managers – The VA Central IRB Managers are responsible for carrying out the daily activities of the VA Central IRB including but not limited to coordinating all project review functions of the VA Central IRB with the designated VA Central IRB reviewers, the VA Central IRB Co-Chairs, and the study teams in accordance with established policies and procedures. The VA Central IRB Managers maintain all required documentation, including but not limited to a record of all actions taken by the VA Central IRB in regard to their assigned projects.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 5 of 18

4 PROCEDURE

- 4.1 Review of Research. All research involving human participants submitted to the VA Central IRB, whether it is an initial or continuing review, will be reviewed either at convened meetings of the VA Central IRB or through expedited review procedures, unless it meets the criteria for exempt research.
- 4.1.1 Research meeting the criteria for exempt research will be reviewed and documented in accordance with VA Central IRB SOP 107, Requests for Exemption Review and Determination.
- 4.1.2 Except where an expedited review procedure is used, the VA Central IRB reviews proposed research at convened meetings where a quorum is present, including at least one voting member whose primary concern is in a non-scientific area. If the research to be reviewed is FDA-regulated, a voting licensed physician member must be included in the quorum.
- 4.1.3 The review conducted by the VA Central IRB, whether at a convened meeting or utilizing expedited review procedures, will include review of the VA Central IRB applicable application forms, the research protocol, and all other relevant documents as applicable, to include the informed consent form and the HIPAA authorization or any requests for waiver of informed consent or the requirement to obtain a HIPAA authorization.
- 4.2 Review Requirements. In conducting the review, the VA Central IRB determines that all of the below listed requirements are satisfied in accordance with 38 CFR 16 and VHA Handbook 1200.05. This includes review of amendments if an amendment affects any of the following criteria:
- 4.2.1 Risks, both physical and non-physical, to human participants are minimized by using procedures that are consistent with sound research design; that do not unnecessarily expose participants to risk; and, whenever appropriate, using procedures already being performed on the participants for diagnostic or treatment purposes.
- 4.2.2 Risks, both physical and non-physical, to human participants are reasonable in relation to any anticipated benefits to participants (the risk/benefit ratio), and the importance of the knowledge that may reasonably be expected to result. Validity of research design is taken into consideration in determining the risk/benefit ratio.
- 4.2.2.1 Protocols involving treatment or services that constitute “usual care” must include a narrative section that clearly differentiates the research interventions from usual care, whether usual care is delivered to only some or to all research participants. If the differentiation is not clear, the IRB must



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 6 of 18

seek additional clarification from the investigators and, if warranted, seek guidance from qualified experts. The IRB must document any findings.

4.2.2.2 The VA Central IRB must ensure the informed consent process clearly defines for the research participant which potential risks are related to the research, and therefore, need to be discussed with the research team, versus those associated solely with usual care provided by the participant's health care provider. The informed consent process must include language advising participants to review the risks of the latter with their health care provider.

4.2.2.3 The IRB is not to consider possible long-range effects of applying knowledge gained in the research as among those research risks within the purview of its responsibility.

4.2.3 The selection of participants is equitable for the purposes of the research and the research setting.


4.2.3.1 The VA Central IRB is particularly cognizant of the special issues of research involving vulnerable populations such as children, prisoners, pregnant women, or persons with impaired decision-making capability, as well as special classes of participants such as economically or educationally disadvantaged individuals, and will determine if additional safeguards are required for these populations in the projects reviewed.

4.2.3.2 If the recruitment of non-Veterans is involved, the VA Central IRB must ensure that the use of non-Veterans is justified and appropriate. The determination of the VA Central IRB concerning the use of non-Veterans must be documented in writing.

4.2.4 Informed consent will be sought for each prospective participant, or the participant's legally authorized representative, and a written informed consent document is included as part of the research project, if applicable.

4.2.4.1 The wording of the informed consent form includes all required elements, and any additional elements as applicable, per 38 CFR 16.116 and in accordance with VHA Handbook 1200.05. This includes appropriate blocks for signatures and dates.

4.2.4.2 The VA-required language for a valid authorization to release Protected Health Information under the Health Insurance Portability and Accountability Act (HIPAA) is included as a separate document. The VA Central IRB may waive the requirement for an authorization or may alter the authorization only

 <p>Veterans Health Administration Research & Development Improving Veterans' Lives www.research.va.gov</p>	VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES		
Document No.: RD-IRB- SOP 101	Revision: 08	Effective Date: Jul 24, 2014	Page 7 of 18

in accordance with VHA Handbook 1605.1, Privacy and Release of Information.

- 4.2.4.3 The IRB must determine that the protocol is consistent with the informed consent document and HIPAA authorization as applicable.
- 4.2.5 Documentation of how the informed consent process is conducted must be included in the research project. It is the responsibility of the VA Central IRB to ensure that the proposed project contains documentation concerning how informed consent will be sought from each participant or their legally authorized representative, and that only a person knowledgeable about the consenting process and the research conducted obtains the informed consent.
- 4.2.6 When appropriate, the project plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. The VA Central IRB reviews the data safety and monitoring plan to ensure adequate protections have been included for participant populations. This plan may include:
 - 4.2.6.1 Establishing a Data Monitoring Committee (DMC) or Data Monitoring Safety Board (DSMB) as required by VA or other federal requirements and a plan for reporting DMC/DSMB findings to the VA Central IRB and sponsor.
 - 4.2.6.2 For studies that do not have or are not required to have a DMC and are blinded, have multiple sites, enroll vulnerable populations, or employ high risk interventions, the VA Central IRB will carefully review the data safety and monitoring plan and may suggest the creation of a DMC if the IRB determines that it is warranted by the risks of the study.
- 4.2.7 Adequate provisions are included in the project to protect the privacy of participants and to maintain the confidentiality of individually identifiable data. The requirements of the HIPAA Privacy Rule and other federal requirements regarding the protection and use of Veterans' information should be considered in the provisions.
- 4.2.8 The IRB must determine that applicable VHA and VA information security policies pertaining to research are implemented and continually monitored to ensure compliance as set forth in VA Directive 6500 and its handbooks.
- 4.2.9 Additional safeguards are included in each project, if applicable, to protect the welfare of vulnerable participants or other special classes of participants who may be vulnerable to coercion or undue influence.
- 4.2.10 Steps to manage, reduce, or eliminate potential or real conflicts of interest (financial, professional or personal role relationships, and/or institutional) have been taken.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 8 of 18

4.2.11 The Principal Investigator/Study Chair (PI/SC) and all other investigators who will be involved in the proposed project have met all current educational requirements for the protection of human research participants as mandated by the facility's assurance and VA policy, and that they have the appropriate background and experience to conduct the research.

4.3 Actions Taken by the VA Central IRB. The VA Central IRB notifies the PI/SC and the local VA facilities participating in the project in writing of its decision to approve or disapprove a project activity, or of modifications required to secure approval. IRB approval of a study means the IRB has determined that the research has satisfied all relevant approval criteria and may be conducted at an institution within the constraints set forth by the IRB and by other applicable local, VA, and other federal requirements.

4.3.1 Prior to issuing an approval letter, the VA Central IRB ensures that all the requirements of 38 CFR 16.111 and 38 CFR 16.116 and 117 as applicable and detailed in paragraph 4.2 have been met.

4.3.2 If modifications are required to secure approval, these are detailed in the letter to the investigator. The following additional review by the VA Central IRB is then required depending upon the type of modification that was requested and the review that was conducted:

4.3.2.1 If the convened VA Central IRB requires substantive modifications or clarifications to the project and/or informed consent, the convened VA Central IRB must review and approve all materials submitted by the PI in response before an approval letter can be issued.

4.3.2.2 If the convened VA Central IRB requires minor modifications in a project, one of the VA Central IRB Co-Chairs or another qualified voting member designated by the Co-Chair, may review the PI/SC's response and, using an expedited review procedure, approve the revised research project on behalf of the VA Central IRB.

4.3.2.3 If modifications are required during the expedited review process, these modifications will be reviewed by the original reviewer and the Co-Chair prior to an approval letter being issued. If the original reviewer is unavailable in a timely manner, the Co-Chair may perform the review and sign the approval letter if all modifications have been satisfactorily made.

4.3.3 If the VA Central IRB disapproves a project, a written statement detailing the reasons for its decision is sent to the PI/SC, giving the PI/SC an opportunity to respond in writing. If the PI/SC wishes to respond to the VA Central IRB decision in person, the



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 9 of 18

PI/SC will be invited to present the response via teleconference at a convened meeting. The PI/SC may also present in person if in the local area and available at the time of the meeting. If a project is disapproved by the VA Central IRB, the decision cannot be overruled by a higher authority or a participating facility. No person may approve non-exempt human research that has not been approved by the IRB.

4.4 Required Written Procedures. The VA Central IRB establishes written procedures for, but not limited to the following:

- 4.4.1 Conducting initial and continuing review of research and for reporting the VA Central IRB's findings to the investigator and appropriate local VA participating facility Institutional Officials as designated per the MOU.
- 4.4.2 Determining which projects require review more than annually and which projects require verification from sources other than the investigator that no substantive modifications or changes have occurred since the previous review.
- 4.4.3 Requiring that investigators promptly report proposed changes in a research project to the VA Central IRB, including amendments to a project, to include the consent form, and for ensuring that such changes in approved projects are not initiated without the VA Central IRB's review and approval, except when necessary to eliminate apparent immediate hazard to the participants.
- 4.4.4 Requiring prompt reporting of serious or continuing non-compliance with the policies and procedures detailed in VHA Handbook 1200.05, the requirements or determinations of the VA Central IRB, or other applicable local, VA, or Federal requirements.
- 4.4.5 Reporting of adverse events to include any serious unanticipated adverse events, whether related or unrelated to the research, and unanticipated problems involving risks to subjects or others as required by VA and other federal requirements, to the VA Central IRB and for notifying appropriate oversight authorities of any serious adverse events or unanticipated problems that cause substantive harm or a genuine risk of substantive harm to the safety, rights or welfare of human participants or others in accordance with VHA Handbook 1058.01 or that substantively compromise the effectiveness of the facility's HRPP.
- 4.4.6 Terminating or suspending VA Central IRB approval of a research project.
- 4.4.7 Observing, or having a third party observe, the informed consent process when the VA Central IRB determines it to be appropriate.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 10 of 18

- 4.4.8 Notifying VA Central IRB members of studies that have been approved under expedited review procedures and documenting, in the VA Central IRB minutes or the VA Central IRB study file, the expedited review category under which the research qualifies for expedited review.
- 4.4.9 Documenting approvals of requests for Waiver of Informed Consent, Waiver of Documentation of Informed Consent, and Waiver of HIPAA Authorization in the VA Central IRB minutes or the VA Central IRB project file, as well as the protocol-specific findings justifying the determinations.
- 4.4.10 Conducting audits of projects and other VA Central IRB activities.
- 4.4.11 Ensuring that initial and continuing educational requirements for the VA Central IRB Co-Chairs, members, and alternates are met.
- 4.4.12 Reporting to the VHA Privacy Officer and coordinating with local VA facilities for local reporting of any unauthorized use, loss, or disclosure of individually identifiable patient information, and for reporting violations of VA information security requirements to the appropriate VHA Information Security Officers within one hour.
- 4.4.13 Preparation and maintenance of adequate documentation in VA Central IRB records of the activities of the VA Central IRB to include: VA Central IRB project files, VA Central IRB minutes, correspondence between the VA Central IRB and investigators, an IRB roster meeting the requirements of 38 CFR 16.103(b) (3) and 38 CFR 16.115(a) (5), VA Central IRB member files to include a resume for each voting member; and VA Central IRB SOPs. All records will be maintained in accordance with VHA records retention requirements.

4.5 Ongoing Monitoring.

- 4.5.1 The VA Central IRB has the authority to conduct audits or to request that the local RCO conduct an audit of pertinent local VA facility files to ensure all written procedures are followed and to review research records and research case histories for compliance with written procedures and other requirements. This includes monitoring the informed consent process and the research or having a designated third party perform the monitoring.
- 4.5.2 The VA Central IRB will review all routine regulatory and informed consent audits performed by local VA facility Research Compliance Officers (RCOs), as well as any for cause audits conducted, for those studies for which the VA Central IRB serves as the IRB of record for the local facility.
- 4.5.3 The VA Central IRB may also review the results of audits conducted by other entities.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 11 of 18

4.6 Continuing Review.

4.6.1 The VA Central IRB conducts continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. In the continuing review, the VA Central IRB determines that all the requirements detailed in paragraph 4.2 of this SOP are satisfied.

4.6.2 If the continuing review does not occur and the project approved for continuation within the timeframe set by the VA Central IRB, the VA Central IRB approval automatically lapses. See VA Central IRB SOP 112, Continuing Review and Approval Requirements for Investigators, for further information on projects with lapsed approval.

4.7 Maintenance of Documentation: The VA Central IRB prepares and maintains complete documentation of its activities to include the following:

- Current status of FWA and IRB Registration
- Current MOUs and local site designation letters or memos
- VA Central IRB roster and member qualifications
- Meeting minutes of the VA Central IRB
- Copies of all items reviewed as part of the project file
- Copies of all project determinations made by the VA Central IRB
- Records of continuing review
- Statements of significant new findings provided to participants
- Copies of all official correspondence between the investigators and the VA Central IRB and between the participating sites and the VA Central IRB
- Reports of unanticipated serious adverse events, complaints, unanticipated problems involving risks to subjects or others, reports of apparent serious non-compliance, and submitted audit reports, as well as all actions taken by the VA Central IRB in response or connection to these reports

4.8 Serving as an IRB of Record.

4.8.1 When the VA Central IRB serves as an IRB of record for a participating site in a multi-site project, it has the authority and responsibilities detailed in paragraphs 4.1 through 4.7 of this SOP. Additionally, the VA Central IRB adheres to all duties and responsibilities as detailed in the attached MOU (Attachment 2).

4.8.1.1 In review of the research as it will be conducted at local participating site, the VA Central IRB evaluates each local site's resources, qualifications of the investigators, and any other local context issues such as the characteristics of



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 12 of 18

the site's patient population; and determines that the site is capable of carrying out the proposed research.

4.8.1.2 Each site having its own FWA enters into an MOU with the VA Central IRB, irrespective of other IRB arrangements. The associated Non-Profit Corporation (NPC) also is a party to the MOU and must also add the VA Central IRB to the NPC FWA. If a facility does not have an associated NPC, the version of the MOU without the NPC included as a signatory is used (Attachment 3).

4.8.2 If an MOU is not in place, the local facility follows these procedures to establish an MOU with the VA Central IRB.

4.8.2.1 The local facility submits a completed MOU based on the approved template for signature to the local facility IO and the applicable VA Integrated Service Network (VISN) Director. It also adds the VA Central IRB as an IRB of record to the facility FWA. VA Central IRB administrative staff will assist the local facility in providing all the required information concerning the VA Central IRB in order for the amended FWA, revised VA FWA addendum, and MOU to be prepared.

4.8.2.2 The local VA facility notifies ORO when the amended FWA and the revised VA FWA addendum are ready for review. ORO electronically reviews the revisions and notifies the facility when to submit the revisions to OHRP. The local VA facility then submits a signed hard copy of the FWA and the VA addendum to ORO.

4.8.2.3 The local VA facility submits the signed copy of the MOU to the VA Central IRB Administrative Office. Personnel in the VA Central IRB Administrative Office obtain the signature of the VHA Central Office IO designee, currently the VHA Central Office Human Protections Administrator, and forwards a signed copy to both the local VA facility and to ORO.

4.8.3 No research may be reviewed by the VA Central IRB as an IRB of Record from a site until the site's amended FWA is approved by ORO and OHRP and is posted on the OHRP website listing the VA Central IRB as an IRB of record for that site. The signed MOU with the site must also be on file.

4.8.4 The MOU with each site will be reviewed and updated as necessary.

4.8.4.1 The MOU must be reviewed every five years or, if there is a change in a local facility IO or local NPC IO, the MOU must be amended through submission



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 13 of 18

of VA Central IRB Form 143, Amendment to Memorandum of Understanding (MOU) (Attachment 4). Upon receipt of a notice from OHRP of a change in Signatory Official on the FWA for a VA facility or local NPC that lists the VA Central IRB as an IRB of record, and the VA Central IRB has not received the required amendment, the site is contacted and asked to submit an amendment with the current IO's signature within 30 days. If there is no change within the five years, this is noted by both the site and the VA Central IRB Administrative Office via e-mail and a copy of the e-mail filed with the current MOU, which will then remain in effect.

4.8.4.2 If there is a change in the HPA or if there is an update in the current IO information, such as changing an "Acting Director" title to a "Director" title an amendment need not be submitted.

4.8.5 The SOPs for the VA Central IRB are posted on the VA Central IRB website to facilitate access by participating sites in order for them to update local site SOPs to incorporate the policies and procedures of the VA Central IRB.

4.9 Independence of VA Central IRB. The VA Central IRB is an independent authority. The Co-Chairs and individual members are recruited from throughout the nation. Its structure and oversight mechanisms have been developed to minimize the possibility of any Institutional COI or undue influence. However, in the event that an investigator, VA Central IRB member, human research participant, or any other interested party believes there has been an attempt to unduly influence the VA Central IRB or one of its members, the following actions should be taken:

4.9.1 Anyone who wishes to report what they believe is an attempt to unduly influence the VA Central IRB or one of its members can report such an attempt to one or more of the following entities:

- VA Central IRB Co-Chair
- VA Central IRB Administrator
- VA Central IRB Manager
- The Director, PRIDE
- HPA for VHA Central Office HRPP
- CRADO, Deputy CRADO, or ORD Administrative Officer
- The Principal Deputy Under Secretary for Health (IO for the VHA Central Office)

4.9.2 Upon receipt of a report to unduly influence the VA Central IRB or one of its members, the individual receiving the report immediately informs the IO of the VHA Central Office. The IO will appoint an individual or individuals to investigate the allegations and prepare a report of findings.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 14 of 18

4.9.3 Depending upon the allegations and the outcome of the investigation, the VA Central IRB or IO as applicable may take one or more of the following actions:

- Bar an investigator from submitting any further research to the VA Central IRB
- Suspend or terminate any currently approved research projects pertaining to the allegations in accordance with approved procedures
- Terminate the membership of any VA Central IRB members involved (IO only).

4.9.4 Other administrative or disciplinary actions may be taken by the appropriate supervisory authorities as applicable depending upon the results of the investigation.

5 REQUIREMENTS

- 5.1 The SOPs for the VA Central IRB are maintained electronically and posted on the VA Central IRB website.
- 5.2 The VA Central IRB prepares and maintains electronic and hard copy documentation of FWA and IRB Registrations, current MOUs; VA Central IRB rosters and member qualifications.
- 5.3 It also maintains IRB meeting minutes; copies of all items reviewed as part of the project file; copies of all project determinations made by the VA Central IRB; records of continuing review; statements of significant new findings provided to participants; copies of all official correspondence between the investigators and the VA Central IRB and between the participating sites and the VA Central IRB; and reports of unanticipated serious adverse events, complaints, unanticipated problems involving risks to subjects or others, reports of apparent serious non-compliance, and submitted audit reports, as well as all actions taken by the VA Central IRB in response or connection to these reports. All records will be maintained in accordance with VHA records retention requirements.



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 15 of 18

6 REFERENCES

- 6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects
- 6.2 VHA Handbook 1200.01, Research and Development Committee
- 6.3 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
- 6.4 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research
- 6.5 VHA Handbook 1605.1, Privacy and Release of Information
- 6.6 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Board
- 6.7 45 CFR 164.508, HIPAA Privacy Rule
- 6.8 MOU checklists developed by ORO and ORD



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

Document No.: RD-IRB- SOP 101

Revision:
08

Effective Date:
Jul 24, 2014

Page 16 of 18

Revision History:

Revision:	Description:	Date:
00	Original	7/24/14



VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES

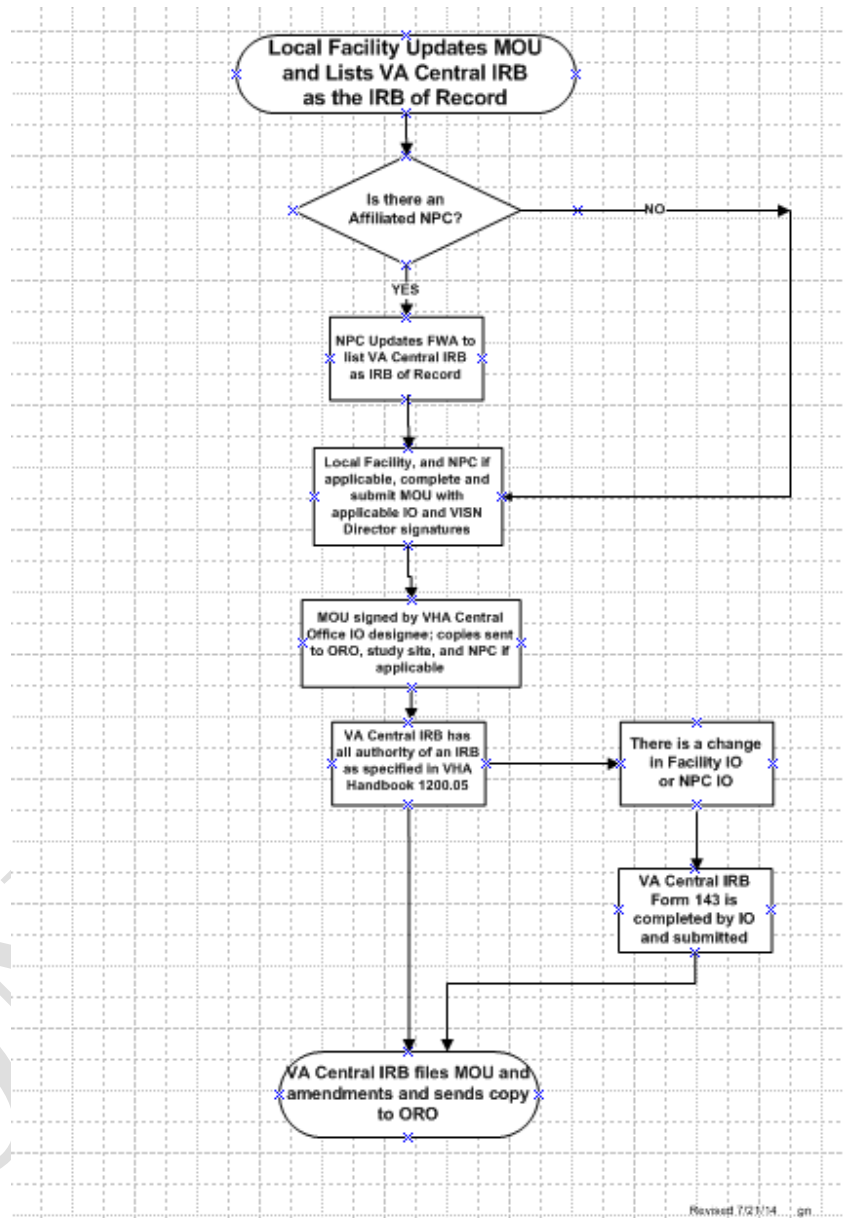
Document No.: RD-IRB- SOP 101


Revision:
08

Effective Date:
Jul 24, 2014

Page 17 of 18

Attachment1: VA Central IRB SOP 101 Process Chart



 <p>Veterans Health Administration Research & Development Improving Veterans' Lives www.research.va.gov</p>	VA CENTRAL IRB AUTHORITY, RESPONSIBILITIES AND ACTIVITIES		
Document No.: RD-IRB- SOP 101	Revision: 08	Effective Date: Jul 24, 2014	Page 18 of 18

Attachments:

2. Memorandum of Understanding to include NPC

<http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx>

3. Memorandum of Understanding not including NPC

<http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx>

4. VA Central IRB Form 143, Amendment to Memorandum of Understanding (MOU)

<http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx>

CONTROLLED COPY

Memorandum of Understanding



MEMORANDUM OF UNDERSTANDING BETWEEN VETERANS HEALTH ADMINISTRATION (VHA) CENTRAL OFFICE

AND

{NAME OF LOCAL VETERANS AFFAIRS (VA) FACILITY}

AND

{NAME OF LOCAL VA NONPROFIT CORPORATION}
created and operated under the laws of
[insert State of Incorporation]

A. PURPOSE

1. This Memorandum of Understanding (MOU) sets forth the agreed upon respective authorities, roles, and responsibilities of the Veterans Health Administration (VHA) Central Office, operating the VA Central Office Institutional Review Board (IRB), hereinafter referred to as the VA Central IRB, the {Name of Local VA Facility} and the {Name of Local VA Facility Nonprofit Corporation} (NPC) for the VA Central IRB to serve as an additional IRB of Record for {Name of Local VA Facility} and the NPC.
2. This MOU does not preclude {Name of Local VA Facility} and NPC from continuing to participate in any existing agreements the {Name of Local VA Facility} and NPC may have with other VA or non-VA entities. This MOU is between the signatories only and does not include any other entities that are independently operating under their own Federalwide Assurances (FWAs), and it specifically excludes other entities with which {Name of Local VA Facility} and NPC may have a separate MOU for IRB and/or Research and Development (R&D) Committee services.

B. GENERAL PROVISIONS

1. The conduct of the parties will be guided by the “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” as set forth in The Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in April 1979.
2. VHA employees conducting or reviewing research are subject to the Federal Criminal Code and the Standards of Ethical Conduct for Executive Branch Employees. The obligation to act in accordance with ethics laws and regulations applies to all individuals while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and employees under the Intergovernmental Personnel Act (IPA) of 1970. Ethics officials in the Office of General Counsel are available to provide guidance on dealing with actual or potential conflicts of interest. Both VA Central IRB and the {Name of Local VA Facility} will implement current VHA policies related to conflict of interest and notify the VA Central IRB of any issues they identify. The VA Central IRB will review these issues and take appropriate measures to address them. Additionally, subject to the requirements of VHA Handbook 1200.17 section 9, each NPC must establish a written policy on conflicts of interest applicable to NPC Directors, officers, and employees.
3. Parties will adhere to 38 CFR 16 and 17, 21 CFR 50 and 56; and other pertinent VA and Federal requirements applicable to human subjects research, including VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research. The VA Central IRB or the {Name of Local VA Facility} will not approve a research project if it does not meet all these requirements. VHA Handbook 1200.05 will serve as the reference source for the definitions of all terms used in this MOU.
4. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR 164.512(i), and VHA Handbook 1605.01, Privacy and Release of Information, the VA Central IRB may grant a HIPAA Waiver of Authorization for use or disclosure of protected health information (PHI) for research reviewed by the VA Central IRB, if justified and if all criteria for a waiver of authorization are met. The VA Central IRB must document these findings as required by 45 CFR 164.512(i).
5. The VA Central IRB Privacy Officer and Information Security Officer (ISO) Representatives will perform the required privacy and information security reviews. The local Privacy Officer does not conduct a separate privacy review of studies overseen by the VA Central IRB. However, the local

ISO may need to review some studies overseen by the VA Central IRB due to local project-specific information security issues. In those cases the VA Central IRB ISO works with the local ISO to address the issues.

6. The VHA Central Office, the {Name of Local VA Facility} and the NPC will each maintain a current FWA through the VA Office of Research Oversight (ORO) and the Department of Health and Human Services Office for Human Research Protections (OHRP) listing the VA Central IRB as an IRB of record. Any lapse in approval, restriction, suspension, termination, or failure to maintain an approved FWA by any of the parties to this MOU will be reported to the others immediately in writing.
7. Both the VHA Central Office and the {Name of Local VA Facility} will secure and maintain accreditation of their Human Research Protection Programs (HRPPs) through the VA-designated accrediting organization in accordance with VA requirements.
8. There will be no charge to the {Name of Local VA Facility}, the NPC, or to investigators for the use of the VA Central IRB.
9. This agreement will go into effect the date of signature of the VHA Central Office Institutional Official's designee and will remain in effect until terminated per this agreement or the agreement is amended and/or revised per mutual agreement of all Institutions. This MOU must be reviewed and revised as conditions change and renewed every 5 years. The MOU must be amended when there is a change in any of the signatory officials, with a copy of the amendment sent to ORO per VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

C. RESPONSIBILITIES OF THE VHA CENTRAL OFFICE HRPP AND VA CENTRAL IRB

The VHA Central Office HRPP assures {Name of Local VA Facility} and NPC that the VHA Central Office HRPP and VA Central IRB will carry out the following functions and responsibilities in accordance with all applicable requirements:

1. The Institutional Official will ensure that the VA Central IRB is provided, through the Chief Research and Development Officer (CRADO), with sufficient resources to support its operations. These resources will include, but not be limited to, adequate meeting space, equipment, financial support, and staff.

2. The VA Central IRB will maintain a current OHRP IRB registration in accordance with the requirements specified in VHA Handbooks 1200.05 and 1058.03.
3. All VA Central IRB members and staff will receive appropriate initial and ongoing training with regard to VA and other Federal requirements for the protection of human subjects.
4. In coordination with counsel, the VA Central IRB will ensure compliance of any conflicts of interest of IRB members in accordance with criminal conflict of interest laws and Standards of Ethical Conduct for Executive Branch employees.
5. The VHA Central Office HRPP will maintain policies and Standard Operating Procedures (SOPs) that incorporate by inclusion or reference, Federal statutes and regulations, as well as VA, VHA, and other requirements applicable to reviewing human subjects research.
6. The VA Central IRB will meet a minimum of once a month, and can meet more often if determined necessary by the VA Central IRB Co-Chairs and VA Central IRB administrative staff. Members will attend in-person or via audio or video conference. If the Co-Chairs and administrative staff determine there are no agenda items that require action by the convened IRB, the scheduled meeting may be cancelled.
7. The VA Central IRB will perform initial and continuing review of selected multi-site research projects.
8. The VA Central IRB will evaluate local context for each project submitted using one or more of the following methods:
 - a. Reviewing the {Name of Local VA Facility}'s Local Site Investigator (LSI) Application (VA Central IRB Form 104), and any additional information submitted by the LSI, or the {Name of Local VA Facility}.
 - b. Knowledge of the local research context by one or more of VA Central IRB members or staff. Such knowledge may have been obtained through direct experience with the {Name of Local VA Facility}, its subject populations, and/or the local community.
 - c. Obtaining relevant information from an appropriate ad hoc advisor(s) who has had direct experience with the {Name of Local VA Facility}, its subject populations, and/or the local community.

- d. Systematic, reciprocal, and documented communication between the VA Central IRB and {Name of Local VA Facility}. This communication will include regular interactions with one or more designated site liaisons by one or more VA Central IRB members or administrative staff and/or periodic visits to the {Name of Local VA Facility}, as prescribed by VA Central IRB and {Name of Local VA Facility}'s SOPs.
- 9. The VA Central IRB will provide timely written notice, usually within 10 working days, of IRB determinations to the {Name of Local VA Facility} of all actions involving the conduct of the project at {Name of Local VA Facility}. This includes, but is not limited to, VA Central IRB's contingent approvals and requested modifications for a project, the final project approval, and continuing reviews.
 - 10. The VA Central IRB will notify facilities when signed copies of approved minutes are posted on the VA Central IRB SharePoint site.
 - 11. The VA Central IRB will provide a copy of the annual evaluation of the VHA Central Office HRPP to the {Name of Local VA Facility} in accordance with VA Central IRB Standard Operating Procedures.
 - 12. VA Central IRB oversight of approved projects will include, but not be limited to:
 - a. Reviewing serious adverse events, unanticipated problems involving risks to subjects or others, protocol deviations, complaints, local Research Compliance Officer (RCO) audit reports, and any audit reports from sponsors, VA oversight bodies or other oversight agencies, regarding projects for which the VA Central IRB is serving as the IRB of record in accordance with VHA Handbooks 1058.01 and 1200.05.
 - b. Working closely with the {Name of Local VA Facility} to investigate and make required IRB determinations, if applicable, regarding:
 - i. Any complaints from subjects or others;
 - ii. Apparent serious or continuing noncompliance;
 - iii. Unanticipated problems involving risks to subjects or others;
 - iv. Unanticipated serious adverse events (whether related or unrelated to the research); and
 - v. Suspension or termination of research project activities;

13. The VA Central IRB will work closely with the {Name of Local VA Facility} to ensure the {Name of Local VA Facility} Facility Director receives information necessary to comply with required reporting to ORO and facilitate prompt reporting to regulatory agencies in accordance with VA Central IRB SOPs, local site SOPs, and all VA and other Federal requirements.
14. If the VA Central IRB determines a given project does not constitute research, does not constitute human research, or that a particular site is not engaged in human subjects research pertaining to that project, it will provide written correspondence concerning its decision to the Principal Investigator (PI) and to each VA site referenced in the materials provided for review.
15. If the VA Central IRB determines that a given project is exempt from IRB review, it will provide written correspondence concerning its decision to the PI and forward a copy to each local site involved in the project as listed in the submitted materials.
16. The VA Central IRB will distribute correspondence through its secure SharePoint site or via e-mail. Documents placed on its SharePoint site will be uploaded to the specific project folder, site folder, or site liaison folder. The VA Central IRB then will send an unencrypted e-mail to the applicable project and/or local site points of contact notifying them that the documents are available for review and/or download. The VA Central IRB will grant access to the local SharePoint site to the local site officials as designated in Section D.21. of this MOU, as well as to the local RCO, R&D Committee Coordinator, and ISO.
17. The VA Central IRB Administrative Office will maintain a website that contains the VA Central IRB SOPs, application forms, application submission instructions, a list of local VA facilities and NPCs that have designated the VA Central IRB as an IRB of record, VA Central IRB meeting dates, and other relevant information about the VHA Central Office HRPP and the VA Central IRB.
18. The VHA Central Office HRPP will seek feedback from the PI, LSIs, participating local VA facilities on the efficiency and effectiveness of VA Central IRB operations as part of the continuous quality improvement process.
19. The VA Central IRB Administrative Office will maintain all project documentation, membership documents, and other relevant records in accordance with VA Central IRB SOPs, and all VA and other Federal requirements.

- a. The VA Central IRB Administrative Office will provide {Name of Local VA Facility} and the VA ORO ready access to pertinent VA Central IRB records, documents, or reports relevant to compliance reviews for review and/or copying as needed.
- b. The VA Central IRB Administrative Office will provide information to support any VA HRPP accreditation review, regulatory requirement, or any matter concerned with the oversight of VA Central IRB-approved projects and oversight of the local HRPP.

D. RESPONSIBILITIES OF {NAME OF LOCAL VA FACILITY}

The {Name of Local VA Facility}'s Institutional Official assures the VHA Central Office HRPP that {Name of Local VA Facility} will assume the following responsibilities in accordance with all applicable VA and other Federal requirements. {Name of Local VA Facility} will:

- 1. Retain ultimate responsibility for oversight of its local HRPP including but not limited to:
 - a. Ensuring that all human subjects research approved or determined exempt by the VA Central IRB that involves the local site is submitted to the local site R&D Committee for review.
 - b. Safeguarding the rights and welfare of human subjects of all research approved by its R&D Committee.
 - c. Educating the members of its research community to establish and maintain a culture of compliance with all VA and other Federal requirements, as well as all {Name of Local VA Facility} requirements relevant to the protection of human subjects.
 - d. Instituting appropriate local oversight mechanisms to ensure compliance with the determinations of the VA Central IRB. This includes performing routine compliance audits and monitoring of locally conducted VA Central IRB-approved projects, and reporting results of these auditing and monitoring activities to the VA Central IRB as appropriate, in accordance with VHA policy, and local and VA Central IRB SOPs. This includes routine and other compliance audits conducted by the local RCO, as well as any special audit requests made by the VA Central IRB as part of its oversight responsibilities for projects for which it serves as the IRB of record.
 - e. Promptly informing the VA Central IRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others;

unanticipated serious adverse events; suspension or termination of research activities; and/or apparent serious or continuing noncompliance encountered in VA human subjects research projects overseen by the VA Central IRB.

- f. The {Name of Local VA Facility} will work with the VA Central IRB to ensure all VA and other Federal reporting requirements are met including, but not limited to, those specified in VHA Handbook 1058.01, Research Compliance Reporting Requirements.
 - g. Advising the VA Central IRB of any investigator conflict of interest issues of which it becomes aware.
 - h. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and the VA Facility Privacy Officer any unauthorized use, loss, or disclosure of individually identifiable information in research overseen by the VA Central IRB.
 - i. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and VAMC ISO any violations of VA information security requirements of which it becomes aware in research overseen by the VA Central IRB.
- 2. Modify its existing FWA, through ORO per VHA Handbook 1058.03, to designate the VA Central IRB as an IRB of record, maintain currency and validity of the VA FWA, and advise the VA Central IRB of any changes in the status of the FWA.
 - a. If the {Name of Local VA Facility} uses one or more of its local academic affiliate's IRBs as an IRB of record, the {Name of Local VA Facility} will review the relevant MOU {Name of Local VA Facility} holds with its academic affiliate and, if necessary, modify the MOU between {Name of Local VA Facility} and its academic affiliate to describe the respective jurisdiction and oversight of each IRB.
 - b. If the {Name of Local VA Facility} uses the services of another VA facility's Research and Development Committee, then {Name of Local VA Facility} will review the relevant MOU with the other VA facility and, if necessary, modify the MOU to extend Research and Development Committee oversight to the VA Central IRB.
- 3. Communicate with NPC staff to assist the NPC in maintaining validity of the NPC FWA.
- 4. Maintain documentation that all training, credentialing, and applicable privileging and scope of practice statements required to perform VA

research are current for all local HRPP staff and for all local research team members of VA Central IRB-approved projects.

5. Work with the LSIs in preparing the initial LSI Application to participate in any research project that has been designated for review by the VA Central IRB. The LSI will submit the LSI Application to the PI or SC and through the local Associate Chief of Staff (ACOS) for R&D (or equivalent). The PI or SC will be responsible for submitting the LSI Application to the VA Central IRB.
6. Provide comments and/or suggestions to the VA Central IRB about the VA Central IRB's initial review determinations regarding a new project within 15 calendar days from the date of receipt of the VA Central IRB request for local comment.
7. Ensure that the project is not initiated until it has been approved by the VA Central IRB, and the requirements of VHA Handbook 1200.01 as well as other VA and local requirements have been met.
8. Forward any Freedom of Information Act (FOIA) requests received by {Name of Local VA Facility} for any records concerning VA Central IRB documents to the VHA Central Office FOIA Officer for review and release as applicable.
9. Agree not to independently modify any VA Central IRB-approved protocol except where necessary to eliminate apparent immediate hazards to the human subjects in accordance with 21 CFR 56.108(a) and 38 CFR 16.103(b)(4) and notify the VA Central IRB within 5 working days if such an action is taken.
10. The VA Central IRB does not review emergency use of test articles. Such use must be reviewed at the local level in accordance with the {Name of Local VA Facility}'s policies and procedures.
11. Notify the VA Central IRB immediately of apparent research impropriety, suspension, debarment, or restriction of any local research team member associated with a VA Central IRB-approved project.
12. Provide the VA Central IRB (including VA Central IRB members, staff, or designees) access to all relevant research project records if required as part of any oversight or monitoring of the VHA Central Office HRPP or the VA Central IRB. These records include, but are not limited to, facility research records, sponsor agreements, and all investigator records including but not limited to data files, regulatory files/binders, case report forms, sponsor queries, internal and external monitoring reports, and

research subjects' clinical records and/or case files as required for VA Central IRB oversight or monitoring activities.

13. Cooperate with the VHA Central Office in its preparation of the annual review of the VHA Central Office HRPP in accordance with VA Central IRB SOPs.
14. Include the VA Central IRB in the {Name of Local VA Facility} local R&D Committee's review and evaluation of its subcommittees in accordance with VHA Handbook 1200.01.
15. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects. {Name of Local VA Facility} should consult its VA Regional Counsel Office or Office of General Counsel as needed.
16. Provide procedures for coordinating approval of local committees including but not limited to the R&D Committee, Radiation Safety Committee, Biosafety Committee, Institutional Animal Care and Use Committee (IACUC), and/or any other relevant local committees in accordance with local SOPs.
17. Maintain a file on each VA Central IRB-approved project. The contents of the file will include the PI/SC New Project Application, the {Name of Local VA Facility}'s LSI Application if applicable, VA Central IRB-approved consent form that will be used locally, other documents associated with the initial application, VA Central IRB final approval documents, {Name of Local VA Facility} R&D Committee approvals, local audits and monitoring reports, and all correspondence, amendments, continuing review reports and approvals, and any other pertinent documents. Maintain records until disposition instructions are approved by the National Archives and Records Administration and are published in the VHA's Records Control Schedule (RCS 10-1).
18. Maintain current written SOPs that incorporate {Name of Local VA Facility}'s specific responsibilities when submitting applications to and conducting research overseen by the VA Central IRB as an IRB of Record as outlined in this MOU.
19. Comply with all VA Central IRB SOPs as applicable.
20. The {Name of Local VA Facility} will not:
 - a. Submit a LSI Application for a specific project to the VA Central IRB if another IRB of record for {Name of Local VA Facility} has already disapproved that VA facility's participation in the project.

- b. Submit an application to another IRB of record for review if the VA Central IRB has disapproved the application.
- 21. The {Name of Local VA Facility}'s Institutional Official will provide a letter to VA Central IRB Administrative Office designating in writing which local official [e.g., Associate Chief of Staff for Research and Development (ACOS for R&D), Administrative Officer for R&D, R&D Committee Chair, local VA IRB Chair] is authorized to perform each of the following functions on behalf of {Name of Local VA Facility} (NOTE: One local official may have authority to perform both functions, or each function may be delegated to a different local official). The appointment letter must also include the names and contact information for each designated local official, including what function each official is performing if more than one is appointed.
 - a. Providing comments and/or suggestions to the VA Central IRB in response to the VA Central IRB initial review determinations.
 - b. Serving as the local site liaison to the VA Central IRB. This individual will serve as the main point of contact for the VA Central IRB for communicating VA Central IRB determinations and other issues requiring local site response and/or review.

E. RESPONSIBILITIES OF THE NPC

- 1. The NPC is entering into this MOU under the authority of 38 U.S.C. §§ 7361-66 and VHA Handbook 1200.17.
- 2. The NPC is a flexible funding mechanism of {Name of Local VA Facility} for the conduct of, and to facilitate functions related to the conduct of, approved VA research and education. Each research project approved by a {Name of Local VA Facility} is considered to be a VA research project regardless of the source of funding, the entity administering the funds, or the research site.
- 3. The NPC will modify its existing FWA to designate the VA Central IRB as an additional IRB of record. The NPC will maintain the accuracy of the existing FWA with respect to its Institutional Official and Human Protections Administrator. The NPC agrees to comply with VHA Handbook 1058.03 requirements to update the FWA within 30 days of a change in these officials.
- 4. The NPC agrees to manage and facilitate actions and documentation related to applicable research projects with {Name of Local VA Facility} and the VA Central IRB. Such coordination may involve assisting local

{Name of Local VA Facility} employees and the R&D Committee with research project related actions and documentation.

5. When applicable, if required as part of any VA Central IRB oversight or monitoring, the NPC shall grant the VA Central IRB (including any VA Central IRB member, administrative staff member, or designee) access to all relevant research project records at the premise of an NPC. These records include, but are not limited to, data files, regulatory files/binders, case report forms, internal and external monitoring reports, as well as the research subjects' clinical records and/or case files.
6. The NPC through the local VA Facility Research Office will maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

F. TERMINATION PROVISIONS

1. This MOU may be terminated by the {Name of Local VA Facility}, or the VHA Central Office HRPP without cause by giving a 60 day advance written notice of termination to the other institutions and to ORO. The 60 day notice period will not start until receipt of the written notice by the other party. The agreement may be terminated for cause only under the direction and guidance of ORO. {NPC} may withdraw from this MOU by giving notice to the {Name of Local VA Facility} and VA Central IRB in writing. Subsequently within 30 days of the NPC's notice, the NPC shall execute an amendment to this document identifying its immediate withdrawal. NPC's withdrawal amendment will not impact the requirements between {Name of Local VA Facility} and VA Central IRB identified in this document.
2. All current and active research projects will continue to be monitored under the provisions of the agreement until all VA Central IRB-approved projects active at the {Name of Local VA Facility} have been closed or safely moved to another site. The {Name of Local VA Facility} will maintain all documentation regarding the site's participation in the project in accordance with the time frames specified in VA and other Federal requirements.

Signature Page:

Signature of Local VA Facility Director
Name of Local VA Facility Director
Name of Local VA Facility
Local VA Facility Address

Date: _____

Signature of Network Director
Name of Network Director
Network Name
Network Address

Date: _____

Signature of Local NPC Institutional Official
Name of Local NPC Institutional Official
Name of Local NPC
Local NPC Address

Date: _____

Holly Birdsall, M.D.
Deputy Chief Research and Development Officer
as VHA Central Office Human Protections Administrator
on behalf of VHA Central Office HRPP Institutional Official
Office of Research and Development (10P9)
810 Vermont Avenue, NW
Washington, DC 20420

Date: _____

Memorandum of Understanding



MEMORANDUM OF UNDERSTANDING

BETWEEN

VETERANS HEALTH ADMINISTRATION (VHA)
CENTRAL OFFICE

AND

{NAME OF LOCAL VETERANS AFFAIRS (VA) FACILITY}

A. PURPOSE

1. This Memorandum of Understanding (MOU) sets forth the agreed upon respective authorities, roles, and responsibilities of the Veterans Health Administration (VHA) Central Office, operating the VA Central Office Institutional Review Board (IRB), hereinafter referred to as the VA Central IRB, and the {Name of Local VA Facility} for the VA Central IRB to serve as an additional IRB of Record for {Name of Local VA Facility}.
2. This MOU does not preclude {Name of Local VA Facility} from continuing to participate in any existing agreements the {Name of Local VA Facility} may have with other VA or non-VA entities. This MOU is between the signatories only and does not include any other entities that are independently operating under their own Federalwide Assurances (FWAs), and it specifically excludes other entities with which {Name of Local VA Facility} may have a separate MOU for IRB and/or Research and Development (R&D) Committee services.

B. GENERAL PROVISIONS

1. The conduct of the parties will be guided by the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" as set forth in The Belmont Report, published by the National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research in April 1979.

2. VHA employees conducting or reviewing research are subject to the Federal Criminal Code and the Standards of Ethical Conduct for Executive Branch Employees. The obligation to act in accordance with ethics laws and regulations applies to all individuals while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and employees under the Intergovernmental Personnel Act (IPA) of 1970. Ethics officials in the Office of General Counsel are available to provide guidance on dealing with actual or potential conflicts of interest. Both VA Central IRB and the {Name of Local VA Facility} will implement current VHA policies related to conflict of interest and notify the VA Central IRB of any issues they identify. The VA Central IRB will review these issues and take appropriate measures to address them.
3. Parties will adhere to 38 CFR 16 and 17, 21 CFR 50 and 56; and other pertinent VA and Federal requirements applicable to human subjects research, including VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research. The VA Central IRB or the {Name of Local VA Facility} will not approve a research project if it does not meet all these requirements. VHA Handbook 1200.05 will serve as the reference source for the definitions of all terms used in this MOU.
4. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR 164.512(i), and VHA Handbook 1605.01, Privacy and Release of Information, the VA Central IRB may grant a HIPAA Waiver of Authorization for use or disclosure of protected health information (PHI) for research reviewed by the VA Central IRB, if justified and if all criteria for a waiver of authorization are met. The VA Central IRB must document these findings as required by 45 CFR 164.512(i).
5. The VA Central IRB Privacy Officer and Information Security Officer (ISO) Representatives will perform the required privacy and information security reviews. The local Privacy Officer does not conduct a separate privacy review of studies overseen by the VA Central IRB. However, the local ISO may need to review some studies overseen by the VA Central IRB due to local project-specific information security issues. In those cases the VA Central IRB ISO works with the local ISO to address the issues.
6. The VHA Central Office and the {Name of Local VA Facility} will each maintain a current FWA through the VA Office of Research Oversight (ORO) and the Department of Health and Human Services Office for Human Research Protections (OHRP) listing the VA Central IRB as an IRB of record. Any lapse in approval, restriction, suspension, termination,

or failure to maintain an approved FWA by any of the parties to this MOU will be reported to the others immediately in writing.

7. Both the VHA Central Office and the {Name of Local VA Facility} will secure and maintain accreditation of their Human Research Protection Programs (HRPPs) through the VA-designated accrediting organization in accordance with VA requirements.
8. There will be no charge to the {Name of Local VA Facility} or to investigators for the use of the VA Central IRB.
9. This agreement will go into effect the date of signature of the VHA Central Office Institutional Official's designee and will remain in effect until terminated per this agreement or the agreement is amended and/or revised per mutual agreement of all Institutions. This MOU must be reviewed and revised as conditions change and renewed every 5 years. The MOU must be amended when there is a change in any of the signatory officials, with a copy of the amendment sent to ORO per VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

C. RESPONSIBILITIES OF THE VHA CENTRAL OFFICE HRPP AND VA CENTRAL IRB

The VHA Central Office HRPP assures {Name of Local VA Facility} that the VHA Central Office HRPP and VA Central IRB will carry out the following functions and responsibilities in accordance with all applicable requirements:

1. The Institutional Official will ensure that the VA Central IRB is provided, through the Chief Research and Development Officer (CRADO), with sufficient resources to support its operations. These resources will include, but not be limited to, adequate meeting space, equipment, financial support, and staff.
2. The VA Central IRB will maintain a current OHRP IRB registration in accordance with the requirements specified in VHA Handbooks 1200.05 and 1058.03.
3. All VA Central IRB members and staff will receive appropriate initial and ongoing training with regard to VA and other Federal requirements for the protection of human subjects.
4. In coordination with counsel, the VA Central IRB will ensure compliance of any conflicts of interest of IRB members in accordance with criminal

conflict of interest laws and Standards of Ethical Conduct for Executive Branch employees.

5. The VHA Central Office HRPP will maintain policies and Standard Operating Procedures (SOPs) that incorporate by inclusion or reference, Federal statutes and regulations, as well as VA, VHA, and other requirements applicable to reviewing human subjects research.
6. The VA Central IRB will meet a minimum of once a month, and can meet more often if determined necessary by the VA Central IRB Co-Chairs and VA Central IRB administrative staff. Members will attend in-person or via audio or video conference. If the Co-Chairs and administrative staff determine there are no agenda items that require action by the convened IRB, the scheduled meeting may be cancelled.
7. The VA Central IRB will perform initial and continuing review of selected multi-site research projects.
8. The VA Central IRB will evaluate local context for each project submitted using one or more of the following methods:
 - a. Reviewing the {Name of Local VA Facility}'s Local Site Investigator (LSI) Application (VA Central IRB Form 104), and any additional information submitted by the LSI, or the {Name of Local VA Facility}.
 - b. Knowledge of the local research context by one or more of VA Central IRB members or staff. Such knowledge may have been obtained through direct experience with the {Name of Local VA Facility}, its subject populations, and/or the local community.
 - c. Obtaining relevant information from an appropriate ad hoc advisor(s) who has had direct experience with the {Name of Local VA Facility} its subject populations, and/or the local community.
 - d. Systematic, reciprocal, and documented communication between the VA Central IRB and {Name of Local VA Facility}. This communication will include regular interactions with one or more designated site liaisons by one or more VA Central IRB members or administrative staff and/or periodic visits to the {Name of Local VA Facility}, as prescribed by VA Central IRB and {Name of Local VA Facility}'s SOPs.
9. The VA Central IRB will provide timely written notice, usually within 10 working days, of IRB determinations to the {Name of Local VA Facility} of all actions involving the conduct of the project at {Name of Local VA

Facility}. This includes, but is not limited to, VA Central IRB's contingent approvals and requested modifications for a project, the final project approval, and continuing reviews.

10. The VA Central IRB will notify facilities when signed copies of approved minutes are posted on the VA Central IRB SharePoint site.
11. The VA Central IRB will provide a copy of the annual evaluation of the VHA Central Office HRPP to the {Name of Local VA Facility} in accordance with VA Central IRB Standard Operating Procedures.
12. VA Central IRB oversight of approved projects will include, but not be limited to:
 - a. Reviewing serious adverse events, unanticipated problems involving risks to subjects or others, protocol deviations, complaints, local Research Compliance Officer (RCO) audit reports, and any audit reports from sponsors, VA oversight bodies or other oversight agencies, regarding projects for which the VA Central IRB is serving as the IRB of record in accordance with VHA Handbooks 1058.01 and 1200.05.
 - b. Working closely with the {Name of Local VA Facility} to investigate and make required IRB determinations, if applicable, regarding:
 - i. Any complaints from subjects or others;
 - ii. Apparent serious or continuing noncompliance;
 - iii. Unanticipated problems involving risks to subjects or others;
 - iv. Unanticipated serious adverse events (whether related or unrelated to the research); and
 - v. Suspension or termination of research project activities;
13. The VA Central IRB will work closely with the {Name of Local VA Facility} to ensure the {Name of Local VA Facility} Facility Director receives information necessary to comply with required reporting to ORO and facilitate prompt reporting to regulatory agencies in accordance with VA Central IRB SOPs, local site SOPs, and all VA and other Federal requirements.
14. If the VA Central IRB determines a given project does not constitute research, does not constitute human research, or that a particular site is not engaged in human subjects research pertaining to that project, it will

provide written correspondence concerning its decision to the Principal Investigator (PI) and to each VA site referenced in the materials provided for review.

15. If the VA Central IRB determines that a given project is exempt from IRB review, it will provide written correspondence concerning its decision to the PI and forward a copy to each local site involved in the project as listed in the submitted materials.
16. The VA Central IRB will distribute correspondence through its secure SharePoint site or via e-mail. Documents placed on its SharePoint site will be uploaded to the specific project folder, site folder, or site liaison folder. The VA Central IRB then will send an unencrypted e-mail to the applicable project and/or local site points of contact notifying them that the documents are available for review and/or download. The VA Central IRB will grant access to the local SharePoint site to the local site officials as designated in Section D.21. of this MOU, as well as to the local RCO, R&D Committee Coordinator, and ISO.
17. The VA Central IRB Administrative Office will maintain a website that contains the VA Central IRB SOPs, application forms, application submission instructions, and a list of local VA facilities that have designated the VA Central IRB as an IRB of record, VA Central IRB meeting dates, and other relevant information about the VHA Central Office HRPP and the VA Central IRB.
18. The VHA Central Office HRPP will seek feedback from the PI, LSIs, participating local VA facilities on the efficiency and effectiveness of VA Central IRB operations as part of the continuous quality improvement process.
19. The VA Central IRB Administrative Office will maintain all project documentation, membership documents, and other relevant records in accordance with VA Central IRB SOPs, and all VA and other Federal requirements.
 - a. The VA Central IRB Administrative Office will provide {Name of Local VA Facility} and the VA ORO ready access to pertinent VA Central IRB records, documents, or reports relevant to compliance reviews for review and/or copying as needed.
 - b. The VA Central IRB Administrative Office will provide information to support any VA HRPP accreditation review, regulatory requirement, or any matter concerned with the oversight of VA Central IRB-approved projects and oversight of the local HRPP.

D. RESPONSIBILITIES OF {NAME OF LOCAL VA FACILITY}

The {Name of Local VA Facility}'s Institutional Official assures the VHA Central Office HRPP that {Name of Local VA Facility} will assume the following responsibilities in accordance with all applicable VA and other Federal requirements. {Name of Local VA Facility} will:

1. Retain ultimate responsibility for oversight of its local HRPP including but not limited to:
 - a. Ensuring that all human subjects research approved or determined exempt by the VA Central IRB that involves the local site is submitted to the local site R&D Committee for review.
 - b. Safeguarding the rights and welfare of human subjects of all research approved by its R&D Committee.
 - c. Educating the members of its research community to establish and maintain a culture of compliance with all VA and other Federal requirements, as well as all {Name of Local VA Facility} requirements relevant to the protection of human subjects.
 - d. Instituting appropriate local oversight mechanisms to ensure compliance with the determinations of the VA Central IRB. This includes performing routine compliance audits and monitoring of locally conducted VA Central IRB-approved projects, and reporting results of these auditing and monitoring activities to the VA Central IRB as appropriate, in accordance with VHA policy, and local and VA Central IRB SOPs. This includes routine and other compliance audits conducted by the local RCO, as well as any special audit requests made by the VA Central IRB as part of its oversight responsibilities for projects for which it serves as the IRB of record.
 - e. Promptly informing the VA Central IRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; unanticipated serious adverse events; suspension or termination of research activities; and/or apparent serious or continuing noncompliance encountered in VA human subjects research projects overseen by the VA Central IRB.
 - f. The {Name of Local VA Facility} will work with the VA Central IRB to ensure all VA and other Federal reporting requirements are met including, but not limited to, those specified in VHA Handbook 1058.01, Research Compliance Reporting Requirements.

- g. Advising the VA Central IRB of any investigator conflict of interest issues of which it becomes aware.
 - h. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and the VA Facility Privacy Officer any unauthorized use, loss, or disclosure of individually identifiable information in research overseen by the VA Central IRB.
 - i. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and VAMC ISO any violations of VA information security requirements of which it becomes aware in research overseen by the VA Central IRB.
2. Modify its existing FWA, through ORO per VHA Handbook 1058.03, to designate the VA Central IRB as an IRB of record, maintain currency and validity of the VA FWA, and advise the VA Central IRB of any changes in the status of the FWA.
 - a. If the {Name of Local VA Facility} uses one or more of its local academic affiliate's IRBs as an IRB of record, the {Name of Local VA Facility} will review the relevant MOU {Name of Local VA Facility} holds with its academic affiliate and, if necessary, modify the MOU between {Name of Local VA Facility} and its academic affiliate to describe the respective jurisdiction and oversight of each IRB.
 - b. If the {Name of Local VA Facility} uses the services of another VA facility's Research and Development Committee, then {Name of Local VA Facility} will review the relevant MOU with the other VA facility and, if necessary, modify the MOU to extend Research and Development Committee oversight to the VA Central IRB.
 3. Maintain documentation that all training, credentialing, and applicable privileging and scope of practice statements required to perform VA research are current for all local HRPP staff and for all local research team members of VA Central IRB-approved projects.
 4. Work with the LSIs in preparing the initial LSI Application to participate in any research project that has been designated for review by the VA Central IRB. The LSI will submit the LSI Application to the PI or SC and through the local Associate Chief of Staff (ACOS) for R&D (or equivalent). The PI or SC will be responsible for submitting the LSI Application to the VA Central IRB.
 5. Provide comments and/or suggestions to the VA Central IRB about the VA Central IRB's initial review determinations regarding a new project within

15 calendar days from the date of receipt of the VA Central IRB request for local comment.

6. Ensure that the project is not initiated until it has been approved by the VA Central IRB, and the requirements of VHA Handbook 1200.01 as well as other VA and local requirements have been met.
7. Forward any Freedom of Information Act (FOIA) requests received by {Name of Local VA Facility} for any records concerning VA Central IRB documents to the VHA Central Office FOIA Officer for review and release as applicable.
8. Agree not to independently modify any VA Central IRB-approved protocol except where necessary to eliminate apparent immediate hazards to the human subjects in accordance with 21 CFR 56.108(a) and 38 CFR 16.103(b)(4) and notify the VA Central IRB within 5 working days if such an action is taken.
9. The VA Central IRB does not review emergency use of test articles. Such use must be reviewed at the local level in accordance with the {Name of Local VA Facility}'s policies and procedures.
10. Notify the VA Central IRB immediately of apparent research impropriety, suspension, debarment, or restriction of any local research team member associated with a VA Central IRB-approved project.
11. Provide the VA Central IRB (including VA Central IRB members, staff, or designees) access to all relevant research project records if required as part of any oversight or monitoring of the VHA Central Office HRPP or the VA Central IRB. These records include, but are not limited to, facility research records, sponsor agreements, and all investigator records including but not limited to data files, regulatory files/binders, case report forms, sponsor queries, internal and external monitoring reports, and research subjects' clinical records and/or case files as required for VA Central IRB oversight or monitoring activities.
12. Cooperate with the VHA Central Office in its preparation of the annual review of the VHA Central Office HRPP in accordance with VA Central IRB SOPs.
13. Include the VA Central IRB in the {Name of Local VA Facility} local R&D Committee's review and evaluation of its subcommittees in accordance with VHA Handbook 1200.01.
14. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects. {Name of Local

VA Facility} should consult its VA Regional Counsel Office or Office of General Counsel as needed.

15. Provide procedures for coordinating approval of local committees including but not limited to the R&D Committee, Radiation Safety Committee, Biosafety Committee, Institutional Animal Care and Use Committee (IACUC), and/or any other relevant local committees in accordance with local SOPs.
16. Maintain a file on each VA Central IRB-approved project. The contents of the file will include the PI/SC New Project Application, the {Name of Local VA Facility}'s LSI Application if applicable, VA Central IRB-approved consent form that will be used locally, other documents associated with the initial application, VA Central IRB final approval documents, {Name of Local VA Facility} R&D Committee approvals, local audits and monitoring reports, and all correspondence, amendments, continuing review reports and approvals, and any other pertinent documents. Maintain records until disposition instructions are approved by the National Archives and Records Administration and are published in the VHA's Records Control Schedule (RCS 10-1).
17. Maintain current written SOPs that incorporate {Name of Local VA Facility}'s specific responsibilities when submitting applications to and conducting research overseen by the VA Central IRB as an IRB of Record as outlined in this MOU.
18. Comply with all VA Central IRB SOPs as applicable.
19. The {Name of Local VA Facility} will not:
 - a. Submit a LSI Application for a specific project to the VA Central IRB if another IRB of record for {Name of Local VA Facility} has already disapproved that VA facility's participation in the project.
 - b. Submit an application to another IRB of record for review if the VA Central IRB has disapproved the application.
20. The {Name of Local VA Facility}'s Institutional Official will provide a letter to VA Central IRB Administrative Office designating in writing which local official [e.g., Associate Chief of Staff for Research and Development (ACOS for R&D), Administrative Officer for R&D, R&D Committee Chair, local VA IRB Chair] is authorized to perform each of the following functions on behalf of {Name of Local VA Facility} (NOTE: One local official may have authority to perform both functions, or each function may be delegated to a different local official). The appointment letter must also include the names and contact information for each designated local

official, including what function each official is performing if more than one is appointed.

- a. Providing comments and/or suggestions to the VA Central IRB in response to the VA Central IRB initial review determinations.
- b. Serving as the local site liaison to the VA Central IRB. This individual will serve as the main point of contact for the VA Central IRB for communicating VA Central IRB determinations and other issues requiring local site response and/or review.

E. TERMINATION PROVISIONS

1. This MOU may be terminated by the {Name of Local VA Facility}, or the VHA Central Office HRPP without cause by giving a 60 day advance written notice of termination to the other institutions and to ORO. The 60 day notice period will not start until receipt of the written notice by the other party. The agreement may be terminated for cause only under the direction and guidance of ORO. .
2. All current and active research projects will continue to be monitored under the provisions of the agreement until all VA Central IRB-approved projects active at the {Name of Local VA Facility} have been closed or safely moved to another site. The {Name of Local VA Facility} will maintain all documentation regarding the site's participation in the project in accordance with the time frames specified in VA and other Federal requirements.

Signature Page:

Signature of Local VA Facility Director
Name of Local VA Facility Director
Name of Local VA Facility
Local VA Facility Address

Date: _____

Signature of Network Director
Name of Network Director
Network Name
Network Address

Date: _____

Holly Birdsall, M.D.
Director, Program for Research Integrity Development and Education (PRIDE)
as VHA Central Office Human Protections Administrator
on behalf of VHA Central Office HRPP Institutional Official
Office of Research and Development (10P9)
810 Vermont Avenue, NW
Washington, DC 20420

Date: _____

Amendment to Memorandum Of Understanding (MOU)



This amendment is to be completed when a Signatory Official to the Memorandum of Understanding (MOU) Between the VHA Central Office and the Local VA Medical Facility and/or its Associated Non-Profit Corporation (NPC) changes.

I. Facility/Organization Information

Date of MOU:

Amendment Number:

Facility/ Organization Name:

Name of New Institutional Official:

For NPCs Only:

Institutional Official's Contact Information:

Associated VA Facility:

Telephone:

Facility/Organization Address:

Line 1:

Email:

Line 2:

Line 3:

Fax:

II. Institutional Official's Certification

As the Institutional Official for the above named Institution, I certify that I have read the terms of the Memorandum of Understanding between our Facility/Organization and the VHA Central Office concerning the use of the VA Central IRB as one of our IRBs of Record. No changes are required to the current agreement.

Signature of Institutional Official

Date of Amendment

Printed Name of Institutional Official

Forward the completed, signed form to the VA Central IRB Administration Office by sending a PDF copy to the VA Central IRB Administrator, faxing a copy to 202-495-6155, or sending via an express courier service to the VA Central IRB, Office of Research and Development (10P9P), 810 Vermont Avenue, Washington, DC 20420.