

# 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, which consists of one or more appropriately constituted IRB panels, and the {Name of Local VA Facility} and the {Name of Local VA Facility Nonprofit Corporation} (NPC) for the VA Central IRB panels to serve as additional IRB(s) 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 obligate or place limitations on any other entities not party to this MOU. This MOU 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.

3. This MOU also distinguishes, as applicable, between the overall Principal Investigator (PI) or Study Chair (SC) and participating Local Site Investigators (LSIs). The responsibilities of Local Site Liaisons (LSLs) are also described.

## **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 the VA Central IRB and the {Name of Local VA Facility} will implement current VHA policies related to conflict of interest. The VA Central IRB will ensure that the facility and/or the Office of General Counsel has/have addressed any identified conflicts with the investigator prior to approving the study. 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 Directive 1200.05, Requirements for the Protection of Human Subjects in Research. The parties will ensure that all VA requirements for informed consent are met, including specific indemnification and notification language. Neither the VA Central IRB nor the {Name of Local VA Facility} may approve a research project if it does not meet all these requirements unless there is an appropriately approved exception to policy. VHA Directive 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) Privacy Rule, 45 CFR 164.512(i), and VHA Directive 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). The VA Central IRB will also ensure the HIPAA authorization is consistent with the informed consent document.

5. The VA Central IRB Privacy Officer and Information System Security Officer (ISSO) 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 ISSO 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 ISSO Representative will work with the local ISSO 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 all applicable panels of the VA Central IRB as IRBs 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 other party immediately in writing.
7. Both the VHA Central Office, the {Name of Local VA Facility}, and the NPC will maintain their Human Research Protection Programs (HRPPs) per VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.
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 when reviewing VA-funded or sponsored studies. There may be charges to non-VA institutions or sponsors when the VA Central IRB reviews non-VA funded or non-VA sponsored research.
9. This agreement will go into effect on the date of signature of the VHA Central Office Institutional Official's designee, who will sign the agreement after it has been signed and returned by the facility and NPC Institutional Officials 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 or otherwise renewed without changes every five years. The MOU will remain in effect through changes in signatory officials if no

revisions (e.g., as required by local policy, or as required by a new signatory official) have occurred during the five-year approval cycle.

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

The VHA Central Office has established policies and procedures through the HRPP to assure {Name of Local VA Facility} and the 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 VHA Central Office 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, administrative staff, and experienced IRB members to accomplish the workload in an efficient and regulatory compliant manner.
2. The VA Central IRB will maintain current OHRP IRB registrations for all active panels in accordance with the requirements specified in VHA Directive 1200.05 and VHA Handbook 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 as outlined in the VA Central IRB SOPs. IRB voting members are appointed by ORD from among the VA facilities, with the exception of the non-affiliated members, who will be appointed from the local communities.
4. In coordination with counsel, the VA Central IRB will ensure compliance of any conflicts of interest management plans 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. Each VA Central IRB panel will be scheduled to meet a minimum of twice a month. The VA Central IRB can meet more often if determined necessary by the Co-Chairs of the IRB panels and VA Central IRB administrative staff. Most meetings are held via audio or video conference with in-person meetings and training sessions held twice a year if the

budget permits. If the Co-Chairs and administrative staff determine there are no agenda items that require immediate action by the convened IRB, a scheduled meeting may be cancelled. Meetings may also be cancelled due to local or national emergencies.

7. The VA Central IRB will perform initial, and continuing review if required, of selected multi-site research projects in which two or more facilities are engaged in the research, with some exceptions in which it may review a study when only one site is currently engaged but the study will likely add additional sites in the future. The number and types of studies accepted for review may vary depending upon the VA Central IRB's workload and available resources. The VA Central IRB website will have the most current information concerning the types of projects accepted for review and how to submit a new project. This MOU does not guarantee that any number of multi-site protocols, or any specific multi-site protocols from investigators at local VA facilities will be accepted for review.
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.
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 a project at {Name of Local VA Facility}. Written notification includes, but is not limited to, VA Central IRB's contingent approvals and requested modifications for a project; the final project approval; approval of amendments; determinations made

regarding submitted serious adverse events, protocol deviations, and unanticipated problems; and continuing review approvals.

10. The VA Central IRB will notify LSL within five working days when un-redacted, signed copies of approved VA Central IRB meeting minutes are posted on the VA Central IRB SharePoint site.
11. The VA Central IRB will provide {Name of Local VA Facility} a copy of the annual self-evaluation of the VHA Central Office HRPP via upload to the VA Central IRB SharePoint site of the VHA Central Office HRPP to the {Name of Local VA Facility} in accordance with VA Central IRB Standard Operating Procedures. Notification of the upload will be sent to the designated facility LSL to the VA Central IRB.
12. VA Central IRB oversight of approved projects will also include, but not be limited to: reviewing serious adverse events, unanticipated problems involving risks to subjects or others, apparent serious noncompliance reports, 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 a panel of the VA Central IRB is serving as the IRB of record in accordance with VHA Handbook 1058.01 and VHA Directive 1200.05. The VA Central IRB will work closely with the {Name of Local VA Facility} and study teams to investigate and obtain the necessary information to make required IRB determinations.
13. The VA Central IRB will also 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, OHRP, and the Food and Drug Administration (FDA), if applicable, in order to facilitate prompt reporting in accordance with VA Central IRB SOPs, local site SOPs, and all VA and other Federal requirements.
14. The VA Central IRB will perform limited IRB review for designated multi-site exempt projects after each local site makes (or documents) the initial determination that the research meets an exempt category(ies) requiring limited IRB review. The VA CIRB will verify the exemption category and perform the review or, it may change the exemption category or indicate the project does not meet any of the exemption category criteria and that the project must undergo expedited review or convened board review. The VA Central IRB will provide written correspondence concerning its review decision to the PI and forward a copy to each local site involved in the project, if known, at the time of review as listed in the submitted materials. Amendments to exempt studies requiring limited IRB review (including the addition of sites) must only be reported to the VA Central

IRB when the amendment affects any area of the study covered under the limited IRB review.

15. The VA Central IRB will distribute correspondence through its secure SharePoint site, via e-mail, or through another designated electronic platform as described in VA Central IRB SOPs.
16. The VA Central IRB Administrative Office will maintain a website that contains the VA Central IRB SOPs, VA Central IRB submission forms, submission instructions, a list of local VA facilities that have designated the VA Central IRB panels as IRBs of record, VA Central IRB panel meeting dates, and other relevant information about the VHA Central Office HRPP and the VA Central IRB.
17. The VHA Central Office HRPP will seek feedback from the PI, LSIs, and participating local VA facilities on the efficiency and effectiveness of VA Central IRB operations as part of the continuous quality improvement process. This will be done in the form of periodic VA Central IRB Liaison feedback through webinars and surveys.
18. The VA Central IRB Administrative Office will maintain IRB files which include but are not limited to all project documentation, VA Central IRB membership documents, meeting minutes, 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 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 {Name of Local Facility} any required information to support any VA HRPP review, regulatory requirement, or any matter concerned with the oversight of VA Central IRB-approved projects and oversight of the local HRPP unless prohibited by law.

#### **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} is responsible for:

1. Retaining ultimate responsibility for oversight of its local HRPP including but not limited to:

- a. Ensuring that all human subjects research reviewed and approved by the VA Central IRB (e.g., limited, expedited or convened IRB reviews) that involves the local site is approved in accordance with local R&D requirements prior to allowing the research to begin at the local site.
- b. Safeguarding the rights and welfare of human subjects and providing support to researchers by promoting an institutional culture where research is encouraged within a framework of regulatory compliance to include federal, VA, and local requirements.
- c. Instituting appropriate local oversight mechanisms to ensure compliance with the determinations of the VA Central IRB. This includes performing routine compliance audits, monitoring of locally conducted VA Central IRB-approved projects and reporting results of these auditing and monitoring activities to the VA Central IRB as applicable, in accordance with VHA policy, and local and VA Central IRB SOPs. This pertains to routine and other compliance audits conducted by the local RCO, as well as any special audit requests made by a VA Central IRB panel as part of its oversight responsibilities for projects for which it serves as the IRB of record. It also includes reporting to the VA Central IRB the results of any external audits (FDA, OHRP, etc.) that involve studies for which the VA Central IRB serves as an IRB of Record.
  - 1) Routine RCO audits that have no immediately reportable findings requiring review by the VA Central IRB will be submitted by the RCO to the local study team who will in turn submit them to the VA Central IRB as part of the study continuing review application or, if continuing review approval is not required for a project, as part of an annual project status update required by the VA Central IRB for those studies not undergoing continuing review.
  - 2) RCOs identifying instances of apparent serious and/or continuing noncompliance will submit a report directly to the VA Central IRB in accordance with VHA Handbook 1058.01 and VA Central IRB SOPs.
  - 3) RCOs who identify an issue that is not immediately reportable or apparent serious and/or continuing noncompliance, but in their opinion requires review by the VA Central IRB, will submit the report directly to the VA Central IRB with a request for review of the specific issue.



- d. 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 that are related or probably/possibly related to the research; suspension or termination of research activities; and/or apparent serious and/or continuing noncompliance encountered in VA human subjects research projects overseen by the VA Central IRB.
  - e. The {Name of Local VA Facility} will work with the VA Central IRB to ensure all VA reporting requirements are met including, but not limited to, those specified in VHA Handbook 1058.01, Research Compliance Reporting Requirements. The {Name of the Local VA Facility}, through the local Institutional Official, will also report all reportable determinations made by the VA Central IRB to ORO, OHRP, and to the FDA, as applicable and required per each agency, after receipt of such notification from the VA Central IRB to the local Institutional Official. Copies of these external notifications will be provided to the VA Central IRB.
  - f. Advising the VA Central IRB if any investigator, or other study team member, has any conflict of interest issues of which it becomes aware regarding the research being overseen by the VA Central IRB.
  - g. 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.
  - h. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and VAMC ISSO any violations of VA information security requirements of which it becomes aware in research overseen by the VA Central IRB.
2. Maintaining its existing FWA and VA Addendum to the FWA, through ORO per VHA Handbook 1058.03. 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 to ensure that the MOU also extends that Research and Development Committee's oversight of the local facility to the VA Central IRB as one of the facility's external IRBs that is internal to the VA.
  3. Maintaining 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. Review all PI/SC applications if PI is located at {Name of facility}, as well as all local LSI applications prior to submission to the VA Central IRB to ensure that the site has the necessary resources to support the research and that the investigators are appropriately credentialed and are current in all human subjects training requirements. The PI/ SC or LSI will be responsible for submitting the PI/SC or LSI Application to the VA Central IRB. LSI Applications can only be submitted after approval of the PI/SC Application as directed by the PI/SC study team or VA Central IRB staff members.
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 Directive 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 deviate from a research activity as approved by the IRB except where necessary to eliminate apparent immediate hazards to the human subjects in accordance with 21 CFR 56.108(a), if applicable, and 38 CFR 16.108 (a)(iii) 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 or non-emergency/compassionate 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. 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 activities by 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.

11. 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.
12. 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 Special Team Advising Research (STAR) Office or Office of General Counsel as needed.
13. Ensure procedures concerning reliance on the VA Central IRB are included in local SOPs, to include ensuring appropriate communications and coordination of VA Central IRB reviews with local committees including but not limited to the R&D Committee, Radiation Safety Committee, Biosafety Committee, and/or any other relevant local committees as applicable.
14. Maintain IRB and Investigator files 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 (if applicable), other documents associated with the initial application (if applicable), VA Central IRB final approval documents, {Name of Local VA Facility} R&D Committee approvals, local audits and monitoring reports, and all correspondence, amendments, status reports/continuing review reports (if applicable) and approvals, and any other pertinent documents. All records will be maintained in accordance with the VHA's Records Control Schedule (RCS 10-1).
15. Maintain current written SOPs that incorporate {Name of Local VA Facility}'s specific responsibilities when submitting applications to and conducting research overseen by VA Central IRB panels as IRBs of Record as outlined in this MOU.
16. Comply with all VA Central IRB SOPs as applicable and respond promptly to VA Central IRB annual request to update all local facility points of contact to ensure continuous, efficient, and effective communications.
17. 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.

18. 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.
  - b. Serving as the LSL 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. Up to **one** alternate Liaison can be appointed if desired by the appointing official.

#### **E. RESPONSIBILITIES OF THE NPC**

1. The NPC is entering into this MOU under the authority of 38 U.S.C. §§ 7361-7366 and VHA Directive 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 {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 ensure that the active VA Central IRB panels have been designated as IRBs of record on its FWA. 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.
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 the 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 and in cooperation with, 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 90 day advance written notice of the intent to terminate to the other institutions and to ORO. This agreement may be amended to describe the process and timeline for termination.
2. All parties agree that the rights and welfare of subjects participating in the research must be protected. 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 IRB of record. This MOU will not be terminated until all studies under the oversight of the VA Central IRB have been safely closed or moved. 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: \_\_\_\_\_

\_\_\_\_\_  
Mary M. Klote, MD  
Director, Office of Research Protections, Policy, & Education  
as VHA Central Office Human Protections Administrator  
on behalf of VHA Central Office HRPP Institutional Official  
Office of Research and Development (10X2)  
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

4. 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, which consists of one or more appropriately constituted IRB panels, and the {Name of Local VA Facility} for the VA Central IRB panels to serve as additional IRB(s) of Record for {Name of Local VA Facility}.
5. 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 obligate or place limitations on any other entities not party to this MOU. This MOU 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.
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11. 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 the VA Central IRB and the {Name of Local VA Facility} will implement current VHA policies related to conflict of interest. The VA Central IRB will ensure that the facility and/or the Office of General Counsel has/have addressed any identified conflicts with the investigator prior to approving the study.
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13. In accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR 164.512(i), and VHA Directive 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). The VA Central IRB will also ensure the HIPAA authorization is consistent with the informed consent document.
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separate privacy review of studies overseen by the VA Central IRB. However, the local ISSO 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 ISSO Representative will work with the local ISSO to address the issues.

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18. This agreement will go into effect on the date of signature of the VHA Central Office Institutional Official's designee, who will sign the agreement after it has been signed and returned by the facility Institutional Official 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 or otherwise renewed without changes every five years. The MOU will remain in effect through changes in signatory officials if no revisions (e.g., as required by local policy, or as required by a new signatory official) have occurred during the five-year approval cycle.

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

The VHA Central Office has established policies and procedures through the HRPP to assure {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:

19. The VHA Central Office 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, administrative staff, and experienced IRB members to accomplish the workload in an efficient and regulatory compliant manner.
20. The VA Central IRB will maintain current OHRP IRB registrations for all active panels in accordance with the requirements specified in VHA Directive 1200.05 and VHA Handbook 1058.03.
21. 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 as outlined in the VA Central IRB SOPs. IRB voting members are appointed by ORD from among the VA facilities, with the exception of the non-affiliated members who will be appointed from the local communities.
22. In coordination with counsel, the VA Central IRB will ensure compliance of any conflicts of interest management plans of IRB members in accordance with criminal conflict of interest laws and Standards of Ethical Conduct for Executive Branch employees.
23. 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.
24. Each VA Central IRB panel will be scheduled to meet a minimum of twice a month. The VA Central IRB can meet more often if determined necessary by the Co-Chairs of the IRB panels and VA Central IRB administrative staff. Most meetings are held via audio or video conference with in-person meetings and training sessions held twice a year if the budget permits. If the Co-Chairs and administrative staff determine there are no agenda items that require immediate action by the convened IRB, a scheduled meeting may be cancelled. Meetings may also be cancelled due to local or national emergencies.
25. The VA Central IRB will perform initial, and continuing review if required, of selected multi-site research projects in which two or more facilities are engaged in the research, with some exceptions in which it may review a study when only one site is currently engaged but the study will likely add additional sites in the future. The number and types of studies accepted for review may vary depending upon the VA Central IRB's workload and available resources. The VA Central IRB website will have the most

current information concerning the types of projects accepted for review and how to submit a new project. This MOU does not guarantee that any number of multi-site protocols, or any specific multi-site protocols from investigators at local VA facilities will be accepted for review.

26. 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.
27. 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 a project at {Name of Local VA Facility}. Written notification includes, but is not limited to, VA Central IRB's contingent approvals and requested modifications for a project; the final project approval; approval of amendments; determinations made regarding submitted serious adverse events, protocol deviations, and unanticipated problems; and continuing review approvals.
28. The VA Central IRB will notify LSL within five working days when un-redacted, signed copies of approved VA Central IRB meeting minutes are posted on the VA Central IRB SharePoint site.
29. The VA Central IRB will provide {Name of Local VA Facility} a copy of the annual self-evaluation of the VHA Central Office HRPP via upload to the VA Central IRB SharePoint site of the VHA Central Office HRPP to the {Name of Local VA Facility} in accordance with VA Central IRB Standard

Operating Procedures. Notification of the upload will be sent to the designated facility LSL to the VA Central IRB.

30. VA Central IRB oversight of approved projects will also include, but not be limited to: reviewing serious adverse events, unanticipated problems involving risks to subjects or others, apparent serious noncompliance reports, 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 a panel of the VA Central IRB is serving as the IRB of record in accordance with VHA Handbook 1058.01 and VHA Directive 1200.05. The VA Central IRB will work closely with the {Name of Local VA Facility} and study teams to investigate and obtain the necessary information to make required IRB determinations.
31. The VA Central IRB will also 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, OHRP, and the Food and Drug Administration (FDA), if applicable, in order to facilitate prompt reporting in accordance with VA Central IRB SOPs, local site SOPs, and all VA and other Federal requirements.
32. The VA Central IRB will perform limited IRB review for designated multi-site exempt projects after each local site makes (or documents) the initial determination that the research meets an exempt category(ies) requiring limited IRB review. The VA CIRB will verify the exemption category and perform the review or, it may change the exemption category or indicate the project does not meet any of the exemption category criteria and that the project must undergo expedited review or convened board review. The VA Central IRB will provide written correspondence concerning its review decision to the PI and forward a copy to each local site involved in the project, if known, at the time of review as listed in the submitted materials. Amendments to exempt studies requiring limited IRB review (including the addition of sites) must only be reported to the VA Central IRB when the amendment affects any area of the study covered under the limited IRB review.
33. The VA Central IRB will distribute correspondence through its secure SharePoint site, via e-mail, or through another designated electronic platform as described in VA Central IRB SOPs.
34. The VA Central IRB Administrative Office will maintain a website that contains the VA Central IRB SOPs, VA Central IRB submission forms, submission instructions, a list of local VA facilities that have designated the VA Central IRB panels as IRBs of record, VA Central IRB panel

meeting dates, and other relevant information about the VHA Central Office HRPP and the VA Central IRB.

35. The VHA Central Office HRPP will seek feedback from the PI, LSIs, and participating local VA facilities on the efficiency and effectiveness of VA Central IRB operations as part of the continuous quality improvement process. This will be done in the form of periodic VA Central IRB Liaison feedback through webinars and surveys.
36. The VA Central IRB Administrative Office will maintain IRB files which include but are not limited to all project documentation, VA Central IRB membership documents, meeting minutes, 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 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 {Name of Local Facility} any required information to support any VA HRPP review, regulatory requirement, or any matter concerned with the oversight of VA Central IRB-approved projects and oversight of the local HRPP unless prohibited by law.

#### **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} is responsible for:

19. Retaining ultimate responsibility for oversight of its local HRPP including but not limited to:
  - a. Ensuring that all human subjects research reviewed and approved by the VA Central IRB (e.g., limited, expedited or convened IRB reviews) that involves the local site is approved in accordance with local R&D requirements prior to allowing the research to begin at the local site.
  - b. Safeguarding the rights and welfare of human subjects and providing support to researchers by promoting an institutional culture where research is encouraged within a framework of regulatory compliance to include federal, VA, and local requirements.

- c. Instituting appropriate local oversight mechanisms to ensure compliance with the determinations of the VA Central IRB. This includes performing routine compliance audits, monitoring of locally conducted VA Central IRB-approved projects and reporting results of these auditing and monitoring activities to the VA Central IRB as applicable, in accordance with VHA policy, and local and VA Central IRB SOPs. This pertains to routine and other compliance audits conducted by the local RCO, as well as any special audit requests made by a VA Central IRB panel as part of its oversight responsibilities for projects for which it serves as the IRB of record. It also includes reporting to the VA Central IRB the results of any external audits (FDA, OHRP, etc.) that involve studies for which the VA Central IRB serves as an IRB of Record.
  - 1) Routine RCO audits that have no immediately reportable findings requiring review by the VA Central IRB will be submitted by the RCO to the local study team who will in turn submit them to the VA Central IRB as part of the study continuing review application or, if continuing review approval is not required for a project, as part of an annual project status update required by the VA Central IRB for those studies not undergoing continuing review.
  - 2) RCOs identifying instances of apparent serious and/or continuing noncompliance will submit a report directly to the VA Central IRB in accordance with VHA Handbook 1058.01 and VA Central IRB SOPs.
  - 3) RCOs who identify an issue that is not immediately reportable or apparent serious and/or continuing noncompliance, but in their opinion requires review by the VA Central IRB, will submit the report directly to the VA Central IRB with a request for review of the specific issue.
- d. 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 that are related or probably/possibly related to the research; suspension or termination of research activities; and/or apparent serious and/or continuing noncompliance encountered in VA human subjects research projects overseen by the VA Central IRB.
- e. The {Name of Local VA Facility} will work with the VA Central IRB to ensure all VA reporting requirements are met including, but not limited to, those specified in VHA Handbook 1058.01, Research Compliance Reporting Requirements. The {Name of the Local VA Facility}, through

the local Institutional Official, will also report all reportable determinations made by the VA Central IRB to ORO, OHRP, and to the FDA, as applicable and required per each agency, after receipt of such notification from the VA Central IRB to the local Institutional Official. Copies of these external notifications will be provided to the VA Central IRB.

- f. Advising the VA Central IRB if any investigator, or other study team member, has any conflict of interest issues of which it becomes aware regarding the research being overseen by the VA Central IRB.
  - g. 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.
  - h. Complying with VHA and VA policy with respect to reporting to the VA Central IRB and VAMC ISSO any violations of VA information security requirements of which it becomes aware in research overseen by the VA Central IRB.
20. Maintaining its existing FWA and VA Addendum to the FWA, through ORO per VHA Handbook 1058.03. 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 to ensure that the MOU also extends that Research and Development Committee's oversight of the local facility to the VA Central IRB as one of the facility's external IRBs that is internal to the VA.
21. Maintaining 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.
22. Review all PI/SC applications if PI is located at {Name of facility}, as well as all local LSI applications prior to submission to the VA Central IRB to ensure that the site has the necessary resources to support the research and that the investigators are appropriately credentialed and are current in all human subjects training requirements. The PI/ SC or LSI will be responsible for submitting the PI/SC or LSI Application to the VA Central IRB. LSI Applications can only be submitted after approval of the PI/SC Application as directed by the PI/SC study team or VA Central IRB staff members.

23. 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.
24. Ensure that the project is not initiated until it has been approved by the VA Central IRB, and the requirements of VHA Directive 1200.01 as well as other VA and local requirements have been met.
25. 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.
26. Agree not to independently deviate from a research activity as approved by the IRB except where necessary to eliminate apparent immediate hazards to the human subjects in accordance with 21 CFR 56.108(a), if applicable, and 38 CFR 16.108 (a)(iii) and notify the VA Central IRB within 5 working days if such an action is taken.
27. The VA Central IRB does not review emergency use or non-emergency/compassionate 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.
28. 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 activities by 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.
29. 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.
30. 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 Special Team Advising Research (STAR) Office or Office of General Counsel as needed.
31. Ensure procedures concerning reliance on the VA Central IRB are included in local SOPs, to include ensuring appropriate communications and coordination of VA Central IRB reviews with local committees



including but not limited to the R&D Committee, Radiation Safety Committee, Biosafety Committee, and/or any other relevant local committees as applicable.

32. Maintain IRB and Investigator files 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 (if applicable), other documents associated with the initial application (if applicable), VA Central IRB final approval documents, {Name of Local VA Facility} R&D Committee approvals, local audits and monitoring reports, and all correspondence, amendments, status reports/continuing review reports (if applicable) and approvals, and any other pertinent documents. All records will be maintained in accordance with the VHA's Records Control Schedule (RCS 10-1).
33. Maintain current written SOPs that incorporate {Name of Local VA Facility}'s specific responsibilities when submitting applications to and conducting research overseen by VA Central IRB panels as IRBs of Record as outlined in this MOU.
34. Comply with all VA Central IRB SOPs as applicable and respond promptly to VA Central IRB annual request to update all local facility points of contact to ensure continuous, efficient, and effective communications.
35. 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.
36. 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.
- b. Serving as the LSL 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. Up to **one** alternate Liaison can be appointed if desired by the appointing official.

#### **E. TERMINATION PROVISIONS**

3. This MOU may be terminated by the {Name of Local VA Facility} or the VHA Central Office HRPP without cause by giving a 90 day advance written notice of the intent to terminate to the other institutions and to ORO. This agreement may be amended to describe the process and timeline for termination.
4. All parties agree that the rights and welfare of subjects participating in the research must be protected. 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 IRB of record. This MOU will not be terminated until all studies under the oversight of the VA Central IRB have been safely closed or moved. 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: \_\_\_\_\_

\_\_\_\_\_  
Mary M. Klote, MD  
Director, Office of Research Protections, Policy, & Education  
as VHA Central Office Human Protections Administrator  
on behalf of VHA Central Office HRPP Institutional Official  
Office of Research and Development (10X2)  
810 Vermont Avenue, NW  
Washington, DC 20420

Date: \_\_\_\_\_

# Amendment to Memorandum Of Understanding (MOU)



*This amendment is to be completed when a local facility Signatory Official (SO) 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/Non-Profit Organization Information

**Date of Current MOU:**

**Amendment Number:**

**Type of MOU Amendment:**  Change in Medical Center SO  Change in Non-Profit SO

**Name of New Signatory Official:**

**Facility/Non-Profit Organization Name:**

**Facility/Organization Address:**

**E-mail:**

**Telephone:**

## II. Institutional Official's Certification

**As the Signatory Official for the above named Institution, I certify that I have read the terms of the Memorandum of Understanding between our Facility/Non-Profit 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.**

**I certify that the Federalwide Assurance for my institution is correct and current.**

\_\_\_\_\_  
Signature of Signatory Official

\_\_\_\_\_  
Date

Printed Name of Signatory Official

***Forward the completed form to the VA Central IRB Administration Office by sending a PDF copy to the VA Central IRB Administrator or by e-mail to [vacentralirb@va.gov](mailto:vacentralirb@va.gov).***

Date: **Date**

From: Institutional Official, **Name of VA Medical Facility**

Subj: Designation of Local Official(s) from **Name of VA Medical Facility** in Accordance with Memorandum of Understanding between **Name of VA Medical Facility** and VHA Central Office HRPP

To: VA Central IRB  
Office of Research and Development (10P9P)  
810 Vermont Avenue, NW  
Washington, DC 20420

As requested, in the Memorandum of Understanding (MOU) between VHA Central Office and **Name of VA Medical Center**, I hereby designate the following officials to perform the duties of:

1. Serving as the **Site Designee** by providing comments and/or suggestions to VA Central IRB in response to VA Central IRB initial review considerations.

AUTHORIZED: **Person's Name & Title**

Contact Information: **Phone number, Fax number and VA e-mail address**

2. Serving as the **Site Liaison** among VA Central IRB, the Local Site Investigator, and the **Name of VA Medical Center** for assisting in coordinating review actions and for monitoring purposes.

AUTHORIZED: **Person's Name & Title**

Contact Information: **Phone number, Fax number and VA e-mail address**

This delegation is effective until superseded.

Director's Name  
Director, **Name of VA Medical Center**  
Institutional Official

# Information for Appointed VA Central IRB Local Site Liaisons and Site Designees



*VA Central IRB Local Site Liaisons and Site Designees are appointed by a VA facility's Medical Center Director in accordance with the signed Memorandum of Understanding (MOU) between the facility and the Veterans Health Administration Central Office Human Research Protections Program (VHACO HRPP). The Local Site Liaison assists the VA Central IRB in facilitating its oversight, compliance, and monitoring functions as they pertain to VA Central IRB-approved studies conducted at the Liaison's site. The Site Designee provides comments and/or suggestions to VA Central IRB in response to VA Central IRB initial review considerations.*

## **Section 1: VA Central IRB Local Site Liaison**

1. Serves as the main point of contact at a site for the VA Central IRB concerning local site issues.
2. Informs other applicable local research office personnel of the availability of approved study documents on SharePoint.
3. Assists Site Designee in performing initial review functions per the MOU and in relaying the results to the VA Central IRB.
4. Provides the results of audits by local facility staff or outside agencies on projects overseen by the VA Central IRB if not already submitted by the local study team.
5. Makes local site records available to the VA Central IRB as required to facilitate its oversight, compliance, and monitoring functions.
6. Informs the VA Central IRB of actions taken by the local site involving any restriction, suspension, or termination of research privileges involving the Local Site Investigator or other research team members associated with a VA Central IRB-approved project.
7. Provides feedback to the VA Central IRB on its operations and ensure the VA Central IRB is included in the local site annual HRPP review.
8. Informs the VA Central IRB when personnel designated to perform functions per the MOU or other local research office personnel change. This ensures that the appropriate individuals receive e-mail notifications when documents are uploaded to the VA Central IRB SharePoint site and allows the VA Central IRB staff to maintain up-to-date access controls for the site.

## **Section 2: VA Central IRB Site Designee**

1. Provides comments and/or suggestions to VA Central IRB in response to VA Central IRB initial review considerations.
2. Ensures that any comments that may affect the local R&D Committee approval of the project are forwarded to the VA Central IRB and to the applicable PI/LSI.

### **Section 3: VA Central IRB**

1. Provides timely notification to the VA Central IRB Local Site Liaison and other applicable site personnel when documents have been uploaded onto the VA Central IRB SharePoint site, such as requests for comment on initial VA Central IRB review of PI/SC Applications, the availability of newly approved study documents or notices of other VA Central IRB actions, such as determinations of serious noncompliance.
2. Provides access to the VA Central IRB secure SharePoint site to authorized site personnel (Site Liaison, Site Designee, RCO, R&D Coordinator, ISO).
3. Makes VA Central IRB records available as needed to local site officials for compliance monitoring or other oversight obligations.
4. Responds in a timely manner to any audit reports or other findings involving the operations of the VA Central IRB.
5. Provides input or information as requested to a local site request for information concerning the annual review of its HRPP (or its accreditation/re-accreditation process) and notifies Site Liaisons when the VHA Central Office HRPP annual report is posted to SharePoint
6. Notifies Site Liaisons when there are changes in VA Central IRB policies and procedures directly affecting the local sites.

### **Section 4: Use of SharePoint Site**

Each VA Central IRB Local Site Liaison is granted access on the VA Central IRB SharePoint Site to the relevant PI study folders, LSI folders for their site, and the Site Liaison folders.

Each VA Central IRB Site Designee is granted access on the VA Central IRB SharePoint Site to the relevant PI study folders and LSI folders for their site.

1. The VA Central IRB Local Site Liaison Folder contains the following subfolders:
  - a. Signed Expedited Listings – grouped in subfolders by year and meeting date
  - b. Site Liaison and RCO Information Sheets
  - c. VA Central IRB minutes - grouped in subfolders by year and are searchable.
  - d. VA Central IRB Table of Reporting Requirements
  - e. VA Central IRB Membership Rosters – both current and archived rosters.
  - f. VHA Central Office HRPP Evaluations - by year
2. Study-specific folders that the VA Central IRB Local Site Liaison and Site Designee can access:
  - a. PI/SC Project Documents – approved application package, including the protocol, informed consent forms, amendments, updates, and continuing review documents.
  - b. LSI Project Documents – the approved LSI Application, approved LSI amendments, updates, and continuing review applications.



- c. VA Central IRB Notifications - new notifications from the VA Central IRB to study teams and VA Central IRB Local Site Liaisons, such as requests for local site review.
  - d. Study Team Responses - used to submit responses, to include revised documents, to previous VA Central IRB correspondence. A subfolder for each type of response should be created by the liaison or study team when uploading documents. After uploading items, a separate e-mail message should be sent to the appropriate VA Central IRB Manager to facilitate timely communication.
3. The VA Central IRB Local Site Liaisons and Site Designees can set alerts on folders to which they have access. These alerts will generate an immediate e-mail notification when new documents have been uploaded.

*Questions? Contact the VA Central IRB at 877-254-3130 or at [VACentralIRB@va.gov](mailto:VACentralIRB@va.gov)*

# Information for Research Compliance Officers



*Research Compliance Officer (RCO) responsibilities regarding the VA Central IRB are essentially the same as for their local IRBs in regard to studies that are approved and overseen by the VA Central IRB as an IRB of Record for the RCO's site.*

## **Section 1: Local Site RCO**

1. Local RCOs should become familiar with the provisions of the local site's Memorandum of Understanding with the VHA Central Office for the use of the VA Central IRB as an IRB of Record for the site.
2. RCO audits for studies overseen by the VA Central IRB should be conducted in the same manner as for the local IRB with the results communicated as follows:
  - a. All reports of apparent serious noncompliance should be submitted directly to the VA Central IRB via either the VA Central IRB Manager assigned to the study or the VA Central IRB Administrator. All reports should clearly identify if apparent or serious noncompliance is being reported by indicating this in the findings section or at the beginning of the report.
  - b. Copies of routine regulatory and informed consent audit reports that do not require immediate review and/or action by the VA Central IRB will be submitted by the local study teams at the time of continuing review.
3. If a local site's SOPs require that an RCO submit other types of reports to the VA Central IRB for review, these may be submitted to the VA Central IRB Administrator. An explanation of why the document is being submitted should also be included. If the report pertains to a specific study, the report may also be submitted to the VA Central IRB Manger for that study if known.
4. Local RCOs may be asked to conduct audits or perform other functions, such as observing the informed consent process, by the VA Central IRB in regard to the studies it oversees. The VA Central IRB may request an audit or action be completed due, but not limited to, cases of serious or continuing non-compliance, concerns about the consenting process or documentation requirements, or if there is a complicated study design or inexperienced study teams. Audits can be as narrow or as broad as the IRB needs in order to address any human subject protection concerns and are often required by the IRB as part of a corrective action plan.

## **Section 2: VA Central IRB**

1. RCOs are automatically given access to the VA Central IRB SharePoint site to the study folders for studies active at their site. This includes the PI/SC study folder and the individual local site study folder. If there are any changes in the RCO or the RCO's contact information, this should be communicated to the VA Central IRB Local Site Liaison, who will in turn inform the VA Central IRB SharePoint Liaison.
2. The VA Central IRB will provide written determinations regarding the RCO audit reports or other reports it reviews as applicable, to the RCO, local sites, and local study teams in a timely manner.
3. The VA Central IRB will make available through SharePoint or other means, specified VA Central IRB records that are required in order for RCOs to carry out their local auditing and compliance functions.

4. RCOs will be included in invitations to VA Central IRB Liaison webinars and other educational programs conducted by the VA Central IRB for local sites.
5. The VA Central IRB will maintain copies of SOPs, forms, and other VA Central IRB-specific guidance on the VA Central IRB website for reference.

### **Section 3: SharePoint Site**

RCOs can access documents approved by the VA Central IRB through the VA Central IRB SharePoint site. Upon notification of a change in RCO at a site, the new RCO will be provided with the link via e-mail. Upon sign-in, RCOs should see study folders for all studies active or in the process of review at their local site.

Study folder contains the following subfolders:

1. PI/SC Project Documents – approved application package, including the protocol, model informed consent forms, model recruitment materials, amendments, and continuing review documents.
2. LSI Project Documents – the approved LSI Application, to include the approved, stamped informed consent forms and site-specific recruitment materials, approved LSI amendments, and continuing review applications.
3. VA Central IRB Notifications - new notifications to study teams and VA Central IRB Local Site Liaisons, such as reminders for continuing review.
4. Study Team Responses - used to submit responses, to include revised documents, to previous VA Central IRB correspondence. A subfolder for each type of response should be created by the RCO or study team when uploading documents. After uploading items, a separate e-mail message should be sent to the appropriate VA Central IRB Manager to facilitate timely communication

Note: RCOs who also serve as VA Central IRB Liaisons should also reference the handout for Site Liaisons.

*Questions? Contact the VA Central IRB at 877-254-3130 or at [VACentralIRB@va.gov](mailto:VACentralIRB@va.gov)*