

Memorandum of Understanding



MEMORANDUM OF UNDERSTANDING

BETWEEN
VETERANS HEALTH ADMINISTRATION (VHA)
CENTRAL OFFICE

AND

RALPH H. JOHNSON
VETERANS AFFAIRS MEDICAL CENTER (VAMC)

AND

CHARLESTON RESEARCH INSTITUTE
The local VA Nonprofit Corporation (NPC) created and operated
under the laws of SOUTH CAROLINA

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 Ralph H. Johnson VAMC and the Charleston Research Institute (NPC) for the VA Central IRB to serve as an additional IRB of Record for Ralph H. Johnson VAMC and the NPC.
2. This MOU does not preclude Ralph H. Johnson VAMC and NPC from continuing to participate in any existing agreements the Ralph H. Johnson VAMC 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 Ralph H.

Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC, 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC's Local Site Investigator (LSI) Application (VA Central IRB Form 104), and any additional information submitted by the LSI, or the Ralph H. Johnson VAMC.
 - 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 Ralph H. Johnson VAMC, 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 Ralph H. Johnson VAMC its subject populations, and/or the local community.
 - d. Systematic, reciprocal, and documented communication between the VA Central IRB and Ralph H. Johnson VAMC. 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 Ralph H. Johnson VAMC, as prescribed by VA Central IRB and Ralph H. Johnson VAMC's SOPs.

9. The VA Central IRB will provide timely written notice, usually within 10 working days, of IRB determinations to the Ralph H. Johnson VAMC of all actions involving the conduct of the project at Ralph H. Johnson VAMC. 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC to ensure the Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 RALPH H. JOHNSON VAMC

The Ralph H. Johnson VAMC's Institutional Official assures the VHA Central Office HRPP that Ralph H. Johnson VAMC will assume the following responsibilities in accordance with all applicable VA and other Federal requirements. Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC uses one or more of its local academic affiliate's IRBs as an IRB of record, the Ralph H. Johnson VAMC will review the relevant MOU Ralph H. Johnson VAMC holds with its academic affiliate and, if necessary, modify the MOU between Ralph H. Johnson VAMC and its academic affiliate to describe the respective jurisdiction and oversight of each IRB.
 - b. If the Ralph H. Johnson VAMC uses the services of another VA facility's Research and Development Committee, then Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC'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 Ralph H. Johnson VAMC 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. Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC'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, Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC'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 Ralph H. Johnson VAMC will not:
 - a. Submit a LSI Application for a specific project to the VA Central IRB if another IRB of record for Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC'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 Ralph H. Johnson VAMC (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 Ralph H. Johnson VAMC for the conduct of, and to facilitate functions related to the conduct of, approved VA research and education. Each research project approved by a Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC and the VA Central IRB. Such coordination may involve assisting local Ralph

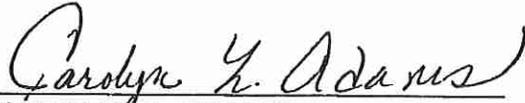
H. Johnson VAMC employees and the R&D Committee with research project related actions and documentation.

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 Ralph H. Johnson VAMC 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. The Charleston Research Institute may withdraw from this MOU by giving notice to the Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC 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 Ralph H. Johnson VAMC have been closed or safely moved to another site. The Ralph H. Johnson VAMC 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:



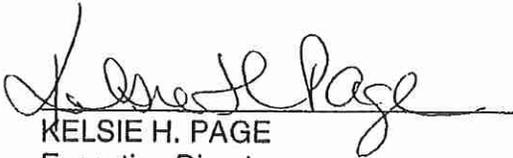
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Date: 8/30/12



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K. LYNN CATES, M.D.
On behalf of VHA Central Office HRPP Institutional Official
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Date: 10/4/12