# All of Us (AoU) IRB SOP

PURPOSE: The purpose of this Standard Operating Procedure is to document the process for Communication between the NIH AoU IRB, the Coordinating Center and Minneapolis VA Health Care System (MVAHCS).

This SOP is stored with Research Service/HRPP SOPs located on the Research Service drive for MVAHCS. It is consistent with the NIH/AoU SOP located at https://vaww.ord.research.va.gov/CSP/Boston/ERIC/AoU/CentralFile/Central%20IRB/Forms/AllItems.aspx?RootFolder=%2FCSP%2FBoston%2FERIC%2FAoU%2FCentralFile%2FCentral%20IRB%2F3%2E%20AoU%20IRB%20SOPs&FolderCTID=0x012000B17E64650FC39E4597C5FB0887CC12DA&View={E8F4F2F6-B505-40DA-A0B6-0131648FEFA0}

## Background

BACKGROUND: A national Memorandum of Understanding (MOU) is in place between the Department of Veterans Affairs (DVA) Veterans Health Administration (VHA) Office of Research and Development (ORD), and National Institutes of Health concerning the *All of Us* Institutional Review Board Initiative (AoU IRB) for human research involving the *All of Us* Research Program project(s) to be conducted by VA Medical Facilities.

Participating Sites have signed a MOU with the NIH AoU IRB for the AoU IRB to serve as the IRB of Record for the *All of Us* Research Program. The MOU content was approved at the national level by the Office of Research Oversight (ORO), ORD and NIH. No local changes are required. The agreement will be reviewed and approved by the local R&DC and signed by the Institutional Official (Facility Director) at each Participating VA Site and by the NIH Associate Director for Science, Outreach, and Policy.

## Signatory Official – VA Medical Center Director Responsibilities

A. Signs the All of Us IRB Agreement, which takes the place of the VHA Memorandum of Understanding for use of an IRB operated by another institution. The initial IRB Agreement and a copy of each update must be sent to OROPE@va.gov, attn. Priscilla Craig. The content of the MOU may not be changed per agreement with NIH.
B. Reports unanticipated problems and serious and/or continuing noncompliance originating at the VAMC as required by VHA Handbook 1058.01 to the IRB, to ORO and to the Office for Human Research Protections (OHRP) as required by the facility Federalwide Assurance or to other external federal agencies or oversight bodies. The AoU IRB will report to NIH as referenced in IRB SOP 0204, however, the VA Institutional Official is still legally required to report on behalf of the VA facility.
C. Updates and signs the FWA and VA Addendum through ORO.

**Responsibilities of Research & Development Committee and ACOS/R&D**

A. Oversees the conduct of the research protocols and monitors protocol compliance by reviewing reports submitted by the All of Us IRB and the Research Compliance Officer (RCO). Provides a mechanism to receive and address concerns from local study participants and others about the conduct of the research as documented in Res Svc-RD-005 Reporting Research Events; Complaints - Research Pt Rights Grievance Process SOP
B. Responds to requests from the AoU IRB for questions related to review or conduct of the research at MVAHCS.
C. Ensure review of initial and ongoing qualifications of investigators and research staff as documented in Res Svc-RD-010 Research Training; Res Svc-RD-008 Scopes of Practice.
D. Receives documentation of centralized Information Security Officer (ISO) and Privacy Officer (PO) review from the Local Site Investigator as part of the application packet of the All of Us research program by the R&D Committee. Utilizes centralized ISO and PO reviews for any additional ISO and PO reviews for the conduct of the All of Us research program at the local site.
E. Receives written notification of initial and continuing review project approvals from the All of Us IRB for the All of Us Research Program. Notice of IRB approvals will be sent by the IRB through the AoU Study Chairs' office and then distributed to the LSI and the designated local site liaison.
F. Reviews and approves minutes of the AoU IRB as required by ORD policies. Expedited Review Sessions generated by the All of Us IRB will be reviewed and approved in the same way as minutes as documented in Res Svc-RD-001 Research and Development Committee. Documentation of Expedited Review Sessions will be sent by the AoU IRB through the Study Chairs Office and then distributed to the Local Site Investigator who is responsible for sending to the Research Office.
G. Requires all applicable subcommittee and approvals to be in place before the ACOS/R&D notifies the Investigator that the All of Us Research Program can be initiated by the local investigator as documented in Res Svc-RD-011 ACOS Approval Prior to Initiation of Research.
H. Conducts an annual review of the All of Us IRB and submits to the VA Facility Medical Center Director as required by ORD policy in VHA Handbook 1200.01 as documented in Res Svc-RD-001 Research and Development Committee. Information for these reviews of the All of Us IRB will be sent by ORD to the local site liaison to provide to the R&D Committee.
I. Confirms that any Conflict of Interest reported as part of the Local Site Investigator Application submitted to the All of Us IRB is appropriately mitigated prior to R&D Committee approval and generating the Notice to Proceed.

**Research Service Responsibilities**

A. Verifies that the necessary agreements (Reliance Agreement, NPC Addendum) are signed and executed by MVAHCS prior to use of the All of Us IRB and are kept current with copies sent to ORO.

B. Correspondence from the All of Us IRB and Study Chairs' Office will be sent to the local site liaison who is responsible for forwarding the information to the MVAHCS R&D Committee as applicable.
C. In the event of a change in the Local Site Investigator, the former LSI notifies the local site liaison and coordinates with the new LSI a transfer of the approved study. Approval also requires that the AoU Study Chairs approve the new LSI. The LSI must amend the LSI application and submit directly to the AoU IRB for approval.

**Local Site Investigator Responsibilities**

A. Submits a copy of centralized ISO and PO reviews and the VA Central IRB approved waiver of HIPAA authorization for recruitment to the R&D Committee via the local site liaison as part of the R&D Committee materials for initial review and approval.
B. Submits any documentation received from the Study Chairs' Office or the All of Us IRB requiring notification (event reporting, newly-approved versions of the protocol/consent/HIPAA authorization or any other IRB-approved supporting documents) to the research office, R&D Committee, ACOS/R&D, RCO, or any other applicable individual as per the local policies and procedures.
C. Notify the VA Study Chairs' Office if a change in the Local Site Investigator is proposed for the VA All of Us Research Program at this site. The Local Site Investigator must also notify the research office and the R&D Committee via the local site liaison. Submit an amended LSI application directly to the AoU IRB for approval.
D. Notify the VA All of Us Study Chairs if a modification to the VA Central IRB-approved waiver of HIPAA authorization is required for local site-specific recruitment activities. The VA All of Us Study Chairs' Office will submit the HIPAA waiver request to the VA Central IRB and determination to the Local Site Investigator.
E. Maintains a copy of all study-related correspondence, including obtaining access to the site-specific SharePoint site for the All of Us Research Program.
F. Uses the written HIPAA authorization approved for use by the All of Us Study.
G. Reports unanticipated problems involving risks to subjects or others, serious unanticipated problems involving risks to subjects or others, local unanticipated serious adverse events, apparent serious or continuing noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research, including any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI, in accordance with VHA Handbook 1058.01 and the All of Us IRB SOP 0312 to the IRB and submits a copy of the report simultaneously to the VA Study Chairs and per local policy described in Res Svc-RD-005 Reporting Research Events. If the local event requires reporting to the Information Security Officer and/or Privacy Officer submit those directly to the local ISO and PO and notify the VA Study Chairs' Office that the local ISO and PO have been notified. Privacy and Information Security events affecting the entire study will be reported by the Study Chairs' Office to ORD & the VHA Privacy Office. Copies of these reports will be distributed to all participating sites.

H. Submits a copy of the regulatory audit report to the AoU IRB and the VA Study Chairs' Office when a regulatory or informed consent audit has been conducted which identifies a deficiency.
I. Informs the AoU IRB and the VA Study Chairs immediately (within 24 hours of being informed) that a local VA subject consented into the All of Us Study has been incarcerated.
J. Adheres to All of Us IRB Standard Operating Procedures for the IRB oversight of the All of Us research program.

**Research Compliance Officer (RCO) Responsibilities:**

A. Conducts routine audits to ensure compliance with applicable federal, VA and local policy per the RCO Audit Plan/SOP. Modifies RCO audit plan and/or policy and procedure to include responsibilities for auditing studies under the oversight of the All of Us IRB and how audit findings are reported to the Local Site Investigator.
B. Reports any study-specific incident, experience, or outcome that may rise to the level of an apparent unanticipated problem and/or apparent serious or continuing noncompliance per the requirements of VHA Handbook 1058.01. Written notification to the oversight committee (IRB) will occur simultaneously with notification to the Local Site Investigator. In accordance with VA Handbook 1058.01 and Res Svc-RD-005 Reporting Research Events the LSI will have 5 business days of becoming aware of the apparent serious or continuing noncompliance to report to the IRB.
C. Submit audit findings of apparent serious unanticipated problems involving risks to subjects or others or apparent serious and/or continuing noncompliance reportable to the IRB and ORO requiring immediate action to the R&D Committee As documented in Res Svc-RD-005 Reporting Research Events.

**Routine Study-Related Communication**

The VA All of Us Coordinating Center (AoU CC) on behalf of the Study Chairs will serve as the liaison between the AoU IRB and Participating Local Site Investigators for matters related to routine conduct and/or management of studies and data collection.

A. Communication between Study Chairs through the VA AoU Coordinating Center and Participating Sites (Study Chairs and Local Site Investigator):

    1. AoU CC will provide the following documents to each Participating site:
        a. Draft AoU IRB application and then subsequent AoU IRB Approval
        b. AoU protocol and approved VA main study IRB application
        c. Documentation of VACO centralized ISO and PO review
        d. Access to the All of Us central SharePoint file which includes all AoU IRB SOPs, policies and study documents
    2. Participating sites will provide to the AoU CC:
        a. Completed AoU IRB LSI application when submitted to the AoU IRB per IRB SOP.

b. Once IRB approval and any other relevant subcommittee approval is received (e.g., SRS), sites will provide a copy of the R&DC approval letter.

B. Communication between VA Study Chairs (through the AoU Coordinating Center) and AoU IRB:

1. The VA Study Chairs will serve as the Point of Contact for the AoU IRB for all Participating VA sites for routine study conduct, nationwide amendments or administrative matters. The Chairs will rely on the VA AoU CC to facilitate communication with the AoU IRB.

2. The Study Chairs will also assist participating sites with answering questions or concerns from the AoU IRB. The VA Study Chairs will also assist participating sites with completion and submission of annual review of the AoU IRB.

3. The AoU IRB will provide AoU IRB Approval notifications to the Study Chairs for all Participating sites and to the specific LSI.

C. Communication between LSIs at Participating Sites and local R&D Offices

1. Local Site Investigators at participating sites are expected to provide documentation received from the AoU CC and/or AOU IRB to the local R&D Office, R&DC, and/or local RCO as described in this Procedure.

2. Local Site Investigators should contact the Study Chairs or the AoU CC directly by telephone or email, should there be any questions or concerns with communications or operations of the AoU IRB.

Effective Date:

Revision History: ☒ New Standard Operating Procedure

☐ Replaces SOP dated _____

Rescission Date: none

Reference: VHA Handbook 1200.05
AoU MOU
VHA Handbook 1058.01