# SOP: Veterans Affairs Research

## 1 PURPOSE

1.1 Within the Department of Veterans Affairs (VA) is the Veterans Health Administration (VHA). The VHA is America's largest integrated health system, providing care at over 1,300 health facilities. The VHA is also the only organizational component of the VA that can conduct human subject research. The VHA Office of Research and Development (ORD) is responsible for the creation of human research policies. This policy addresses the human subject research protections considerations when the UCI IRB reviews a human subject research protocol supported by the VHA.

## 2 REVISIONS FROM PREVIOUS VERSION

1.1 None

## 3 POLICY

3.1.1 The VHA has the ability to fund veteran-centric research led by VA investigators. To serve as a VA investigator, one must be a VA employee.

3.1.2 The VHA Directive 1200.05(3): Provides the requirements for the protection of human research subjects. This is generally aligned with Office for Human Research Protections (OHRP) guidance.

3.1.3 The VA also aligns with the 2018 Common Rule at 38 CFR 16. The 2018 Common Rule applies to VA research regardless of funding.

3.1.4 The VA follows the Privacy Rule (Health Insurance Portability and Accountability Act of 1996)

3.1.5 The VA Long Beach Healthcare System (VALBHS) Medical Center Director is the individual legally authorized as a Signatory Official to commit VCALBHS to an Assurance.

## 4 RESPONSIBILITIES

4.1 If the UCI-IRB determines a given VALBHS project does not constitute research, does not constitute human subjects research, or that a particular site is not engaged in human subjects research pertaining to that project, the UCI PI will provide written correspondence concerning its decision to the VALBHS Principal Investigator (PI) via the IRB electronic submission system.

4.2 The UCI-IRB Research Office will seek feedback from the VALBHS PIs, and VALBHS on the efficiency and effectiveness of UCI-IRB operations as part of a continuous quality improvement process.

4.3 If UCI obtains accreditation of the Human Research Protection Program (HRPP) from an accrediting body but fails to maintain accreditation, UCI will notify the VALBHS and ORD in writing within ten (10) business days.

4.4 The UCI-IRB Research Office and UCI-IRB will maintain all VALBHS project documentation, membership documents, and other relevant records in accordance with UCI-IRB SOPs, and all VA and other Local, State, and Federal requirements.

4.5 The VA facility is responsible for ancillary reviews, including Conflict of Interest, and an assessment of the Principal Investigator and Study Team (e.g., expertise, training, including human subject training, credentialed, etc.) not the reviewing IRB.

## 5 PROCEDURE

### 5.1 Initial Submission

5.1.1 The VA requires both an initial privacy and information security review, prior to IRB review. A final privacy and information security review occurs prior to VA Research and Development Committee (R&D) review.

### 5.2 Single IRB

5.2.1 The VA is agreeable to single IRB; Prior to the 2018 Common Rule, the VA created a central IRB for ORD-funded multi-site studies.

5.2.2 Exceptions from single IRB may be requested from the ORD by VA facility research leadership (i.e., not the investigator).

5.2.3 The VA IRB cannot serve as the IRB of record for any non-VA site.

5.2.4 Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a Cooperative Research and Development Agreement [CRADA] or a Data Use Agreement) that addresses such issues as the responsibilities of each party, the ownership of the data, and the reuse of the data for other research. Any use or reuse of data must be consistent with the protocol, the informed consent document, and the Health Insurance Portability and Accountability Act (HIPAA) authorization.

5.3 **Greater than Minimal Risk Research**

5.3.1 Human research protocols involving greater than minimal risk must include a Data Safety Monitoring Board or Committee. The meeting frequency, as well as the scope of the Board or Committee must be described in the protocol.

5.3.2 Any minutes, reports or records related to the Data Safety Monitoring Board or Committee will be accessible to the VA.

5.4 **Informed Consent Considerations**

5.4.1 Informed consent documents must be both signed and dated by the subject or the subject's legally authorized representative.

5.4.2 Electronic consent is allowable should the process confirm to VA requirements for use of electronic signatures. The VA requirements for use of electronic signatures must meet governmental requirements for authenticity and identification.

5.4.3 Broad consent can only be used when identifiable data or biospecimens are collected solely for *research* purposes in accordance with the requirements in section 17.f of the VHA Directive 1200.05.[1]

5.4.4 Use of the VA ICF template is highly recommended to ensure all the VA mandate elements and boiler plate language is in place.

5.5 **Required Consent Language**

5.5.1 ORD Policy mandates the following consent language, as applicable:

5.5.2 A statement that the VA will provide treatment for research related injury.

5.5.3 A statement that informs VA research subjects that their insurance will not be charged for any costs related to the research. Note: co-payments for standard medical care or services not part of the research procedures may still apply.

5.5.4 When photos, video and/ or audio recordings are taken or obtained exclusively for research purposes:

5.5.4.1 A description of any photographs, video, and / or audio recordings to be taken or obtained for research purposes;

5.5.4.2 How the photographs, video, and / or audio recordings will be used for the research; and

5.5.4.3 Whether the photographs, video, and / or audio recordings will be disclosed outside of the VA

5.6. **When the VA conducts a study protected by a Certificate of Confidentiality (CoC):**

5.6.1. When information about the subject's participation will be included in the VHA medical record, information must be given to the prospective subjects as part of the informed consent process that informs them of this research component.

5.6.2. For studies that mandate informed consent, the consent document approved by the IRB must include the statement that a study has a CoC.

5.7. **Recruitment:**

5.7.1. If prospective participants are being contacted by telephone, the study team must make initial contact in person or by letter prior to any telephone contact and refer to those prior contacts

[1] The VA Long Beach does not allow for the use of Broad Consent.

when phoning the participant unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research.

5.7.2. The initial contact must provide a telephone number or other means that the potential participant can use to verify the study constitutes VA research.

5.7.3. Later Contact – the research team may use telephone calls to the participant by referring to previous contacts and when applicable, the information provided in the informed consent form.

5.7.4. The scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and informed consent forms.

5.8. **HIPAA**

5.8.1. The VHA is a covered entity under HIPAA.

5.8.2. The VA will handle the review of any HIPPA human subject research considerations.

5.8.3. VA Form 10-0493 must be used; a standalone HIPAA authorization document is required. The HIPAA authorization must not be combined with the consent document.

5.8.4. The VA facility must ensure the HIPAA authorization language is valid.

5.8.5. For collaborative research that involves both UCI and the VA, the VA will serve as the privacy board for the VA site. The VALBHS Privacy Officer (PO) and Information System Security Officer (ISSO) Representatives will perform the required privacy and information security reviews and provide these reviews to the IRB with submissions.

5.9. **Reportable Events**

5.9.1. Reviewing serious adverse events, unanticipated problems involving risks to subjects or others, protocol deviations, complaints, Research Compliance Officer (RCO) audit reports, and any audit reports from sponsors, VA oversight bodies or other oversight agencies, regarding projects for which the UCI-IRB is serving as the IRB of record, in accordance with VHA Directive 1058.01 and VHA Directive 1200.05.

5.9.2. Reportable events must be reported to OHRP even if not supported by an agency signed onto the Common Rule. Due to their Federalwide Assurance (FWA), reportable events that occur on non-exempt human subject research mandate reporting.

5.9.3. UCI Principal Investigator (PI) will provide timely written notice, usually within seven (7) calendar days, to VALBHS PI of UCI-IRB determinations involving the conduct of a research project at VALBHS. This includes contingent approvals and requested amendments, etc.

5.9.4. The VA has specific reporting requirements as follows:

5.9.4.1. Death/s at local site/s, both unanticipated and related to the research must be reported to the IRB “immediately.”

5.9.4.2. All local reportable events and unanticipated serious adverse device effects must be reported to the IRB within 5 business days.

5.9.4.3. Protocol deviations and other non-reportable events must be noted in the research file.

5.9.4.4. Local breaches of confidentiality and security must be reported to the IRB within 1 hour, as well as to the necessary privacy offices at the VA.

5.9.5. It is noted that UCI IRB however requires the submission of those events that appear reportable per federal regulations (e.g., unanticipated problems, serious and continuing noncompliance, suspension and terminations of research).

5.10. **Application Supplement Forms:**

5.10.1. **General DoD:** Researchers conducting DoD supported research must complete and submit to the IRB the DoD Supplement Form in addition to the protocol materials submitted to the IRB for initial review. The DoD Supplement Form can be found on the Office of Research (OR), Human Research Protection (HRP) Website at: https://research.uci.edu/human-research-protections/irb-forms/ https://research.uci.edu/wp-content/uploads/WCG-405-Worksheet-Addl-Criteria-DOD.pdf

5.10.2. **Investigational Drugs:** VA Form10-9012, Investigational Drug Information Record is to be provided at initial application when investigational drugs are involved.

## 6 MATERIALS

None

## 7 REFERENCES

*A special thank you to Karen Jeans, Director for Regulatory Affairs for the Office of Research Protections, Policy and Education, Department of Veteran Affairs, whose Smart IRB presentation from March 2024 has been heavily referenced in the creation of this policy.*

38 CFR 16
38 CFR 17.85
VHA Directive 1200.05(3) Requirement for the Protection of Human Subjects in Research: https://www.va.gov/vhapublications/
VHA Directive 1200.05(3), Paragraph 17.d.(10)
VHA Directive 1200.05(3), Paragraph 17.e.(10)
VHA Directive 1200.05(3), Paragraph 17.k.(10)
VHA Directive 1200-01(1) R&D Committee: https://www.va.gov/vhapublications/
https://grants.nih.gov/faqs
https://www.research.va.gov/programs/orppe/irb_relationships.cfm
https://www.research.va.gov/programs/orppe/Checklist-for-VA-Facilities-Using-Independent-Commercial-IRBs-ICDs-and-Combined-ICD-HIPAA-Authorization.docx
https://www.research.va.gov/programs/orppe/VA-HIPAA-Authorization-Requirements-When-Using-an-Independent-Commercial-IRB.docx
https://www.research.va.gov/programs/orppe/VA-Specific-and-Selected-2018-Common-Rule-Informed-Consent-Requirements-When-Using-an-Independent-Commercial-IRB.docx
https://www.research.va.gov/programs/orppe/ORD-IRB-Reliance-Request-Form.docx