

STANDARD OPERATING PROCEDURES

Requirements for the NF/SGVHS Assurance for the Protection of Human Subjects

June 23, 2011

1. PURPOSE

To set forth NF/SGVHS procedures maintaining a human subjects Assurance as required by the Department of Veterans Affairs (VA) regulations Title 38 Code of Federal Regulations (CFR) Part 16 and VHA Handbook 1058.03.

2. BACKGROUND

All human subject research conducted or supported by VA must comply with the Federal Policy (Common Rule) for the Protection of Human Subjects, 56 Federal Register (FR) 28001, June 18, 1991, as codified at 38 CFR Part 16. Each VA facility engaged in human subject research must provide a written Assurance, acceptable to the Secretary of Veterans Affairs, committing the facility to comply with 38 CFR Part 16.

Each non-VA institution engaged in human subject research conducted or supported by VA must provide a written Assurance, acceptable to the Secretary of Veterans Affairs, committing the institution to comply with 38 CFR Part 16. Situations considered indicative of VA support and that would typically require an acceptable Assurance for any non-VA institution engaged in the research are described in VHA Handbook 1058.03.

In accordance with VHA requirements, the VA Medical Center Director or Chief Executive Officer (CEO) is the VA Institutional Official responsible for ensuring that the VA facility conducting research involving human subjects or biological specimens applies through the Office of Research Oversight to the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), for an Assurance.

3. DEFINITIONS RELATED TO THE HUMAN SUBJECT PROTECTION ASSURANCES

a. **Assurance (ASSURANCE OF COMPLIANCE; ASSURANCE OF PROTECTION For Human Subjects; and Human Subject Protection Assurance).** An Assurance is a written commitment to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16. Assurances are reviewed and approved by the HHS OHRP and various other Departments and Agencies under the Federal Policy (Common Rule) for the Protection of Human Subjects (56 FR 28001, June 18, 1991).

b. **Facility.** The facility is an entity operated by VA, including VA hospitals, medical centers, and health care systems. For purposes of this SOP, the terms “facility,” “VA facility” and “VA institution” are considered synonymous.

(1) A VA facility includes all VA-operated components within the facility’s management control, regardless of the component’s physical location, and whether housed in space owned, leased, or rented by VA.

(2) A VA facility may include multiple campuses and satellite components.

(3) A VA facility includes all VA space that is “shared” with a non-VA entity, unless the VA space is leased to a non-VA entity and not used by VA for research.

- c. **Facility Director.** The facility Director is the Director of a VA Medical Center or the Institutional Official or CEO of a VA Health Care System. From this point forward in this policy, the terms “Facility Director,” “Medical Center Director,” “Institutional Official,” and “Health Care System CEO” are considered synonymous.
- d. **Federal-wide Assurance (FWA).** An FWA is an Assurance approved for Federalwide use by OHRP in accordance with Section 103(a) of the Common Rule.
- e. **Human Biological Specimen.** A human biological specimen is any material(s) derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings, or any other cells, whether collected for research purposes or as a residual specimen from a diagnostic, therapeutic, or surgical procedure.
- f. **Human Protections Administrator (HPA).** A HPA is the individual named in an FWA as a primary contact responsible for directing, or having in-depth knowledge of, the daily operations of an institution’s program for protecting human research subjects.
- g. **Human Research Protection Program (HRPP).** An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the Medical Center Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, compliance officers, etc., the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.
- h. **Human Subject.** A human subject is a living individual about whom an investigator conducting research obtains either data through intervention or interaction with the individual or identifiable private information. Individuals who receive test articles or who serve as controls in clinical investigations, including clinical investigations as defined under Food and Drug Administration (FDA) regulations, generally would be considered human subjects for the purposes of this Handbook.
- i. **Institution.** For Assurance purposes, an institution is any public or private entity. This policy distinguishes VA institutions from non-VA institutions.
 - (1) **Non-VA Institution.** A non-VA institution is an entity not operated by VA. Non-VA institutions include, but are not limited to:
 - (a) Any entity that is not a legal component of VA or of a VA facility, including a Contract Research Organization (CRO); industry or private sponsor; or public or private research company, foundation, or group.
 - (b) Entities operated under a contract from VA;
 - (c) Academic institutions, including VA-affiliated medical schools, dental schools, and other academic affiliates;

- (d) VA-affiliated Non-Profit Research and Education Corporations (NPCs); and
 - (e) Other federal departments or agencies.
- (2) **VA Institution.** A VA institution is an entity operated by VA, including VA hospitals, medical centers, and Healthcare Systems.
- j. **Institutional Official (IO).** The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. For VA institutions, the IO is the Medical Center Director or designee who is responsible for ensuring that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO also serves as the official representative of the institution to external agencies and oversight bodies.
 - k. **Institutional Review Board (IRB).** An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with 38 CFR Part 16 and other applicable regulations.
 - l. **IRB of Record.** The IRB of Record is the IRB(s) designated under a VA facility's FWA for review and oversight of the facility's human subject research.
 - m. **Memorandum of Understanding (MOU).** An MOU is a written agreement between two VA facilities or between a VA facility and a non-VA institution documenting their relationship and defining their respective roles and responsibilities within that relationship.
 - n. **Research.** Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations, are considered research for purposes of this policy.
 - o. **VA Investigator.** A VA investigator is any individual who conducts human subject research 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 in accordance VHA Handbook 1200.01.
 - p. **VA Research.** VA research is research that has been reviewed and approved by a VA R&D Committee.

4. POLICY

- a. In order to engage in research involving human subjects or human biological specimens, NF/SGVHS must hold an effective FWA approved by OHRP with an effective VA FWA Addendum approved by the Office of Research Oversight (ORO).
 - (1) The NF/SGVHS holds an FWA through OHRP (FWA00002606). Information on the NF/SGVHS FWA is available on the OHRP website.
- b. The NF/SGVHS FWA covers all research conducted at the facility or by the facility's investigators acting in their official VA capacity. For a list of components covered under the NF/SGVHS FWA see OHRP website.
- c. NF/SGVHS may not apply its FWA to the conduct of VA research by a VA investigator from another VA facility that does not operate a human research program without the approval of ORD and an appropriate MOU, approved by ORO, documenting the arrangement.
- d. The NF/SGVHS FWA may not include or apply to any non-VA institutions or non-VA personnel without written approvals described in VHA Handbook 1058.03.
- e. The NF/SGVHS FWA designates only OHRP registered IRBs of record on its Assurance and as applicable, documents pertinent roles and responsibilities through an appropriate and approved MOU when designating another entity's IRB as the facility IRB of Record. Any changes to NF/SGVHS IRB review arrangements must be in accordance with procedures described in VHA Handbook 1058.03. Information on the IRBs associated with the NF/SGVHS FWA is available on the OHRP website.
- f. The NF/SGVHS must submit changes in its FWA as described in VHA Handbook 1058.03 paragraph 5c.
- g. The NF/SGVHS must renew its FWA prior to expiration of the FWA's approval period, or in accordance with OHRP and ORO guidance. Renewals must be submitted through ORO to OHRP and must be approved by both ORO and OHRP in order to take effect. If the NF/SGVHS FWA is not renewed prior to the end of the approval period, human subjects research may not be conducted.

5. RESPONSIBILITIES

- a. **ORO Responsibilities**
 - (1) Serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance regarding human subject protections.
 - (2) Signs the facility FWA addendum prior to approval by OHRP.
 - (3) Reviews facility MOUs
- b. **VISN Director Responsibilities**
 - (1) Reviews and signs the facility FWA addendum and MOU prior to submission to ORO.

c. MCD Responsibilities

- (1) Serves as the VA Institutional Official legally authorized as Signatory Official to commit NF/SGVHS to an Assurance.
- (2) Ensures that the NF/SGVHS maintains an Assurance through the Office of Research Oversight to the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP).
- (3) Oversees the creation and implementation of an HRPP for research involving human subjects or human biological specimen.
- (4) Ensures that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.
- (5) Completes the OHRP Assurance Training Modules, as well as any other training required by ORD prior to signing the FWA and every three years thereafter (as required by VHA Handbook 1200.05).
- (6) Ensures that any IRB designated as an IRB of record for the facility is established in accordance with the VHA requirements and 38 CFR 16.103(b)(2); is registered with OHRP and the FDA; and is listed as an IRB of record on the facility's FWA.
- (7) Appoints VA representatives, in writing, to IRB-01 in accordance with the requirements of VHA Handbooks 1058.03 and 1200.05 and IRB policies and procedures.
- (8) Ensures a valid, signed MOU is in place between NF/SGVHS and institutions providing IRB services, that the MOU is revised, as needed, in accordance with VHA Handbook 1058.03 and any external designated IRB of record complies with all applicable VA and other Federal requirements including, but not limited to, the provisions of VHA Handbook 1200.05 when reviewing VA research.
- (9) Serves as the official representative of the institution to external agencies and oversight bodies.

d. Associate Chief of Staff for Research and Development (ACOS/R&D)

- (1) Ensures that requirements for maintaining the Facility FWA are met.
- (2) Serves as the Human Protections Administrator for NF/SGVHS FWA.
- (3) Completes the OHRP Assurance Training Modules, as well as any other training required for this purpose by ORD.

e. Administrative Officer for Research (AO/R&D)

- (1) Revises and submits as necessary the FWA, Addendum or MOU with applicable IRBs of record to ORO and other applicable entities
 - (a) Revises and submits an updated FWA to ORO and VISN Director, within 30 days of appointment of a new Facility Director, Acting Facility Director, or HPA the FWA and FWA Addendum.
 - (b) Submits all changes to FWAs as they occur to ORO through OHRP. Modifications other than telephone, address, or email changes require a revised VA FWA Addendum signed by the Facility Director, the VISN Director, and the ORO Chief Officer or designee, prior to approval by OHRP. Telephone, address, or e-mail changes may be made electronically through the OHRP web site upon prior notification of and approval by ORO.

- (c) Initiates renewal of NF/SGVHS FWA prior to expiration of the FWA's approval period in accordance with the requirements and obtains approvals as required from ORO and OHRP for the renewal to take effect.
- (d) Maintains an accurate membership roster for NF/SGVHS IRB(s) of Record in accordance with the requirements of VHA Handbook 1058.03.
 - i. Submits membership roster for any IRB operated by the facility to ORO at the time of registration.
 - ii. Submits a membership roster for any IRB operated by a non-VA entity to ORO at the time of its designation as an IRB of Record on FWA.
 - iii. Provides ORO with an updated roster within 30 days of any change in IR membership.
 - iv. Retains each IRB membership roster for at least 5 years after the date it was superseded or retired.
- (e) Ensures MOU's (as appropriate) are in effect relative to the designation of another entity's IRB as the NF/SGVHS IRB(s) of Record and that the MOUs meet all relevant ORO requirements including those of VHA Handbook 1058.03.
 - i. Revises the MOU as conditions change and submits revisions to ORO within 30 working days of the change.
 - ii. Reviews existing MOU(s) at the time of FWA renewal, or more frequently as warranted, and makes any revisions necessary to reflect current arrangements.
 - iii. Ensures the applicable parties (IO and IO of each non-VA entity taking part in the arrangement) sign the MOU.
 - iv. Maintains MOUs on file at NF/SGVHS as required by VHA Handbook 1058.03 and other VHA record retention policies and makes documents available to ORO and other oversight and accrediting bodies upon request in accordance with applicable law, regulation, and policy.
- (f) Ensures that non-VA institutions receiving VA funds or other VA support for engagement in human subject research hold an Assurance acceptable to VA and verifies that valid Assurances are in place prior to the initiation by the non-VA institution of VA-supported activities involving human subjects.

References:

38 CFR 16
VHA Handbook 1058.03 (May 10, 2007)
VHA Handbook 1058.01 (May 21, 2010)
VHA Handbook 1200.05 (October 15, 2010)

FOLLOW-UP RESPONSIBILITY

This SOP will be reviewed annually, and revised as needed by the ACOS and AO of Research.

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