

ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS IN RESEARCH

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive sets forth policy related to the human subject protection assurances that Department of Veterans Affairs (VA) medical facilities are required to provide under the Federal Policy for the Protection of Human Subjects (Common Rule), which, as applicable to VA research, is codified in Title 38 Code of Federal Regulations (C.F.R.) Part 16.

2. SUMMARY OF MAJOR CHANGES: Policy changes incorporated into this directive are intended to reduce previous burdensome administrative and reporting requirements that had minimal to no demonstrated impact on the protection of human subjects in research. Major changes include the following:

a. Responsibility for approving the restriction or suspension of a VA medical facility's Assurance or VA Federal Wide Assurance (FWA) Addendum, based on a recommendation by the VHA Office of Research Oversight (ORO) Executive Director, has been assigned to the Under Secretary for Health (see paragraph 5.a);

b. A previous requirement that all VA medical facilities must hold a recognized assurance if engaged in human subjects research, regardless of whether such research meets certain regulatory exemption criteria, has been changed such that only VA medical facilities engaged in non-exempt human subjects research must hold such an assurance (see paragraph 6);

c. The requirement for all Institutional Review Boards (IRBs) used by a VA medical facility to be designated on the VA medical facility's FWA has been changed such that only IRBs operated by the VA medical facility must be designated or, in the absence of an IRB operated by the VA medical facility, only the primary external IRB relied upon must be designated (see paragraph 7); and

d. The previous requirement for VA medical facilities to report IRB roster changes to ORO has been eliminated.

3. RELATED ISSUES: VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017; VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 and amended March 3, 2020; VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015.

4. RESPONSIBLE OFFICE: The Office of Research Oversight (ORO) (10R) is responsible for the contents of this directive. Questions may be referred to 202-632-7620.

5. RESCISSIONS: VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research, dated November 21, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of September 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ Douglas Bannerman, PhD
Executive Director, Office of Research
Oversight

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on September 25, 2020.

CONTENTS

ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS IN RESEARCH

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 1

4. POLICY 4

5. RESPONSIBILITIES 4

6. ASSURANCES FOR VA MEDICAL FACILITIES 10

7. IRB REVIEW ARRANGEMENTS FOR VA MEDICAL FACILITIES..... 13

8. TRANSITIONING OVERSIGHT OF RESEARCH FROM AN IRB DESIGNATED ON A VA MEDICAL FACILITY’S FWA TO ANOTHER IRB INTENDED TO BE DESIGNATED ON THE FWA..... 14

9. ASSURANCES FOR NON-VA INSTITUTIONS 15

10. CLOSING A PROGRAM OF HUMAN SUBJECTS RESEARCH..... 16

11. TRAINING 16

12. RECORDS MANAGEMENT 16

13. REFERENCES..... 16

ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS IN RESEARCH

1. PURPOSE

This Veterans Health Administration (VHA) directive sets forth policy related to the human subject protection assurances that institutions are required to provide under Department of Veterans Affairs (VA) regulations at Title 38 Code of Federal Regulations (C.F.R.) Part 16. **NOTE:** *The requirements of this directive apply to all VA medical facilities engaged in the conduct of human subjects research that is not exempt from 38 C.F.R. 16. This directive does not apply to VA medical facilities engaged solely in human subjects research that is exempt from the requirements of 38 C.F.R. 16 based on the research meeting one or more of the exemption categories specified in 38 C.F.R. 16.104.* **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7307 and 38 C.F.R. part 16.

2. BACKGROUND

a. VA is one of twenty federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (hereafter, “Common Rule”). Consequently, all human subjects research conducted or supported by VA must comply with the Common Rule. VA’s adoption of the Common Rule is specified in 38 C.F.R. Part 16.

b. Title 38 Code of Federal Regulations (C.F.R.) Part 16 Section 103(a) provides that each institution engaged in research that is covered by the policy, with the exception of research eligible for exemption under 16.104, and that is conducted or supported by a federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of the policy. It further provides that federal departments and agencies will conduct or support research covered by the policy only if the institution has provided an assurance that it will comply with the requirements of the policy.

c. This directive does not address VA-affiliated Nonprofit Corporations’ (NPC) FWAs. However, VA-affiliated NPCs, as direct awardees of research support from federal agencies, are required by the U.S. Department of Health and Human Services – Office for Human Research Protections (HHS-OHRP) to maintain their own approved FWAs and written IRB agreements for reliance on VA medical facility IRBs. See VHA Handbook 1200.17, VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. §§ 7361 through 7366, dated April 27, 2016 and amended May 9, 2017.

3. DEFINITIONS

a. **Assurance of Compliance (Human Subjects).** An Assurance of Compliance (Human Subjects) is a legally binding written document that commits an institution to comply with the Common Rule and other applicable federal and VA standards for the protection of human subjects. **NOTE:** *The term “Federalwide Assurance” or “FWA” refers to a specific type of assurance that is approved by HHS-OHRP for Federalwide use as specified in 38 C.F.R. 16.103(a).*

b. **Exempt Human Subjects Research.** Exempt human subjects research refers to research involving human subjects determined to be exempt, as applicable, under 38 C.F.R. 16.104 of the 2018 Federal Policy for the Protection of Human Subjects (2018 Common Rule) or under 16.101(b) of the pre-2018 Common Rule. ***NOTE: Research deemed to be exempt under 38 C.F.R. 16 may not necessarily be exempt from the requirements of other regulations that may apply to the research, including regulations promulgated by the U.S. Food and Drug Administration (FDA).***

c. **Human Protections Administrator.** A Human Protections Administrator (HPA) is the individual named in an FWA and the VA FWA Addendum as the primary contact who directs or has in-depth knowledge of the daily operations of an institution's program for protecting human research subjects.

d. **Human Research Protection Program.** A Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of human subjects participating in research. An HRPP consists of a variety of individuals and committees such as: VA medical facility Director, Associate Chief of Staff for Research and Development (ACOS/R&D), Administrative Officer (AO) for R&D, R&D Committee, Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Determinations, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), research compliance officers (RCOs), Information System Security Officers (ISSOs), privacy officers (POs), and research pharmacy staff. The objective of this program is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

e. **Human Subject.** A human subject is a living individual about whom an investigator (whether professional or student) conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

NOTE: Per VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 and amended March 3, 2020, individuals who receive test articles or who serve as controls in clinical investigations, including clinical investigations as defined under FDA regulations in 21 C.F.R. 50.3, 312.3(b), and 812.3(h), are also considered human subjects.

f. **Institution.** For assurance purposes, an institution is any public or private entity. This directive 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 medical facility, including a Contract Research Organization (CRO); industry or private sponsor; or public or private research company, foundation, or group;

(b) Entities operating under a contract from VA, such as some community-based outpatient clinics, or nursing homes;

(c) Academic institutions, including but not limited to VA-affiliated medical and dental schools, and other academic affiliates;

(d) VA-affiliated NPCs; and

(e) Other federal departments or agencies.

(2) **VA Institution.** A VA institution is an entity operated by VA, including VA hospitals, medical facilities, and health care systems.

g. **Institutional Official.** An Institutional Official (IO) is the individual legally authorized as the Signatory Official to commit an institution to an assurance. For VA institutions, the IO must be the VA medical facility Director.

h. **Institutional Review Board.** An Institutional Review Board (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 subjects research in accordance with the Common Rule and other applicable regulations. ***NOTE: For the purposes of this directive, unless otherwise specified, references to IRB include any IRB which is responsible for approval and continuing review of a VA research project to ensure the protection of the rights and welfare of subjects in VA research.***

i. **Institutional Review Board of Record.** Regardless of whether designated on a VA medical facility's FWA, an IRB of Record is any IRB relied upon by a VA medical facility for review and oversight of the facility's human subjects research. The IRB may be operated by the VA medical facility or another entity. (See VHA Directive 1200.05 for IRBs permitted to be relied upon for the review of VA research).

j. **Memorandum of Understanding.** For the purposes of this directive, a Memorandum of Understanding (MOU) is a written agreement between two or more entities for reliance upon the other entity's IRB. Such written agreements document the relationship and define the respective roles and responsibilities of each entity within that relationship. These written agreements may also be referred to as "IRB Signatory Agreements," "Reliance Agreements," or "IRB Authorization Agreements."

k. **Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Per VHA Directive 1200.05, clinical

investigations, including clinical investigations as defined under FDA regulations in 21 C.F.R. 50.3, 312.3(b) and 812.3(h), are considered research. For purposes of this directive, the following activities are not considered research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each Federal agency) in support of intelligence, homeland security, defense, or other national security missions.

l. **VA Federalwide Assurance Addendum.** A VA FWA Addendum is an addendum to a VA medical facility's FWA that must be approved by the Office of Research Oversight (ORO) in order for a VA medical facility to be permitted to engage in non-exempt human subjects research.

m. **VA Research.** VA research is research that is conducted by investigators (serving on VA compensated, without compensation (WOC), or Intergovernmental Personnel Act (IPA) appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval before it is considered VA Research and before it can be initiated.

4. POLICY

It is VHA policy that each VA medical facility engaged in non-exempt human subjects research covered by 38 C.F.R. 16 must hold a valid FWA approved by HHS-OHRP with an effective VA FWA Addendum approved by ORO.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Reviewing recommendations by the Executive Director of ORO to restrict or suspend a VA medical facility's Assurance or VA FWA Addendum to safeguard the safety, rights, or welfare of human subjects.

(3) Reviewing recommendations by the Executive Director of ORO to lift a restriction or suspension of a VA medical facility's FWA or VA FWA Addendum imposed by the Under Secretary for Health.

b. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Ensuring that each VISN Director has sufficient resources to implement this directive in all VA medical facilities conducting non-exempt human subjects research within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive, relevant standards, and applicable regulations.

c. **Executive Director, Office of Research Oversight.** The ORO Executive Director, or ORO staff designated by the ORO Executive Director (hereafter, ORO FWA Staff), is responsible for:

(1) Reviewing VA medical facility proposed FWA submissions to HHS-OHRP for those VA medical facilities initiating a research program involving non-exempt human subjects research.

(2) Reviewing and approving VA FWA Addenda for VA medical facilities initiating a research program involving non-exempt human subjects research.

(3) Reviewing VA medical facility proposed changes to, or renewals of, FWAs.

(4) Reviewing and approving action plans submitted by VA medical facilities that address the deficiencies related to the restriction or suspension of the VA medical facility's FWA or VA FWA Addendum. (See paragraph 6.g.)

(5) Reviewing and approving changes to or renewals of VA FWA Addenda submitted by VA medical facilities.

(6) Recommending restrictions or suspensions of assurances, and the removal or modification thereof:

(a) Recommending to the Under Secretary for Health that restriction or suspension of a VA medical facility's Assurance or associated VA FWA Addendum be imposed when the ORO Executive Director reasonably believes that such action is necessary to safeguard the safety, rights, or welfare of human subjects (see paragraph 6.f.). **NOTE:**

Under 38 U.S.C. § 7307(c)(3)(B), if the ORO Executive Director reasonably believes that activities of a VA research project place human subjects' lives or health at imminent risk, the ORO Executive Director may immediately suspend or limit the activities of that project. See VHA Handbook 1058.01, Research Compliance Reporting Requirements dated June 15, 2015, for reporting requirements.

(b) Recommending to the Under Secretary for Health the removal or modification of the suspension or restriction of a VA medical facility's Assurance or associated VA FWA Addendum upon determining that the safety, rights, and welfare of human subjects are protected adequately. (See paragraph 6.g.)

(7) Notifying the Chief Research and Development Officer (CRADO), Office of Research & Development (ORD), and HHS-OHRP IRB/Assurances staff of the restriction, suspension, or deactivation of any VA FWA or associated VA FWA Addendum and the removal of such a restriction or suspension.

(8) Forwarding a copy of the Under Secretary for Health's determination to restrict or suspend a VA medical facility's Assurance or VA FWA Addendum to the entity that approved the Assurance, the VISN Director, the CRADO, the IO, and other regulatory agencies as appropriate. (See paragraph 6.f.)

(9) Reviewing requests from VA medical facilities to change the IRB(s) of Record that are designated on their FWAs.

(10) Ensuring that ORO assesses for compliance with this directive in the course of its periodic reviews of VA medical facility research programs.

d. **Chief Research and Development Officer, VHA Office of Research & Development.** The CRADO, VHA ORD, or Director, ORD Office of Research Protections, Policy, and Education (ORPPE) as delegated by the CRADO, is responsible for:

(1) Reviewing requests from VA medical facilities to establish a new HRPP. (See VHA Directive 1200.05.)

(2) Reviewing requests from VA medical facilities to change their IRB(s) of Record. (See VHA Directive 1200.05.)

(3) Reviewing an MOU or other type of written IRB agreement to document pertinent roles and responsibilities relative to the use by a VA medical facility of another entity's IRB as the VA medical facility's IRB of Record.

e. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities conducting non-exempt human subjects research within the VISN comply with this directive.

(2) Reviewing requests for approval of a VA medical facility's intention to initiate a research program involving non-exempt human subjects research and forwarding to the CRADO, or ORD ORPPE staff as designated by the CRADO, and the ORO Executive Director, or ORO FWA staff as designated by the ORO Executive Director, those requests, prior to the submission of an FWA.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Serving as the IO for the VA medical facility and signing and ensuring submission of the FWA and the VA FWA Addendum (see paragraph 6.a.). **NOTE:** *This authority must not be delegated except during transitions of leadership when the FWA and VA FWA Addendum may be signed by the Acting or Interim VA medical facility Director. As the IO, the VA medical facility Director is responsible for:*

(a) Ensuring that the VA institution's HRRP functions effectively and that the VA institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.

(b) Serving as the official representative of the institution to external agencies and oversight bodies.

(2) Being familiar with the requirements set forth in the Common Rule and the ethical principles governing human subjects research as outlined in the Belmont Report (accessible at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>). **NOTE:** *A summary of the aforementioned requirements and principles is available on HHS-OHRP's website at <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training>.*

(3) Ensuring the submission of all changes to FWAs within 60 days of the change to ORO FWA staff for review so as to ensure timely submission to HHS-OHRP (through ORO FWA staff) within 90 days of the change occurring. The VA institution's updated FWA must be received by HHS-OHRP within 90 days after changes occur regarding the legal name of the VA institution, the HPA, or the IO. Modifications to the FWA other than telephone, address, or email changes require a revised VA FWA Addendum signed by the VA medical facility Director, and the ORO Executive Director or designee within ORO FWA staff within 90 days of the change (see paragraph 6.c.).

(4) Upon receiving written notification from the ORO Executive Director of the restriction or suspension of the VA medical facility's FWA or VA FWA Addendum:

(a) Immediately restricting or ceasing the conduct of the VA medical facility's human subjects research except where the IRB, or IRB Chairperson, determines that continuation of the research is necessary to protect the safety, rights, or welfare of subjects currently enrolled in specific projects;

(b) Ensuring the development of an action plan that addresses the deficiencies related to the restriction or suspension and submitting it to the ORO Executive Director,

or ORO FWA staff if specified by the Executive Director, for approval within the timeframe specified by the ORO Executive Director or ORO FWA staff; and

(c) Providing written notification of the restriction or suspension, and the action plan to address deficiencies, to relevant VA medical facility staff and other entities, including ORD, regulatory agencies, and sponsors, under any relevant regulations, agreements, or terms of award.

(5) Ensuring that the IRB(s) of Record designated on the VA medical facility's FWA hold a current registration with HHS-OHRP and are constituted in accordance with all applicable federal and VA requirements regardless of whether the IRB(s) are operated by the VA medical facility or by another entity.

(6) For expirations of FWAs:

(a) Ceasing non-exempt human subjects research under an expired or inactivated FWA pending approval of a new or renewed FWA, except where the IRB, or IRB Chairperson, determines that continuation of the research is necessary to protect the safety, rights, or welfare of subjects currently enrolled in specific research projects.

(b) Notifying the ORO Executive Director or designee within ORO FWA staff of expiration or inactivation of the VA medical facility's FWA in accordance with VHA Handbook 1058.01.

(7) Ensuring the submission through ORO FWA staff to HHS-OHRP of initial registration(s) of IRB(s) operated by the Director's VA medical facility. (See paragraph 7.b.)

(8) Ensuring designation of all VA IRBs operated by the VA medical facility (internal IRBs), or if there are no internally-operated IRBs, the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies, as IRB(s) of Record on the VA medical facility's FWA submitted through ORO to HHS-OHRP. (See paragraph 7.a.)

(9) For expirations of Registration of IRB(s) designated on the Assurance:

(a) Ceasing non-exempt human subjects research under the oversight of an IRB designated on the Assurance whose HHS-OHRP registration has expired if the VA medical facility cannot transfer oversight of the research to another registered IRB of Record for it to rely upon, except where necessary to protect the safety, rights, or welfare of subjects currently enrolled in specific projects.

(b) Notifying the ORO Executive Director or ORO FWA staff in writing of the expiration of an IRB registration in accordance with VHA Handbook 1058.01.

(10) Regarding a VA medical facility's reliance on another institution's IRB that will be designated on the VA medical facility's FWA:

(a) Establishing and signing an MOU (or other type of written IRB agreement) to document pertinent roles and responsibilities relative to the use of that other entity's IRB as an IRB of Record for the VA medical facility.

(b) Ensuring revision or amendment of the MOU as conditions outlined in the MOU change, including changes of IO, and submitting such revisions to ORO within 30 days of execution.

(c) Ensuring the submission to ORO of a signed copy of the MOU for any IRBs designated as IRBs of Record on a VA medical facility's FWA within 30 days of execution.

(d) Ensuring MOUs required under this directive are kept on file at the VA medical facility and made available to ORO and other oversight and accrediting bodies upon request and to the extent allowed by applicable law, regulation, and policy. (See paragraph 12.)

(11) Submitting changes to the IRB(s) designated on a VA medical facility's FWA, as well as associated transitions of IRB oversight for active research impacted by the change, to the CRADO, or ORD ORPPE staff designated by the CRADO, and the ORO Executive Director, or ORO FWA staff designated by the ORO Executive Director. (See paragraph 8.a.)

(12) Ensuring that new MOUs and standard operating procedures (SOPs), as applicable, are developed to reflect the new IRB review arrangements. (See paragraph 8.c.)

(13) Ensuring that valid assurances are in place when providing support to non-VA institutions, as described in paragraph 9.a, prior to the provision to the non-VA institution of VA support for non-exempt research activities involving human subjects. FWAs may be verified by consulting the list available on the HHS-OHRP website at <https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>. Other assurances must be verified by contacting ORO.

(14) When initiating a program involving non-exempt human subjects research:

(a) Ensuring that VA medical facility staff contact both ORD ORPPE and ORO FWA staff as early in the process as possible for guidance on the appropriate process.

(b) Notifying, in writing, ORD and ORO, through the VISN Director within which the VA medical facility operates, of the VA medical facility Director's intention to initiate a research program involving non-exempt human subjects research, prior to submitting an FWA.

(c) Ensuring that no non-exempt research involving human subjects is conducted at the VA medical facility or by a VA investigator acting in an official VA capacity prior to approval of the VA medical facility's FWA by HHS-OHRP and prior to the approval of

the VA medical facility's VA FWA Addendum, except as provided under paragraph 6.a.(6).

(15) When closing a program involving non-exempt human subjects research:

(a) Ensuring notification of ORO in writing of plans to close its human subjects research program at least 30 days prior to closure.

(b) Ensuring that each of the VA medical facility's IRB(s) of Record is not dissolved or deactivated until all non-exempt human subjects research studies under the oversight of that IRB are closed or transferred to another IRB.

(c) Ensuring that once a VA medical facility's FWA or VA FWA Addendum is deactivated, no non-exempt human subjects research of any kind is conducted at the VA medical facility, or by individuals acting as the VA medical facility's employees or agents, unless and until the VA medical facility applies for and receives a new FWA approved by HHS-OHRP with an effective VA FWA Addendum approved by ORO, or as provided under paragraph 6.a.(6).

(16) Ensuring the designation of a VA Medical Facility HPA in accordance with paragraph 6.a.(4).

6. ASSURANCES FOR VA MEDICAL FACILITIES

a. **Federalwide Assurances.** Except as indicated in paragraph 6.a.(6), each VA medical facility engaged in non-exempt human subjects research covered by the requirements of 38 C.F.R. 16 must hold a valid FWA approved by HHS-OHRP with an effective VA FWA Addendum approved by ORO.

(1) The FWA for a VA medical facility covers all non-exempt human subjects research conducted at the VA medical facility by the VA medical facility's investigators acting in their official VA capacity. The FWA for a VA medical facility covers all VA-operated components within the facility management's control, regardless of the component's physical location. This includes space owned, leased, or rented under a legal agreement by the VA facility for VA use, remotely located components of the VA facility, and 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. **NOTE:** *The FWA for a VA medical facility does not cover entities operating under a contract from VA, such as some community-based outpatient clinics, or nursing homes, even in instances where the contractor operates in space shared with VA.*

(2) FWAs for VA medical facilities must designate at least one IRB of Record as follows:

(a) All IRBs operated by a VA medical facility (internal IRBs) must be designated on the VA medical facility's FWA.

(b) If a VA medical facility does not operate its own internal IRB, the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies must be designated on the VA medical facility's FWA. **NOTE:** *When an IRB of Record is operated by an entity other than the VA medical facility, an MOU or other written agreement is required (see paragraph 7.d.).*

(3) The VA medical facility Director must serve as the IO responsible for signing the FWA. The VA FWA Addendum must also be signed by the VA medical facility Director and the ORO Executive Director, or designee, in conjunction with approval of the FWA by HHS-OHRP. **NOTE:** *The VA FWA Addendum template may be found on ORO's website at: <https://www.va.gov/ORO/FWA.asp>.*

(4) The ACOS for R&D, AO for R&D, VA IRB Director, or other individual knowledgeable about human research protection requirements and the daily operations of the HRPP must serve as the designated HPA for an FWA and VA FWA Addendum.

(5) If a new VA medical facility Director, Acting VA medical facility Director, or HPA is appointed, the FWA and the VA FWA Addendum must be revised to reflect the appointment and submitted to ORO within 60 days of the appointment so as to ensure timely submission to HHS-OHRP (through ORO FWA staff) within 90 days of the change occurring.

(6) In rare cases and with ORD concurrence, ORO may negotiate or recognize a written assurance of compliance with the requirements of the Common Rule in lieu of an FWA.

b. FWAs and VA FWA Addenda for New Research Programs. FWAs for VA medical facilities initiating a program involving non-exempt human subjects research must be submitted to HHS-OHRP through ORO and must be approved by HHS-OHRP prior to any non-exempt human subjects research being initiated. Further, VA FWA Addenda for VA medical facilities initiating a program involving non-exempt human subjects research must be submitted to ORO and must be approved prior to any non-exempt human subjects research being initiated. A VA medical facility's initial FWA and VA FWA Addendum submission to ORO must include:

- (1) The signed FWA;
- (2) The VA FWA Addendum signed by the IO; and
- (3) Where applicable, signed MOU(s) as described in paragraph 7.d.

c. Changes to FWAs and VA FWA Addenda. All administrative and programmatic changes necessitating a change to a VA medical facility's FWA, as required by HHS-OHRP, must be submitted within 60 days to ORO FWA staff for review so as to ensure timely submission to HHS-OHRP through ORO FWA staff within 90 days of the change. (See <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/update-renew-fwa/index.html>). All programmatic changes necessitating a change to a VA medical facility's VA FWA Addendum, as required by ORO, must be submitted to ORO within 90

days of a change. **NOTE:** *Modifications other than telephone, address, or email require a revised VA FWA Addendum signed by the VA medical facility Director and the ORO Executive Director or designee.*

d. **FWA and VA FWA Addendum Renewals.** To continue conducting non-exempt human subjects research, a VA medical facility must renew its FWA prior to the expiration of the FWA's approval period, or in accordance with HHS-OHRP guidance and renew its VA FWA Addendum prior to the expiration of the VA FWA Addendum approval period, or in accordance with ORO guidance. Renewals of FWAs for VA medical facilities must be submitted through ORO to HHS-OHRP and must be reviewed by ORO and approved by HHS-OHRP in order to take effect. FWA renewals must include the following:

- (1) The signed FWA;
- (2) The signed VA FWA Addendum; and
- (3) Where applicable, signed MOU(s) as described in paragraph 7.d.

e. **Expiration of FWAs and VA FWA Addenda.** FWAs and VA FWA Addenda for VA medical facilities are typically approved for a period of five (5) years and are inactivated if renewals have not been approved by HHS-OHRP and ORO, respectively, prior to the end of the FWA's and VA FWA Addendum's approval period.

(1) Except as noted in paragraph 6.f.(2)(a), a VA medical facility must not conduct non-exempt human subjects research under an expired or inactivated FWA and/or VA FWA Addendum.

(2) Upon expiration or inactivation of a VA medical facility's FWA and/or VA FWA Addendum, cessation of non-exempt human subjects research, as appropriate, and written notification of ORO must occur as soon as possible, and VA medical facility research staff must consult with ORO FWA staff.

f. **Restriction or Suspension of Assurances.** Where the ORO Executive Director determines that restriction or suspension of a VA medical facility's Assurance or associated VA FWA Addendum is necessary because the ORO Executive Director reasonably believes the action is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO Executive Director must recommend such restriction or suspension to the Under Secretary for Health. A decision by the Under Secretary for Health to restrict or suspend a VA medical facility's Assurance or VA FWA Addendum will be communicated by the ORO Executive Director to the IO in writing along with an explanation of the reasons for the restriction or suspension. **NOTE:** *Per 38 U.S.C. § 7307(c)(3)(B), if the ORO Executive Director reasonably believes that activities of a VA research project place human subjects' lives or health at imminent risk, the Director may immediately suspend or limit the activities of that project. See VHA Handbook 1058.01.*

(1) ORO forwards a copy of the Under Secretary for Health's determination to the entity that approved the Assurance, the VISN Director, the CRADO, and other regulatory agencies as appropriate.

(2) The VA medical facility must take the following actions upon notification of the restriction or suspension:

(a) In accordance with the determination of the Under Secretary for Health, immediately restrict or cease the conduct of its human subjects research except where the IRB, or IRB Chairperson, determines that continuation of the research is necessary to protect the safety, rights, or welfare of subjects currently enrolled in specific projects.

(b) Develop an action plan that addresses the deficiencies related to the restriction or suspension and submit it to ORO for approval.

(c) Fulfill the VA medical facility Director's responsibility to notify relevant VA medical facility staff and other entities, including regulatory agencies and sponsors, under any relevant regulations, agreements, or terms of award.

g. **Removal of Restrictions or Suspensions.** The ORO Executive Director may, upon review of the VA medical facility's action plan, recommend to the Under Secretary for Health removal or modification of the restriction or suspension of the VA medical facility's Assurance or associated VA FWA Addendum upon determining that the safety, rights, and welfare of human subjects are protected adequately. A decision by the Under Secretary for Health to remove a restriction or suspension of a VA medical facility's Assurance or VA FWA Addendum will be communicated by the ORO Executive Director to the IO in writing. The ORO Executive Director must forward a copy of the Under Secretary for Health's determination to the entity that approved the Assurance, the VISN Director, the CRADO, and other regulatory agencies as appropriate.

7. IRB REVIEW ARRANGEMENTS FOR VA MEDICAL FACILITIES

a. **IRBs of Record.** A VA medical facility may operate its own IRB(s) of Record or designate as its IRB(s) of Record one or more IRBs operated by another entity as permitted by VHA Directive 1200.05. Regardless of whether the IRB is operated by the VA medical facility or by another entity, the VA medical facility Director of the VA medical facility holding the FWA is responsible under this directive for ensuring that any IRB(s) of Record designated on the FWA and on which it relies has a current registration with HHS-OHRP and is constituted in accordance with all applicable federal and VA requirements.

b. **IRB Registration.** The VA IRB(s) operated by the VA medical facility (internal IRB(s)), or if there are no internally-operated IRBs, at least the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies, must be designated on the VA medical facility's FWA as the IRB(s) of Record.

(1) Initial registrations of IRBs operated by VA medical facilities must be submitted through ORO FWA staff to HHS-OHRP. The VA medical facility operating the IRB must provide the IRB membership roster to ORO FWA staff for review (either the local roster or the proposed HHS-OHRP IRB registration).

(2) IRB registrations must be renewed as required by HHS-OHRP. VA medical facilities must meet HHS-OHRP requirements for updating information required in the IRB Registration.

(3) A VA medical facility must not continue non-exempt human subjects research under the oversight of an IRB designated on its FWA whose HHS-OHRP IRB registration has expired.

(a) If the VA medical facility cannot transfer oversight of the research to another registered IRB of Record, all human subjects research approved by the IRB with an expired registration must cease, except where necessary to protect the safety, rights, or welfare of subjects currently enrolled in specific projects under the purview of that IRB.

(b) The VA medical facility Director or designee must notify the ORO Executive Director or designee within ORO FWA staff of such expiration as soon as possible.

c. **IRB Membership Rosters.** VA medical facilities must maintain, or have readily available access to, accurate up-to-date rosters for all IRBs designated on a VA medical facility's FWA. A membership roster for all IRB(s) required by this directive to be designated on the VA medical facility's FWA must be submitted to ORO FWA staff at the time of the IRB's designation as an IRB of Record on the FWA.

d. **VHA Memoranda of Understanding for IRB(s) Designated on FWAs.** An MOU (or other type of written IRB agreement) is required to document pertinent roles and responsibilities relative to the use of another entity's IRB as a VA medical facility's IRB of Record. For those IRBs that are both required to be designated on a VA medical facility's FWA by this directive and not operated by the VA medical facility holding the FWA:

(1) A signed copy of the MOU must be submitted by the VA medical facility Director to ORO within thirty (30) days of execution; and

(2) Existing MOUs must be revised promptly by the VA medical facility Director as conditions outlined in the MOU change and must be submitted to ORO within thirty (30) days of being revised as final.

8. TRANSITIONING OVERSIGHT OF RESEARCH FROM AN IRB DESIGNATED ON A VA MEDICAL FACILITY'S FWA TO ANOTHER IRB INTENDED TO BE DESIGNATED ON THE FWA

a. **IRB Designations.** Changes to the IRBs designated on a VA medical facility's FWA, as well as associated transitions of IRB oversight for active research impacted by the change, must be approved by the CRADO, or ORD ORPPE staff as designated by

the CRADO, and the ORO Executive Director or ORO FWA staff as designated by the ORO Executive Director. For a VA medical facility planning to change the IRB(s) designated on its FWA:

(1) The VA medical facility must designate the new IRB(s) on the VA medical facility's FWA prior to beginning the transfer of IRB oversight if the designation of the new IRB on the FWA is otherwise required by this directive.

(2) The previously designated IRB must not be removed from the FWA until the transition to a replacement IRB has been completed, and the new IRB is designated on the VA medical facility's FWA.

b. **Documenting Transition Plans.** A written plan documenting the process to be followed for the orderly change in IRBs and the associated transition in the oversight of non-exempt human subjects research must be submitted to the CRADO or ORD ORPPE staff as designated by the CRADO, and the ORO Executive Director or ORO FWA staff as designated by the ORO Executive Director, prior to implementation.

c. **MOUs and Standard Operating Procedures.** The VA medical facility Director must ensure that new MOUs and standard operating procedures (SOPs), as applicable, are developed to reflect the newly designated IRB's review arrangements. As necessary, existing MOUs may need to be amended to reflect responsibilities pertaining to the transition (if not already addressed in existing MOUs).

d. **IRB Oversight During Transition Period.** During the transition period, the new IRB may review and, when appropriate, approve any research projects for which it will assume oversight responsibility. The newly designated IRB may require modifications to a research protocol, to take effect upon full assumption of oversight by the new IRB of that protocol, as a condition for accepting this responsibility.

e. **Completing the Transfer of IRB Oversight.** Once the newly designated IRB and the VA medical facility's R&D Committee have formally accepted the transfer of oversight to the new IRB, the VA medical facility's FWA must be modified through ORO FWA staff to remove the designation of the previous IRB(s), when relevant.

9. ASSURANCES FOR NON-VA INSTITUTIONS

a. **Assurances Required for VA-Supported Research.** In accordance with 38 C.F.R. 16.103(a), non-VA institutions conducting non-exempt human subjects research supported by VA must hold an assurance acceptable to VA as a condition for receiving said support. **NOTE:** *Questions regarding whether a given activity constitutes a VA-supported research activity must be directed to ORPPE, ORD.*

b. **Acceptable Assurances.** FWAs are recognized as satisfying the assurance requirements of paragraph 9.a. In rare instances and with ORD concurrence, the ORO Executive Director or designated ORO FWA staff may negotiate or recognize a written assurance of compliance with the requirements of the Common Rule in lieu of an FWA.

10. CLOSING A PROGRAM OF HUMAN SUBJECTS RESEARCH

a. A VA medical facility holding an FWA and VA FWA Addendum must notify ORO FWA staff and ORPPE, ORD, of its plans to close its human subjects research program. Such notifications must be in writing and submitted by the VA medical facility Director through the VISN. To facilitate a safe and orderly transition and to provide sufficient time for consultation, such notifications must be submitted to ORO and ORD at least thirty (30) days before the planned date of closure.

b. The VA medical facility's IRB(s) of Record must not be dissolved by the VA medical facility until all research studies involving non-exempt human subjects under the IRB's purview are closed or transferred to another VA medical facility.

c. ORO FWA staff will contact HHS-OHRP to request deactivation of the FWA, and where applicable, the IRB(s).

d. When the program has been properly closed, ORO FWA staff will issue a letter notifying ORD and the VA medical facility Director of the deactivation of the FWA and VA FWA Addendum and, where applicable, the IRB(s).

e. Once deactivated, non-exempt human subjects research cannot be conducted at the VA medical facility, or by individuals acting as the VA medical facility's employees or agents, unless and until the VA medical facility applies for and receives a new FWA approved by HHS-OHRP with an effective VA FWA Addendum approved by the ORO Executive Director, or ORO FWA staff as designated by the ORO Executive Director, or as provided under paragraph 6.a.(6).

11. TRAINING

There are no formal training requirements associated with this directive.

12. RECORDS MANAGEMENT

a. All records, regardless of format (paper, electronic, electronic systems) created in this directive, must be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA RCS 10-1. Any questions regarding any aspect of records management should be directed to the VA medical facility Records Manager or Records Liaison.

b. MOUs must be kept on file at the VA medical facility and made available to ORO and other oversight and accrediting bodies upon request and to the extent allowed by applicable law, regulation, and policy.

13. REFERENCES

a. 38 U.S.C. § 7307.

b. 38 C.F.R. Part 16.

c. 45 C.F.R. Part 46.

d. Federal Policy (Common Rule) for the Protection of Human Subjects, 56 Federal Register (FR) 28001, June 18, 1991.

e. Federal Policy for the Protection of Human Subjects published in the Federal Register on January 19, 2017 (82 FR 7149), commonly referred to as the Common Rule, revised January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28495). Effective July 19, 2018.

f. VHA Directive 1200.01, Research and Development (R&D) Committee, dated January 24, 2019.

g. VHA Directive 1200.05, Requirement for the Protection of Human Subjects in Research, dated January 7, 2019, amended March 3, 2020.

h. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015.