Summary of policy changes January 2019

A. Introduction to Policies, revised 1.24.19

Change Summary: deleted requirement of R&D to review polices
Rationale for change: not a VA requirement

Change Specifics:

1. Deleted VA R&D from this sentence: "After the VPR approval, the revised policies are distributed to IRB members for review and approval at the subsequent meeting of each committee."

B. Policy 3, Revision date 1.24.19

Change Summary: added resp for VA PI, changed ISO to ISSO
Rationale for change: VA requests, new VA Directive 1200.05

Change Specifics:

1. Section V, changed ISO to ISSO (Information System Security Officer)
2. PI Responsibilities, added #28, For VA studies, maintain a master list of enrolled subjects
3. PI Responsibilities, added #29, For VA studies, if the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects research, ensure that the firm has its own IRB oversight of the activity and that the Privacy Officer (PO) has determined that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm
4. PI Responsibilities, added #30; For VA studies, if either the awardee of a clinical trial funded or supported by a Federal agency or department other than VA, or conducting a clinical trial funded or supported by a nonFederal agency or department (e.g., university, industry, nonprofit organization) or not funded, posting a copy of the IRB-approved informed consent form used to enroll subjects after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when all sites have closed subject recruitment. See Policy 13 for additional details.

C. Policy 5, Revision date 1.24.19

Change Summary: deleted old VA definition of research
Rationale for change: definition needed to be updated from new VA Directive 1200.05

Change Specifics:

1. Deleted old VA definition of research and inserted, "VHA Directive 1200.05 defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

D. Policy 7, Revision date 1.24.19

Change Summary: new VA requirements for exempt
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Category 2, deleted "insurability"
2. Category 5, added "For VA studies, the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate."
3. For VA studies, added, "For exempt research activities involving the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally: (1) The activity is research; (2) Participation is voluntary; (3) Permission to participate can be withdrawn; (4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and (5) Contact information for the VA Investigator."
4. Added, "For VA studies, exempt categories 2 and 3 require use of a limited IRB review if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. The IRB is required to conduct a limited review to make the determinations."
5. To ethical requirements, added another element of consent: for studies subject to limited review, information about risk of loss of confidentiality

E. Policy 8 and Policy 9, Revision date 12.5.18

Change Summary: made criteria for continuing review interval consistent with policy 11

Rationale for Change: new AAHRPP criteria and inconsistency in policies

Change Specifics:

1. Removed listing of criteria and instead reference policy 11. "The criteria as specified in Policy 11 are considered when determining the review interval for expedited studies."

F. Policy 11, Revision date 1.24.19

Change Summary: removed reference to VA studies requiring CR, updated COC statement
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Deleted "and VA" from this sentence: All FDA research requires continuing review as described in Policy 11.
2. Deleted sentence about flagging studies pertaining to studies that do not have a COC

G. Policy 13, Revision date 1.24.19

Change Summary: revised COC requirements, clarified definition, deleted discussion of master list waiver, adding posting of consent requirements, added review when consent altered

Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Added to definition of LAR, "If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
2. Section IV D, deleted master list discussion re waiver (added maintaining to PI list)
   MasterList

The IRB may waive the VA requirement for the researcher to maintain a master list for a given study if both of the following conditions are met:

1. There is a waiver of written documentation of the consent process
2. The IRB determines the including the participants on such as a master list poses a risk to the participants from a breach of confidentiality.
3. Section IV D, changed "(applicable for studies that do not have Certificates of Confidentiality- Refer to Section VIII.C for studies that DO have Certificates of Confidentiality" to "Refer to Section VIII.C for information about Certificates of Confidentiality"
4. Deleted previous language and inserted, When VA conducts a study that is protected by a Certificate of Confidentiality, the following requirements apply:
   (1) For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record; and
   (2) For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. NOTE: The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included.
5. Added to Section IV, A waiver of HIPAA authorization must be approved by the IRB or Privacy Board prior to accessing any PHI for screening, recruiting, or determining eligibility. Informed consent, or an IRB-approved waiver thereof is required before any research interventions occur after eligibility is determined.
6. Added, The IRB cannot approve a consent procedure that omits/alters any of the general requirements of informed consent. Specifically, the consent process must ensure the following:
   Legally effective informed consent is obtained under circumstances that
   - provide the subject/LAR sufficient opportunity to decide whether to participate;
   - minimize coercion/undue influence and
   - does not include any exculpatory language through which the subject/LAR is made to waive/appear to waive their rights or releases/appears to release the investigator, sponsor, institution or its agents from liability for negligence
   - Information is provided to subjects/LARs in a language they can understand
   - Sufficient information is provided to allow them to make an informed decision
   - A short summary of key information related to participation in the study is provided upfront as part of the consent process

7. Added information about posting, both VA and non-VA:

For VA studies subject to the 2018 Requirements, if a research study is a federally – funded clinical trial, one IRB-approved informed consent form used to enroll subjects, unless the IRB waived documentation of informed consent, must be posted by either the investigator or the Federal department or agency conducting or supporting the study. Multiple versions of the IRB-approved informed consent form are not required to be posted. If the study involves multiple sites, only one IRB-approved informed consent form for the entire clinical trial must be posted and not from separate participating sites.

(1) The informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when the entire study has closed to subject recruitment. Consent forms must be posted on either https://clinicaltrials.gov or a docket folder on http://Regulations.gov (Docket ID: HHSOPHS-2018-0021).

(2) For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form.

(3) For a clinical trial funded or supported by a Federal agency or department other than VA, the awardee is responsible for posting the informed consent form.

(4) For VA studies, a clinical trial funded or supported by a non-Federal agency or department (e.g., university, industry, nonprofit organization) or not funded, the VA Investigator conducting the clinical trial is responsible for ensuring that the informed consent form is posted. If the clinical trial includes multiple sites engaged in the clinical trial, an agreement must exist specifying who is responsible for posting the informed consent form.

5) Any proprietary or personal information (such as names and phone numbers) must be redacted prior to posting the informed consent form

(6) The informed consent form must be posted on https://clinicaltrials.gov or a docket folder on http://Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

For non-VA studies subject to the 2018 Common Rule, researchers conducting clinical trials are required to post trial consent forms on a federal website, "after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol." For a multi-site study, only a single consent form from the entire study is required to satisfy the posting requirement – not a consent

form from each participating site. Only one IRB-approved version of a consent form that has been used in the course of the study to enroll participants needs to be posted.

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. See Policy 5 for the DHHS definition of clinical trial.

The Office for Human Research Protections (OHRP) has identified two publicly available federal websites that will satisfy this consent form posting requirement- https://clinicaltrials.gov and a docket folder (HHS-OPHS-2018-0021) on http://Regulations.gov. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

H. Policy 14, Revision date 1.24.19

Change Summary: now HIPAA can be separate for VA
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Added, "For VA studies, PHI obtained in research for which the IRB of Record or Privacy Board has waived the requirements to obtain a HIPAA authorization may not be disclosed outside VA unless the VA facility PO ensures and documents VA's authority to disclose the PHI to another institution. A waiver of HIPAA authorization by itself is not sufficient to fulfill the requirements of other applicable privacy regulations and statutes such as the Privacy Act of 1974 (5 U.S.C. 552a)."

2. Added,

For studies approved under the 2018 Common Rule, the following rules apply:

Written Authorization. In accordance with the HIPAA Privacy Rule at 45 CFR 164.508, a written authorization signed by the individual to whom the information or record pertains is required when VA medical facilities need to access, collect, develop, use, or disclose individually-identifiable health information for a purpose other than treatment, payment, or health care operations (e.g., research) unless there is legal authority (e.g., waiver, limited data set with data use agreement, etc.) to use and/or disclose such information (see VHA Directive 1605.01).

(1) Authorization must meet all VHA Privacy requirements detailed in VHA Directive 1605.01. The written HIPAA authorization may either be a standalone document or

combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research located at http://vaww.va.gov/vaforms/medical/pdf/10-0493-fill.pdf must be used

(2) All potential disclosures to a non-VHA entity must be listed within the written authorization;

(3) The PO must review the written HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol (see VHA Directive 1605.01); and

(4) Data disclosed under a properly executed written HIPAA authorization must be securely transferred according to VA information security requirements.

I. Policy 15, Revision date 1.24.19

Change Summary: removed restrictions on research with certain vul populations
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Added, "For VA studies, a woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery."
2. To this criteria for studies with pregnant women, added reference to VA- "If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46" *(and for VA, Directive 1200.05).*
3. Added restriction about pregnant kids: For VA studies, research involving clinical interventions with the potential of greater than minimal risk cannot be conducted by VA for children who are pregnant;
4. Deleted all previous requirements about pregnancy and VA studies

5. For VA studies: added the following:

   a. Research that involves provision of in vitro fertilization services can be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. This includes prospective and retrospective research involving provision of or the enhancement of FDA-approved methods of in vitro fertilization for studies involving consenting subjects, both male and female, undergoing or who have undergone in vitro fertilization for the treatment of certain forms of human infertility. In vitro fertilization is any fertilization of human ova that occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

   b. Prospective and retrospective studies that enroll or include pregnant subjects who conceived through in vitro fertilization or other artificial reproductive technologies are permitted.

   c. Research in which the focus is either a fetus, either in-utero or ex-utero can be conducted by VA investigators while on official VA duty, at VA facilities, or at VAapproved off-site facilities. Use of human fetal tissue (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-143.html and https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html) and human stem cells (https://stemcells.nih.gov/policy/2009-guidelines.htm) shall be governed by the policy set by NIH for recipients of NIH research funding.

   d. Research involving the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(b)) cannot be conducted by VA Investigators, at VA facilities, or at VA approved off-site facilities.

   e. Women who are known to be pregnant and their fetuses may be involved in research if all the following requirements above are met and the VA medical facility Director certifies that the VA medical facility has sufficient expertise in women's or reproductive health to conduct the proposed research if the research includes interventional studies or invasive monitoring of pregnant women as subjects, (see guidance at https://www.research.va.gov/resources/policies/default.cfm) including informed consent requirements and the ethical and scientific criteria outlined above.

6. Deleted previous info re neonates and VA, and added

   VA investigators cannot conduct interventions in research that include neonates while on official VA duty, at VA facilities, or at VA-approved off-site facilities. VA investigators may conduct research involving noninvasive monitoring of neonates if the research is determined by the IRB to be minimal risk. Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted.

   The reviewing IRB must have the appropriate expertise to evaluate any VA research involving neonates and must comply with the requirements of 45 CFR 46.205. The VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research.

J. Policy 21, Revision date 1.24.19

Change Summary: clarified when VA can rely on external IRB
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Deleted "Approval by an external IRB is not allowed for VA studies."
2. Added, "VA may only rely on an external IRB that is listed on the VA FWA."
3. Added, "For multisite studies, an IRB of a non-affiliated medical or dental school can serve as the IRB of Record for a VA facility if that IRB has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities."

K. Policy 36, Revision date 1.24.19

Change Summary: added VA requirements for survey firm and for collaborative research
Rationale for Change: new VA Directive 1200.05

Change Specifics:

1. Added, "If the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the Privacy Officer (PO) must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm;"
7. Added Section IV (moved current IV to V)

IV. VA Collaborative Research

Research collaborations between VA and non-VA institutions:

Collaboration is encouraged when VA investigators have a substantive role in the design, conduct, and/or analysis of the research. VA may also serve as a Coordinating Center for collaborative studies.

a. IRB of Record Approval. Each institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted by that institution.

(1) Each collaborating institution engaged in human subjects research must obtain approval from its IRB of Record and hold an FWA or another assurance acceptable to VA (e.g. DoD assurance).

(2) VA investigators must submit a protocol or other documentation to their VA IRB of Record that clearly delineates which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA investigators on VA time or VA property).

(3) Each institution engaged in the Collaborative Research must use the informed consent document and HIPAA authorization required by its respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subjects at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspices

(a) The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study.

(b) The informed consent document and HIPAA authorization (for the VA portion of the collaborative study) must not contain inconsistent provisions.

b. Research Data. The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.

(1) Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA RCS10-1.

(2) All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012; VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015; and VHA Directive 1605.01, any superseding policies.

3) Agreements regarding data use and transmission must be executed as required as applicable in VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, dated March 9, 2009, or any superseding policies revising or replacing it.

NOTE: VA Directive 1200.05 does not preclude other applicable agreements required for the Collaborative Research (e.g., data use agreement).