Summary of policy changes March 2021

A. Policy 14: HIPAA, Revised March 2, 2021

Change Rationale: Removed outdated language regarding HIPAA authorization requirements related to VA research

Change Summary: Revised to allow compound consent and HIPAA authorizations for VA research

Changes Specifics:

1. Page 4, Section IV. Use and Disclosure of PHI for Research with Individual Authorization, Subheading, VA studies, replaced the language with the following:

   "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 (i.e. Material Transfer Agreement, Data Use Agreement). 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).

   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. 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 must be used (See VHA Directive 1200.05 §23.a(1)).
   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)
   4. Data disclosed under a properly executed written HIPAA authorization must be securely transferred according to VA information security requirements.

   For VA research that requires a standalone HIPAA Authorization, the IRB VA Checklist Reviewer will verify receipt of the separate HIPAA authorization that was reviewed and approved by the VA Privacy Officer and ensure that it is consistent with the informed consent document and protocol."

B. Policy 16: Subject Recruitment and Payment, Revised March 2, 2021

Change Rationale: Added exception to informed consent for screening allowed by New Common Rule

Change Summary: Rearranged some sections, added Section VI. Subject Screening, and added to Section VII. IRB Review the details regarding regulatory exception

Change Specifics:

1. Page 1, Section I. Summary, moved VA requirement to its own Section VIII.
2. Page 1, Section I. Summary, updated the first paragraph to add: "The IRB evaluates whether subject selection is fair and equitable by considering both the selection criteria and proposed plans for recruitment of subjects for each research study. Recruitment represents the beginning of the consent process; as such, all recruitment methods and materials must meet ethical guidelines and must be reviewed and approved by the IRB before recruitment begins."
3. Page 1, Section I. Summary, added second paragraph stating: "The IRB must ensure that recruitment methods and materials, including payment amount and timing of disbursement to subjects, are not coercive, misleading, or unduly influential. If the circumstances of the research could give rise to any level of undue influence (e.g., payment for subjects' participation, instructors recruiting their own students, supervisors recruiting their direct reports, health care professionals recruiting their own patients), the study team must provide appropriate safeguards and/or assurances that the decision to participate will not affect the relationship."
4. Page 1, Section II, changed heading to "Recruitment of Subjects" and consolidated prior sections underneath, and added sub-headings for "Healthy Volunteers," "Patient Recruitment," and "ETSU Students & Employees."
5. Page 1, Section II, opening paragraph revised to summarize recruitment requirements.
6. Page 1, Section II, Healthy Volunteers sub-heading, deleted last sentence.
7. Page 2, Section II, Patient Recruitment sub-heading, deleted "at one of the institutions" from the first paragraph.
8. Page 2, Section II, add new sub-heading and context for "ETSU Students & Employees."
9. Page 3, Renamed Section III "Research Advertising Materials Guidelines" (previously Section IV).
10. Page 3, Section III, removed "questionnaires, surveys, testing forms" from first sentence and added second sentence with information about materials not directed to subjects.
11. Page 3, Section III, second and third paragraphs, refined the lists of items allowed and not allowed in advertisements.
12. Page 4, Renamed Section IV "Payment of Participants" (previously Section VI).
13. Page 4, Renamed Section V "Payment to Investigators" (previously Section VII).

14. Page 6, Section VI became "Subject Screening" and details the process and requirements for studies involving screening and eligibility procedures.
15. Page 6, Section VII, Renamed "IRB Review" (previously Section V) and refined content regarding review of recruitment and advertisements.
16. Page 7, Section VII, added last four paragraphs which describe IRB review of screening and allowance under 45 CFR 46.116(g) for approval of screening procedures without prior informed consent.

C. Policy 18: UPIRTSO, Revised March 2, 2021

Change Rationale: Revised to comply with VHA Directive 1058.01, amended 10/22/20

Change Summary: Require PI notification of UPIRTSO determination within 30 days of the meeting and VA subject deaths must be reported to IRB and ACOS/R within 1 day

Change Specifics:

1. Throughout, change "Probably related" to "Possibly related" to harmonize with VA Directive language.
2. Page 7, Section V, IRB Review of Reports, third to last paragraph, added "within 30 days of the convened meeting."
3. Page 8, Section VI. Additional VA Requirements, second paragraph, second bullet, added "time away from work or restricted work activities" and extended "medical" surveillance.
4. Page 8, Section VI, under local death, revised reporting to specify (#1) PIs orally notifying IRB and ACOS/R within 1 hour of becoming aware and (#2) written notification within 1 day; (#3) ACOS/R must notify MCD and ORO within 1 day of written notification, and (#4) within 1 day of written notification the IRB must determine if immediate are needed and initiate.
5. Page 8, Section VI, under local death, (#5) requires IRB review at convened meeting with determination documented within 30 days of meeting.
6. Page 8, Section VI, under local death, (#7) added RCO to list of VA officials receiving notification of IRB determination.
7. Page 9, Section VI, paragraph regarding loss of PHI or confidential information, noted reporting in accordance with VHA Directive.

D. Policy 25: Noncompliance, Revised March 2, 2021

Change Rationale: Revised to comply with VHA Directive 1058.01, amended 10/22/20

Change Summary: Refined the policy definitions and determination timeframes to harmonize with VHA Directive 1058.01

Change Specifics:

1. Page 1, combined prior Section I: Purpose and Section III: Summary Policy into "Section I: Summary Policy" and refined the language.
2. Page 1, Section II: Definitions, removed the additional VA definitions and revised existing to harmonize with VA requirements.
3. Page 2, Section III, renamed "Reporting of Non-compliance" (previously Section IV).
4. Page 2, Section III, Deleted last 2 VA specific paragraphs, and added to second paragraph: "For VA studies, the written report of noncompliance must also be made to the Associate Chief of Staff for Research (ACOS/R) within 5 working days."
5. Page 2, Section IV, renamed "Procedures for Allegations of Non-compliance" (previously Section V).
6. Page 2, Section IV, added to #2 the RCO for notification of VA noncompliance allegations.
7. Page 3, Section V, renamed "Procedures for Findings of Non-compliance" (previously Section VI).
8. Page 3, Section V, #7 revised to add that IRB documentation of not noncompliance determinations to be completed within 60 days of initial report and notification to VA officials within 5 days of the determination.
9. Page 3, Section V, #8 revised to add IRB Chair determination of noncompliance that might be serious and/or continuing is sent to full board within 30 days of initial report.
10. Page 5, Section V, deleted separate requirement for VA studies and VA Facility Director Reporting.
11. Page 5, Section VI, renamed "Report of Findings" (previously Section VII), and deleted last sentence.

E. Policy 34: Reporting to Institutional Officials and Regulatory Agencies, Revised March 2, 2021

Change Rationale: Revised to comply with VHA Directive 1058.01, amended 10/22/20

Change Summary: Refined the policy definitions and determination timeframes to harmonize with VHA Directive 1058.01

Change Specifics:

1. Page 1, Section I. Purpose, updated regulatory citations.
2. Page 2, Section I. Summary Policy, revised to summarize the policy and delete separate VA requirements; note change that HRPP Director to create draft report within 3 working days of IRB meeting determination.
3. Page 1, Section III, renamed "Procedure" and content describes the IRB procedure for complying with reporting requirements; note report to be finalized within 5 days of IRB determination (which complies with VA timeline).

4. Page 2, Section IV, renamed "Report Contents" (previously Section III) and added that it would contain ETSU IRB number.
5. Page 2, Section V, renamed "Report Distribution" (previously Section IV), deleted first paragraph, refined distribution list, and added paragraph clarifying that multiple reports not necessary if one was already made by another party.
6. Page 3, added Section VI. Additional Reporting Requirements for VA Research, and moved all current VA reporting to this section.

F. Policy 2: Exempt Review, Revised March 2, 2021

Change Rationale: Revised based on feedback from AAHRPP about the prisoner review process

Change Summary: Edited section on Limitations of exemptions to make clearer when vulnerable populations impact the exempt eligibility

Change Specifics:

1. Page 1, Section II. Determination of Exempt Status, paragraph 2, added: "The IRB Chair, or designee, may consult appropriate IRB members or others if additional expertise is needed to support the determination."
2. Page 2, Section V. Limitations for Exemptions, bullet 2, added: "…does not involve interaction with prisoners (including obtaining consent), and is not federally funded."
3. Page 2, Section V. Limitations for Exemptions, bullet 3: removed "not" from first sentence, and added "and Category 3." Last sentence, added: "or involves recording identifiable data requiring limited IRB review."

G. Policy 15: Vulnerable Populations, Revised March 2, 2021

Change Rationale: Revised based on feedback from AAHRPP about the prisoner review process and VA children requirement

Change Summary: Added to definition of children to meet VA requirement and clarified the IRB review process for prisoner research

Change Specifics:

1. Page 6, Section III. Research Involving Children as Subjects, Definitions, Children added: "For VA studies, biological specimens and data obtained from children is considered research involving children even if de-identified. If the biological specimens or data were previously collected, they must have been collected under applicable federal policies and ethical guidelines."
2. Page 12, Section IV. Research Involving Pregnant Women, Fetuses, and Neonates, first paragraph, added: "When research is funded by DHHS, or

otherwise subject to DHHS regulations, the IRB applies the additional protections specified in 45 CFR 46 Subpart B."

3. Page 15, Section IV.D, revised second paragraph to remove bullets and incorporate into narrative format.
4. Page 16, Section V. Research Involving Prisoners, second paragraph, added to the end: "When research is funded by DHHS, or otherwise subject to DHHS regulations, the IRB applies the additional protections specified in 45 CFR 46 Subpart C." These safeguards apply to research where any participant is or becomes a prisoner "unless the research qualifies for exemption (and is not subject to Subpart C)."
5. Page 16, Section V, A. IRB Submission and Review, first paragraph after first sentence, added: "The IRB Chair completes the Chair Review xform for each new submission and selects the appropriate review level based on the risks of the research and assigns appropriate expedited or full board reviewers. If the research involves prisoners, the IRB Chair will assign a prisoner advocate reviewer as one of the reviewers, focusing on appropriate additional protections and compliance with Subpart C."
6. Page 16, Section V.A, end of first paragraph, added: "For research reviewed by the convened IRB, the assigned prisoner advocate reviewer must present their review at the meeting with the determinations recorded in the meeting minutes."

H. Policy 42: DoD Research, Revised March 2, 2021

Change Rationale: Revised based on feedback from AAHRPP to incorporate new requirements from DoD Instruction 3216.02, revised April 2020

Change Summary: Edited to comply with DODI 3216.02 and AAHRPP standards

Change Specifics:

1. Page 2, Section III. Definitions, moved second paragraph in Administrative Review definition to Section IV, C. Permissions, new Administrative Approval subheading.
2. Page 3, Section III, edited definition of Research Involving a Human Being as an Experimental Subject.
3. Page 4, Section IV. Requirements, B. Formal Agreements, end of second paragraph, added: "Reliance arrangements for human subjects research must comply with ETSU IRB Policy 21."
4. Page 4, Section IV.B, end of first bullet point, added "…including injuries that are a direct result of activities performed by DoD-affiliated personnel."
5. Page 5, Section IV.B, deleted second bullet, added new second bullet: "The non-DoD institution's IRB is registered in accordance with 45 CFR 46, Subpart E."
6. Page 5, Section IV.B, added third bullet: "The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol."

7. Page 5, Section IV.B, edited fourth bullet to read: "The DoD institution, non-DoD institution, and the non-DoD institution's IRB (even if relying on an independent IRB) have a written reliance agreement defining the responsibilities and authorities of each organization in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02."
8. Page 5, Section IV, C. Permissions, Command Approval for Military Personnel subheading, replace Military with "DoD affiliated" personnel, and added "or component" approval.
9. Page 5, Section IV, C. Permissions, new subheading "Administrative Approval" with new content.
10. Page 7, Section IV. F. DoD Notification of Review or Approval, edited each step to match current process.
11. Page 7, Section IV, G. Additional Reporting Requirements, #1 changed from IRB Chair to "Principal Investigator" reporting to their DOD HRPO when changes are made; bullets edited to match current directive.
12. Page 7, Section IV.G, #2 added "…or governing body, other official entity, foreign government…" to first and second paragraphs. Added last sentence: "Additionally, the HRPP Director for ETSU studies, or VA IO for VA studies, will report to the DOHRP within 5 business days of discovering that such an audit report exists."
13. Page 8, Section IV.G, #3, replaced language with bullets to simplify, and deleted #4-5.
14. Page 8, Section IV, I. Research Monitor, deleted required appointment of research monitor for greater than minimal risk research. Edited to state it would be considered as appropriate and defined requirements if appointing one.
15. Page 8, Section IV, J. Consent Issues, Research Related Injury, last paragraph, added: "For greater than minimal risk research, consent documents must include the disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended."
16. Page 9, Section IV, J. Consent Issues, Other Consent Language, added bullets 3-5, and added IRB appointed-ombudsperson to last bullet point.
17. Page 9, Section IV, J. Consent Issues, Waiver of Consent, added to first sentence: "…informed consent must be obtained from the participant in advance [10 USC 980], and…"
18. Page 9, Section IV.J, Waiver of Consent, replaced Assistant Director of Defense for Research and Engineering with "DoD Office for Human Research Protections (DOHRP)." This change made throughout.
19. Page 10, Section IV.J, Waiver of Consent, first paragraph, last sentence says minimal risk research involving experimental subjects can include waiver of consent so long as it still preserves the integrity of the informed consent process.

20. Page 10, Section IV.J, Consent from LAR, first sentence, added: "…must be obtained in advance…"
21. Page 11, Section IV, J. Consent Issues, Consent from LAR, changed reference to decisionally impaired to "research involving adults with impaired capacity to consent" and change reference to Chapter 14 to "IRB Policy 15."
22. Page 11, Section IV, K. Study Participants, Studies Involving Department of Defense Personnel, deleted Undue Influence subheader, and combined the two subsections for Military and Civilian Personnel changing separate reference to each to DoD Personnel collectively.
23. Page 11, Section IV.K, Studies Involving Department of Defense Personnel, third bullet edited to state requirement for appointment of ombudsman for greater than minimal risk research involving group recruitment and/or consent procedures and sub-bullets state requirements.
24. Page 11, Section IV.K, Studies Involving Department of Defense Personnel, added fourth bullet for new DODI requirement for large-scale genomic data and additional protections.
25. Page 12, Section IV, L. Compensation, second paragraph, replaced first sentence with: "Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited in accordance with law."
26. Page 12, Section IV.L, second paragraph bullets, replaced first and second bullet points with new language.
27. Page 13, Section IV, N. Vulnerable Populations, first sentence, added: "…except where modified by DODI 3216.02 (April 2020)," and deleted second paragraph.
28. Page 11, Section IV.N, Research with Prisoners, second paragraph, replaced first sentence with: "Research involving a detainee or a prisoner of war as a human subject in DoD supported research is prohibited."
29. Page 13, Section IV.N, Research with Prisoners, third paragraph, added second additional category.
30. Page 16, Section IV, P. Surveys, removed Navy policy, and stated that PIs must work with their DoD component for any additional review requirements and timing thereof.
31. Page 16, Section IV, Q. Exclusions, end of first paragraph, added: "Before any excepted testing of chemical or biological agents involving HSR can begin, explicit written approval must be obtained from the DOHRP. The Principal Investigator must sign an attestation of DOD Compliance indicating that this has been met as applicable."
32. Page 17, Section IV.Q, added third and fourth paragraphs about DoDI exclusions and pledge of confidentiality limitations.
33. Page 17, Section IV, R. Responsibilities, PI, moved #4 to #1, and removed #14 about previous monitor requirements.
34. Page 18, Section IV, R. Responsibilities, IRB, administrative updates to form references.