Summary of policy changes April 2018

A. Introduction to Policies, revised 9.14.18

Change Summary: added two required clauses
Rationale for change: revised AAHRPP Instrument for Evaluation

Change Specifics:

1. Added, "If research is disapproved by the IRB, or the IRB requires modifications, the disapproval or need for modifications cannot be overruled by any other authority."
2. Added, "For VA studies, the Facility Director, Research and Development Committee and ORD can disapprove research. "

B. Policy 5, Revision date 9/14/2018

Change Summary: updated definition of research per HIPAA
Rationale for change: revised AAHRPP Instrument for Evaluation

Change Specifics:

1. Section I.A, added definition of research per Privacy Act: Research is defined in the Privacy Rule as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." See 45 CFR 164.501.

C. Policy 11, Revision date 9/14/2018

Change Summary: updated criteria for when studies need more than annual review
Rationale for change: revised AAHRPP Instrument for Evaluation

Change Specifics:

Revised to:
In determining which studies require review more often than annually, the IRB or EC will consider:
(A) The nature of and any risks posed by the clinical investigation.
(B) The degree of uncertainty regarding the risks involved.
(C) The vulnerability of the participants.
(D) The experience of the clinical investigator in conducting clinical research.
(E) The IRB's previous experience with that researcher or sponsor (e.g., compliance history, previous problems with the researcher obtaining informed consent, prior complaints from participants about the researcher).
(F) The projected rate of enrollment.

(G) Whether the study involve novel therapies

D. Policy 34, Revision date 9/14/18

Change Summary: added plan for reporting non-OHRP, non-FDA determinations
Rationale for Change: PG decision

Change Specifics:

1. Added, "For reports (serious or continuing non-compliance, suspensions or terminations, and UPIRTSOs) that are not subject to submission to FDA or OHRP, the VPR will provide a written response to the IRB's determinations. The response will include whether the VPR accepts the actions taken by the IRB, or requires additional actions on behalf of the institution.

E. Policy 25, Revision date 9.14.18

Change Summary: divided considerations re non-compliance into required and optional
Rationale for Change: revised AAHRPP standard

Change Specifics:
After voting, the IRB is required to consider the following range of possible actions:

- Suspension of IRB approval of the research
- Termination of IRB approval of the research
- notification of current participants (required when such information might relate to participants' willingness to continue to take part in the research)

In addition to the required considerations above, the IRB optionally may consider the following possible actions:

- no action;
- modification of the research protocol;
- modification of the information disclosed during the consent process;
- providing additional information to past participants;
- requiring current participants to re-consent to participation;
- modification of the continuing review schedule;
- monitoring of the research;
- monitoring of the consent process;
- obtaining more information pending a final decision, such as requiring an audit;
- referral to other organizational entities (e.g., legal counsel, institutional official);

F. Policy 26, Revision date 9.14.18

Change Summary: clarified authority to suspend/terminate
Rationale for Change: revised AAHRPP standard

Change Specifics:
Added, "Authority to suspend or terminate IRB or EC approval is retained, regardless of whether research was approved by the convened IRB, or through the expedited procedure, or through limited IRB review or is exempt. The IRB or EC retains the ability to suspend or terminate research even when continuing IRB or EC review is not required."

G. Policy 30, Revision date 9.14.18

Change Summary: additional minutes documentation
Rationale for Change: revised AAHRPP standard

Change Specifics:

Added:

- including each member's full name, representative capacity (scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated).-
- If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB on the study.
- The names of non-members and guests, such as IRB support staff, researchers, and study coordinators
- The names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.