TITLE: **Changes Required by the IRB to Secure Approval of After IRB Review**

PURPOSE: Establish the process to review investigator submissions of changes required by the IRB to secure approval of human research protocols

RESPONSIBILTIES: HSPP Staff

PROCEDURES:

The IRB will provide written correspondence regarding the Human Research proposal.

- If the IRB requires changes to secure approval (usually with full committee reviews): Required changes must be submitted to the IRB within 30 days using "F214: Changes Required to Secure Approval of Human Research." If all requested modifications are made, the IRB will issue a final approval. To appeal the required changes, write a response with justification and submit it to the IRB within 30 days of the last IRB/HSPP correspondence. **Research cannot commence until this final approval is received. Note the following timelines**. If a response to the IRB or additional information is not provided within 30 days of the correspondence date, the offer of approval with the requested changes will be withdrawn, and the project will be returned to the PI.
    - When an "F214: Changes required to Secure Approval of Human Research" is received, the IRB Coordinator assesses the information provided to see if the item must be placed on the next available IRB meeting agenda, based on the following information:
        - The investigator requires a review by the convened IRB;
        - The IRB voted to defer the item at the previous meeting; or
        - The changes required by the convened IRB have not been made.
- If the IRB defers the Human Research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable. **If additional information or correspondence is not provided within 30 days of the last IRB/HSPP correspondence, the project will be withdrawn and returned to the PI.**
- If the IRB disapproves the Human Research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing. **If additional information or correspondence is not provided within 30 days of the last IRB/HSPP correspondence, the project will be withdrawn and returned to the PI.**

In all cases, the investigator has the right to discuss any concerns with the IRB.

The changes should be reviewed by the same IRB that originally reviewed the item unless extenuating circumstances exist.

Follow "Operations Manual: Non-Committee Review" for items that do not need review by the convened IRB.

MATERIALS:

- SOP-041: Non-Committee Review
- F214: Changes required to secure approval of human research

- Operations manual

REFERENCES:
None

REVIEW/REVISIONS: From 10/01/10 version: Updated based on current process; Removed reference to the VA.
From 01/2014 version: Renumbered from P&P-022; Reference to P&P-031 revised to SOP-041 to reflect new numbering system.
From 03/24/15 version: Addition of information from Investigators Manual on other determinations the Committee can make.