TITLE: Post-Review

PURPOSE: The IRB reports its findings and actions to the investigator, and others as appropriate.

RESPONSIBILITIES: HSPP staff

PROCEDURES:
The IRB reports its findings and actions to the investigator and others as appropriate within ten (10) business days of the IRB meeting or receipt of the completed Non-Committee Review materials. When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

Attach approved consent documents to the approval email, if appropriate.

IRB determinations of serious non-compliance, continuing non-compliance, an unanticipated problem involving risks to subjects or others, suspension of IRB approval, or termination of IRB approval, copy the following persons:
- HSPP Director;
- Organizational Official;
- Senior Vice President for Research;
- Department Head; and
- Dean of the College.

Project funded or supported by a federal agency that has adopted the common rule: For determinations of serious non-compliance, continuing non-compliance, an unanticipated problem involving risks to subjects or others, suspension of IRB approval, or termination of IRB approval, complete “T516: External Report” and copy the following persons as appropriate:
- Protocol Contact;
- Principal Investigator;
- Sponsor;
- Contract Research Organization;
- Chair or Supervisor of the Principal Investigator;
- Legal Counsel;
- Risk Management;
- The Privacy Officer of an organization, if the report involves unauthorized use, loss, or disclosure of the organization’s individually identifiable information;
- The Information Security Officer of an organization, if the report involves violations of the organization’s information security requirements;
- Others as deemed appropriate by the Institutional Official;
- Vice President for Research; and
- The following regulatory agencies when they conduct, fund, or oversee the research when they want reporting separate from OHRP:
Projects involving prisoners and are funded or supported by Department of Health and Human Services (DHHS) or the Department of Defense (DoD), complete and submit a T522 - Certification of Approval of Research Involving Prisoners to the appropriate agency contact and copy, if applicable:

- Protocol Contact
- Principal Investigator
- Sponsor
- Contract Research Organization
- Chair or Supervisor of the Principal Investigator
- Institutional Official

Update the status of the research in the database.


MATERIALS:

- D600 - Awaiting Receipt
- SOP-041: Non-Committee Review Preparation
- SOP-070: IRB Records
- Operations Manual
- UAR Manual
- T516: External Report
- T522 - Certification of Approval of Research Involving Prisoners
- W302 - Calculation of Approval Intervals and Expiration Dates
REFERENCES:

- 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66
- 22 CFR §225
- 16 CFR §1028
- 7 CFR §1c
- 15 CFR §27
- 32 CFR §219
- 34 CFR §97
- 10 CFR §745
- Public law 108-458 Sec. 8306
- 28 CFR §46
- 49 CFR §11
- 40 CFR §26
- 24 CFR §60
- 14 CFR §1230
- 45 CFR §690
- Public law 7.5.26

REVIEW/REVISIONS: From 10/01/2010 version: Added federal reporting requirements for determinations of continuing non-compliance, serious non-compliance, unanticipated problems involving risks to subjects or others, suspensions, and terminations; Added federal reporting requirement for projects involving prisoners.

From 08/01/2011 version: Removed reference to the VA.

From 01/2014 version: Renumbered from P&P-052; References to P&P-070 revised to SOP-070 and P&P-031 to SOP-041 to reflect new numbering system.