



**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:



- Agency for International Development (22 CFR 225)
- Central Intelligence Agency (Executive order)
- Consumer Products Safety Commission (16 CFR 1028)
- Department of Agriculture (7 CFR 1c)
- Department of Commerce (15 CFR 27)
- Department of Defense (DOD) (32 CFR 219)
- Department of Education (ED) (34 CFR 97)
- Department of Energy (DOE) (10 CFR 745)
- Department of Homeland Security (Public law 108-458 Sec. 8306)
- Department of Justice (DOJ) (28 CFR 46)
- Department of Transportation (49 CFR 11)
- Environmental Protection Agency (EPA) (40 CFR 26)
- Housing and Urban Development (24 CFR 60)
- National Aeronautics and Space Administration (14 CFR 1230)
- National Science Foundation (45 CFR 690)
- Office of Science and Technology Policy (Adoption of policy)
- Social Security Administration (Public law 7.5.26)

**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.

Follow SOP-070: IRB Records.

**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:**

- 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
- 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.