Temple University

SOP: Post Review

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1. PURPOSE

1.1. This procedure establishes the process to communicate the IRB's findings and actions.
1.2. This procedure begins when the IRB has completed a review.
1.3. This procedure ends when the IRB communicated its findings and actions.

2. POLICY

2.1. The [Organization] does not need to directly report to a regulatory agency, if the agency has been notified by alternate mechanisms.
2.2. OHRP does not require organizations to report <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, and <Continuing Noncompliance> when unrelated to the local context.

3. RESPONSIBILITY

3.1. HRPP staff members carry out these procedures.

4. PROCEDURE

4.1. Calculate the <End Approval Date> following "POLICY: End Approval Date (HRP-022)".
4.2. Complete the applicable template notification (See Table 1 in REFERENCES) or when necessary draft a unique notification.
4.3. Update any newly approved consent document with the approval date.
4.4. Within 30 days of a decision send the notification to:

- 4.4.1. The investigator
- 4.4.2. Study contacts
- 4.4.3. The DOD component[1] when the research involving human subjects is DOD-supported and the notification involves any of the following:
  - 4.4.3.1. Significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review
  - 4.4.3.2. A change in the IRB used to review and approve the research to a different IRB
  - 4.4.3.3. Communication from any Federal department or agency or national organization informing the <Organization> that any part of its HRPP is under investigation for cause
- 4.4.4. Sponsor, when the notification is
  - 4.4.4.1. A disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(e)).
  - 4.4.4.2. Information that has been publicly disclosed about the initiation of a study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(7), §56.109(g)).
  - 4.4.4.3. Information that has been publicly disclosed following completion of the study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(7), 5§6.109(g)).
- 4.4.5. Other individuals or organizations determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official].

[1] Send to the Human Research Protections Officer (HRPO) of the DOD component, which is the individual who is delegated the responsibilities as defined in paragraph 48 CFR 252.235. There may be more than one HRPO in a DOD Component. Some DOD Components may use a different title for the person(s) with the defined responsibilities.

4.5. The following individuals or entities must receive notification from the [Organization] or the institution where the research is being conducted, when the notification involves an <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>:

- 4.5.1. [Organizational Official]
- 4.5.2. Sponsor or Contract Research Organization, when the research is sponsored
- 4.5.3. Site Management Organization or equivalent, when the research is reviewed on behalf of such an organization.
- 4.5.4. Institutional contact, when the research associated with an institution.
- 4.5.5. Agency (E.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting
- 4.5.6. Additional contacts, as required by any relevant agreement
- 4.5.7. The local research ethics committee or equivalent, when the research is international or collaborative research involving collaboration with a local research ethics committee or equivalent
- 4.5.8. Other individuals or organizations determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official], such as:
  - 4.5.8.1. Office responsible for oversight of the grant or contract
  - 4.5.8.2. Legal Counsel
  - 4.5.8.3. Risk Management
  - 4.5.8.4. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information
  - 4.5.8.5. Information Security Officer, when the information involves violations of information security requirements

4.6. Make any newly approved consent documents, scripts, or assent documents available to the submitter.

4.7. Update <Regulatory Review> findings as applicable.

5. REFERENCES

5.1. 21 CFR §50.54

5.2. 45 CFR §46.207 and §46.407

5.3. 21 CFR 50.24(e) and 21 CFR 56.109(g)

5.4. DOD Instruction 3216.02 November 8, 2011

5.5. Table 1

Notification	Template
Approve (with continuing review date)	Approval
Approve (with no continuing review date)	Approval
Close	Closure
Conditionally Approve	Approval with conditions
Conditionally Determine Human Research Not Engaged	Determination with conditions
Conditional Determine Not Human Research	Determination with conditions
Defer	Deferral
Disapprove	Disapproval
Expired	Expired
Human Research Not Engaged	Not engaged
Lift Suspension	Lifting of suspension
Not Human Research	Not Human Subject Research Letter
Suspend	Suspension of IRB approval
Terminate	Termination of IRB approval
Information Item	Acknowledgement letter
Information Item determined to be: • <Continuing Noncompliance> • <Serious Noncompliance> • <Suspension of IRB Approval> • <Termination of IRB Approval> • <Unanticipated Problems Involving Risks to Subjects or Others>	External Report Internal Report
Waiver of HIPAA Authorization	HIPAA Waiver
Notification to OHRP of approval of waiver of consent for planned emergency research	Notification of approval of waiver of consent for planned emergency research
Request for FDA or OHRP review of Not Otherwise Approval Research	Notification of not otherwise approvable research
Request for NSR determined to be SR	Significant Risk Device Determination
Request for OHRP certification of prisoner research	Certification of Prisoner Research
Emergency/Compassionate Use	Emergency/Compassionate use