corticalmetrics

SOP: POST-REVIEW

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1. PURPOSE

1.1. This procedure establishes the process to communicate the IRBs 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.
3.2. When review specialist is logged into the electronic IRB system using a valid username and password, and uses the system to generate correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed by the analyst under the authority of the IRB chair and the IRB manager.

4. PROCEDURE

4.1. Calculate the <End Approval Date> following “POLICY: End Approval Date (CM-005)”.
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 the investigator, study contacts, and:
  4.4.1. For approval or disapproval of international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent.
  4.4.2. For DOD-supported research involving human subjects when significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review, the IRB used to review and approve the research changes to a different IRB, when the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause, and <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, <Termination of IRB Approval>: The Human Research Protections Officer (HRPO) of the DOD component[1]
  4.4.3. For disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated: Sponsor
  4.4.4. For <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, <Termination of IRB Approval>:
    4.4.4.1 [Organizational Official]
    4.4.4.2 If sponsored: Sponsor or Contract Research Organization
    4.4.4.3 If funded: Office responsible for oversight of the grant or contract
    4.4.4.4 Legal Counsel

4.4.4.5 Risk Management
4.4.4.6 For unauthorized use, loss, or disclosure of individually identifiable
4.4.4.7 information: Privacy Officer
4.4.4.8 For violations of information security requirements: Information Security Officer
4.4.4.9 For research subject to regulation when reporting is required by the agency (E.g., DOD, EPA, FDA, HHS, VA)
4.4.4.10 For international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent

4.4.5. Other individuals or organizations determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official].

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

4.6. Update <Pre-Review> findings as needed.

5. REFERENCES

5.1. 21 CFR §50.54
5.2. 45 CFR §46.207 and §46.407
5.3. DOD Instruction 3216.02 November 8, 2011
5.4. Table 1