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1. PURPOSE

- 1.1. All Institutional Review Board (IRB) communications regarding its review of **research** activities are in the form of written correspondence. The IRB communicates concerns and suggestions regarding **human subject** protection issues to **Investigators** following each step of its review. This **policy** and **procedure** describes the process for communicating results to study team and other **institutional officials**.

2. POLICY

- 2.1. The IRB reports its findings and actions to the Principal Investigator (PI) and study team members via written letter (correspondence) that is part of the electronic project record.
- 2.2. The IRB reports its findings and actions to the **Institutional Official** or his/her Designee.
- 2.3. The IRB reports or makes available its findings and actions to the regulatory agency(ies) when the research is overseen or regulated by those agencies, and they require separate reporting (e.g., to OHRP when the research is covered by DHHS regulations and/or to the FDA when the research is FDA-regulated).
- 2.4. The study PI and primary contact (if different from the PI) will be notified of a review outcome (e.g., **approve**, **approve with modifications required to secure final approval**, **defer**, **table**, or **disapprove** for protocol reviews; the resulting determinations of an investigation of **non-compliance**, **suspension** or **termination of IRB Approval, and unanticipated problem involving risks to subjects or others**) via system-generated e-mail when the correspondence letter has been added to the project record.
 - 2.4.1. These reporting procedures are to be completed within 10 business days of the IRB meeting or receipt of the completed **Non-Committee Review** materials.
 - 2.4.2. When the IRB disapproves research, the IRB will provide the PI with a statement of the reasons for the decision and gives the PI an opportunity to respond in person or in writing.
- 2.5. Reporting to external or regulatory agencies overseeing the research (e.g., OHRP, FDA, DOD, etc.) of **Serious Non-Compliance**; **Continuing Non-Compliance**; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others is to take place within 30 business days from the recognition of a reportable problem.

3. PROCEDURES: IRB Staff

- 3.1. After the review has been submitted, the electronic system will provide a letter template that corresponds to the review type and recorded action or determination.
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Post-Review and Communication of Review Results

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- 3.2. The IRB Staff will refer to *Worksheet: Communication of Review Results* and prepare the letter by confirming the appropriate template and generating the letter. The action of generating the letter will integrate the study-specific information with the letter template.
- 3.3. The IRB Staff will review the draft correspondence for accuracy and correct as needed.
- 3.4. The IRB Staff will send the letter. This action generates a PDF copy of the correspondence and attaches this to the permanent submission record while sending an e-mail notification to the PI and study primary contact. This also transitions the electronic record to the final state as determined on the submitted review.
- 3.5. The IRB Staff makes relevant IRB findings and actions available to offices and committees such as the Office for Sponsored Programs (OSP), the Office of Research Compliance (ORC), or the Office of Biosafety.
- 3.6. This information is communicated by allowing guest access to the electronic submission record or by providing copies of materials to relevant people.
- 3.7. The IRB Staff will report the results of **Administrative Review** for Determination of Human Subject Research, Developmental Approval, and reliance upon an **External IRB** to the study team via correspondence letter that is part of the electronic project record. The study PI and primary contact (if different from the PI) will be notified of the review outcome via system-generated e-mail when the correspondence letter has been added to the project record.
- 3.8. The IRB will acknowledge a request for closure via correspondence letter that is part of the electronic project records. The study PI and primary contact (if different from the PI) will be notified of acknowledgment of protocol closure via system-generated e-mail when the correspondence letter has been added to the project record.

4. MATERIALS

- 4.1. WORKSHEET: Communication of Review Results
- 4.2. WORKSHEET: Calculation of Approval Intervals

5. REFERENCES

- 5.1. 45 CFR 46.103(b)(4)(i)