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.

4. PROCEDURE

4.1. Calculate the <End Approval Date> following "POLICY: End Approval Date (HRP-022)".
4.2. Complete the applicable template notification or when necessary draft a unique notification.
4.3. Update any newly approved documents with the approval date where necessary.
4.4. Make any newly approved documents available to the submitter.
4.5. Update <Regulatory Review> findings as needed.
4.6. Within 30 days of a decision send the notification to, as applicable:

- 4.6.1. The investigator
- 4.6.2. Study contacts
- 4.6.3. OHSU Clinical and Translational Research Institute (OCTRI)
- 4.6.4. The DOD component[1] when the research involving human subjects is DOD-supported and the notification involves any of the following:
  - 4.6.4.1. Significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review
  - 4.6.4.2. A change in the IRB used to review and approve the research to a different IRB
  - 4.6.4.3. Communication from any Federal department or agency or national organization informing the <Organization> that any part of its HRPP is under investigation for cause
- 4.6.5. Sponsor, when the notification is a disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated
- 4.6.6. OHRP, for approval of prisoner inclusion for a federally funded study
- 4.6.7. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

4.7. Within 30 days of a decision, 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>:

[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.

4.7.1. [Organizational Official]
4.7.2. If sponsored: Sponsor or Contract Research Organization
4.7.3. If funded: Office responsible for oversight of the grant or contract
4.7.4. For unauthorized use, loss, or disclosure of individually identifiable information: Privacy Officer
4.7.5. For violations of information security requirements: Information Security Officer
4.7.6. For research subject to regulation when reporting is required by the agency (E.g., DOD, EPA, FDA, HHS, VA)
4.7.7. For international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent
4.7.8. Additional contacts, when required by any relevant agreement
4.7.9. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

5. REFERENCES

5.1. 21 CFR §50.54
5.2. 45 CFR §46.207 and §46.407