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 (HRP-022)".
4.2. Complete the applicable template notification (See Table 1 in REFERENCES) or when necessary draft a unique notification.
4.3. Finalize "stamp with date" all approved consent documents with the END approval date in the "DO NOT SIGN THIS FORM AFTER THIS DATE" section.
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 a disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated
- 4.4.5. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

4.5. 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>,

[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.

<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. Office responsible for oversight of the grant or contract, when research is funded
4.5.4. Legal Counsel
4.5.5. Risk Management
4.5.6. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information
4.5.7. Information Security Officer, when the information involves violations of information security requirements
4.5.8. Government agency (e.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting
4.5.9. 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
4.5.10. Additional contacts, when required by any relevant agreement
4.5.11. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

4.6. Make any newly approved consent documents, scripts, or assent documents available to the submitter.
4.7. 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

Notification	Template
Acknowledgement of change in research staff	Personnel Update Acknowledgement (HRP-520)
Approve (with no continuing review date)	Approval Without Expiration (HRP-521)
Approve (with continuing review date)	Approval (HRP-522)
Close	Closure Acknowledgement (HRP-523)
Modifications Required to Secure Approval	Modifications Required to Secure Approval (HRP-524)
Modifications Required to Secure Human Research Not Engaged	Modifications Required to Secure Determination of Human Research Not Engaged (HRP-525)
Modifications Required to Secure Not Human Research	Modifications Required to Secure Determination of Not Human Research (HRP-526)
Defer	Deferral (HRP-527)
Disapprove	Disapproval (HRP-528)
Expired	Expiration of Approval (HRP-529)
Human Research Not Engaged	Human Research Not Engaged Determination (HRP-530)
Lift Suspension	Lifting of Suspension (HRP-531)
Not Human Research	Not Human Research Determination (HRP-532)
Suspend	Suspension (HRP-533)
Terminate	Termination (HRP-535)
Transfer of Research to Another IRB	Transfer Acknowledgement (HRP-536)
Information Item	Information Item Report (HRP-540)
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 (HRP-541) Internal Report (HRP-542)
Notification to OHRP of approval of waiver of consent for planned emergency research	Notification of Emergency Waiver (HRP-550)
Request for FDA or OHRP review of Not Otherwise Approval Research	Notification of Not Otherwise Approvable Research (HRP-551)
Request for NSR determined to be SR	Significant Risk Device Determination (HRP-552)
Request for OHRP certification of prisoner research	Certification of Prisoner Research (HRP-553)
Pre-Review of Emergency Use: Criteria Met	Pre-Emergency Use Criteria Met (HRP-560)
Pre-Review of Emergency Use: Criteria Not Met	Pre-Emergency Use Criteria Not Met (HRP-561)
Post-Review of Emergency Use: Criteria Met	Emergency Use Criteria Met (HRP-562)
Post-Review of Emergency Use: Criteria Not Met	Emergency Use Criteria Not Met (HRP-563)