1. PURPOSE
   1. This procedure establishes the process to communicate the IRBs findings and actions.
   2. This procedure begins when the IRB has completed a review.
   3. This procedure ends when the IRB communicated its findings and actions.
2. POLICY
   1. None
3. RESPONSIBILITY
   1. HRPP staff members carry out these procedures.
4. PROCEDURE
   1. Calculate the End Approval Date following “POLICY: End Approval Date (HRP-022)”.
   2. Complete the applicable template notification (See Table 1 in REFERENCES) or when necessary draft a unique notification.
   3. Update any newly approved consent document with the approval date.
   4. Within 30 days of a decision send the notification to the investigator, study contacts, and:
      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.
      2. For initial approval, continuing review approval, approval of significant changes, disapproval, change of reviewing IRB, and notification by a for cause investigation related to DOD research: Director, Defense Research and Engineering (send with minutes)
         1. For Department of Navy research: Undersecretary of the Navy (send with minutes)
      3. For disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated: Sponsor
      4. For Unanticipated Problems Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, Termination of IRB Approval:
         1. Organizational Official
         2. If sponsored: Sponsor or Contract Research Organization
         3. If funded: Office responsible for oversight of the grant or contract
         4. Legal Counsel
         5. Risk Management
         6. For unauthorized use, loss, or disclosure of individually identifiable information: Privacy Officer
         7. For violations of information security requirements: Information Security Officer
         8. For research subject to regulation when reporting is required by the agency (E.g., DOD, EPA, FDA, HHS, VA)
         9. For international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent
      5. Other individuals or organizations determined to be appropriate by the HRPP Administrator, IRB Executive Chair, or Organizational Official.
   5. Make any newly approved consent documents, scripts, or assent documents available to the submitter.
   6. Update Regulatory Review findings as needed.
5. REFERENCES
   1. 21 CFR §50.54
   2. 45 CFR §46.207 and §46.407
   3. Table 1

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| --- | --- |
| **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) |
| Conditionally Approve | Conditional Approval (HRP-524) |
| Conditionally Determine Human Research Not Engaged | Conditional Determination of Human Research Not Engaged (HRP-525) |
| Conditionally Determine Not Human Research | Conditional 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-537)  Internal Report (HRP-538) |
| Waiver of HIPAA Authorization | HIPAA Waiver of Authorization (HRP-539) |
| Notification to OHRP of approval of waiver of consent for planned emergency research | OHRP Notification of Emergency Waiver (HRP-550) |
| Request for FDA or OHRP review of Not Otherwise Approval Research | Federal 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 | OHRP Certification of Prisoner Research (HRP-553) |