1. PURPOSE
   1. This procedure establishes the process for communication after a protocol is reviewed
   2. This procedure begins when:
      1. A Designated Reviewer has completed a Non-Committee Review, or
      2. An IRB meeting was adjourned, or
      3. An IRB Office staff member has verified that stipulations required to secure approval have been made the IRB has completed a review.
   3. This procedure ends when all correspondence related to IRB determinations and correspondences have been sent to the PI and study team.
2. POLICY
   1. The IRB informs the investigator of findings and actions
   2. When the Board tables or disapproves research, correspondence to the investigator will include the reasons of the decisions.
      1. If a submission is tabled, the investigator will have the ability to submit a response for review.
      2. If the submission was disapproved, the investigator may submit a new study with the required changes and recommendations
   3. If the IRB votes to disapprove, suspend, or terminate a research protocol, it will include in its written notification a statement of the reasons for its decision. A principal investigator may appeal this decision by writing a letter to the IRB requesting reconsideration.
   4. When applicable, serious or continuing non-compliance, suspension, and unanticipated problems will be promptly reported to outside agencies.
3. RESPONSIBILITY
   1. HRPP staff members carry out these procedures, with consultation from the Institutional Official, IRB Chair, Office of Integrity and Compliance, and General Counsel when applicable.
4. PROCEDURE
   1. Upon approval of a new study or continuing review, document the approval period
   2. Finalize any newly approved consent documents and all other applicable submitted materials with the approval and expiration dates.
   3. Approved and Approved with Stipulations, correspondence should be completed within 5 business days of the review.
   4. Tabled or Deferred correspondence should be completed within 2 business days after the convened meeting.
   5. Suspension correspondence should be completed within 1 business day of the motion.
   6. Correspondence to the study staff will be sent to:
      1. The Principal Investigator
      2. Study Coordinator or study contact
      3. Other individuals or organizations determined to be appropriate by the Human Protections Administrator and/or IRB Chair, including:
         1. Institutional Official
         2. General Counsel
         3. Research and Development
         4. Office of Integrity and Compliance
         5. Health Analytics Research Team
   7. When researchers submit a response to an item that was not approved (e.g. Tabled), the response will be reviewed by the IRB:
      1. Tabled items will be reviewed by the convened IRB
   8. If an appeal to an IRB decision is received, at the discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB. An appeal of a disapproved, suspended, or terminated research project must be reviewed at a full board meeting. After review and discussion of appeal materials and/or presentation by the researcher, the IRB will vote by simple majority whether to approve the appeal and allow the research to commence. If the IRB upholds its vote to disapprove, suspend, or terminate a project, the decision may not be appealed again, nor may it be reversed by any administrator, other officer or agency
   9. The following individuals or entities must receive notification when the notification involves <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>:
      1. [Organizational Official]
      2. Research and Development
      3. Agency (E.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting
      4. Additional contacts, as required by any relevant agreement
      5. 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
      6. Other individuals or organizations determined to be appropriate by the Human Protections Administrator, IRB Chair, or Institutional Official such as:
         1. General Counsel
         2. Office of Integrity and Compliance
         3. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information
         4. Information Security Officer, when the information involves violations of information security requirements
         5. Department Chair of the PI, or their supervisor
   10. The following individuals or entities must receive notification when the notification involves an <Unanticipated Problems Involving Risks to Subjects or Others>:
       1. [Organizational Official]
       2. Agency (E.g., FDA, HHS, VA, DOD, EPA), when the research is subject to regulation by that agency and the agency requires reporting
       3. Additional contacts, as required by any relevant agreement
       4. 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
       5. Other individuals or organizations determined to be appropriate by the Human Protections Administrator, IRB Chair, or Institutional Official such as:
          1. General Counsel
          2. Office of Integrity and Compliance
          3. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information
          4. Information Security Officer, when the information involves violations of information security requirements
          5. Department Chair of the PI, or their supervisor
   11. Make any newly approved consent documents, scripts, or assent documents available to the submitter.
   12. Update <Regulatory Review> findings as applicable.
5. APPROVAL AND REVISIONS
   1. 06 APR 21: HRPO Director, Carley Emerson, originally created and approved
6. REFERENCES
   1. 21 CFR §50.54
   2. 45 CFR §46.207 and §46.407
   3. 21 CFR 50.24(e) and 21 CFR 56.109(g)
   4. DOD Instruction 3216.02 November 8, 2011
   5. Table 1

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| --- | --- |
| **Notification** | **Template** |
| Approve (with continuing review date) | Approval |
| Approve (with no continuing review date) | Approval |
| Close | Closure |
| Conditionally Approve | Approval with conditions |
| Conditionally Determine Human Research Not Engaged | Determination with conditions |
| Conditional Determine Not Human Research | Determination with conditions |
| Defer | Deferral |
| Disapprove | Disapproval |
| Expired | Expired |
| Human Research Not Engaged | Not engaged |
| Lift Suspension | Lifting of suspension |
| Not Human Research | Not Human Subject Research Letter |
| Suspend | Suspension of IRB approval |
| Terminate | Termination of IRB approval |
| Information Item | Acknowledgement letter |
| 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  Internal Report |
| Waiver of HIPAA Authorization | HIPAA Waiver |
| Notification to OHRP of approval of waiver of consent for planned emergency research | Notification of approval of waiver of consent for planned emergency research |
| Request for FDA or OHRP review of Not Otherwise Approval Research | Notification of not otherwise approvable research |
| Request for NSR determined to be SR | Significant Risk Device Determination |
| Request for OHRP certification of prisoner research | Certification of Prisoner Research |
| Emergency/Compassionate Use | Emergency/Compassionate use |