1. PURPOSE
   1. This procedure establishes the process to communicate the IRB’s 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. The [Organization] does not need to directly report to a regulatory agency, if the agency has been notified by alternate mechanisms.
   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
   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:
      1. The investigator
      2. Study contacts
      3. The DOD component[[1]](#footnote-2) when the research involving human subjects is DOD-supported and the notification involves any of the following:
         1. Significant changes to the research protocol are approved by the IRB, such as:
            1. Changes to key investigators or institutions.
            2. Decreased benefit or increased risk to participants in greater than minimal risk research.
            3. Addition of vulnerable populations as participants.
            4. Addition of DoD-affiliated personnel as participants.
         2. Results of the IRB continuing review.
         3. A change in the IRB used to review and approve the research to a different IRB.
         4. Communication from any Federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government informing the <Organization> that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol.
         5. Reports of audits of DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.
         6. For a non-Exempt protocol, when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, they will stay enrolled, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
         7. When a previously enrolled participant becomes a prisoner, they will stay enrolled, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
         8. Closure of a DoD-supported study.
      4. Sponsor, when the notification is
         1. A disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(e)).
         2. Information that has been publicly disclosed about the initiation of a study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(7), §56.109(g)).
         3. Information that has been publicly disclosed following completion of the study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR §50.24(7), 5§6.109(g)).
      5. Other individuals or organizations determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official].
   5. 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. [Organizational Official]
      2. Sponsor or Contract Research Organization, when the research is sponsored
         1. This can include federal agencies and should be done in concert with research administration.
      3. Site Management Organization or equivalent, when the research is reviewed on behalf of such an organization.
      4. Institutional contact, when the research is associated with an institution
      5. Agency (E.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting
      6. Additional contacts, as required by any relevant agreement
      7. 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
      8. Other individuals or organizations determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official], such as:
         1. Office responsible for oversight of the grant or contract
         2. Legal Counsel
         3. Risk Management
         4. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information
         5. Information Security Officer, when the information involves violations of information security requirements
   6. Make any newly approved consent documents, scripts, or assent documents available to the submitter.
   7. Update <Regulatory Review> findings as applicable.
5. 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
   5. Table 1

|  |  |
| --- | --- |
| **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 |

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. [↑](#footnote-ref-2)