|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Revisions** |
| R00 | 3/25/14 | Original issue |
| R00 | 11/18/2019 | Reviewed, no changes. |
| R00 | 12/16/2020 | Annual review, no changes |
| R00 | 10/15/2021 | Annual review, no changes |
| R00 | 11/21/22 | Annual review, no changes |
| R00 | 11/15/23 | Annual review, no changes |

**System-Generated Letter Templates:**

|  |
| --- |
| The purpose of this worksheet is to provide support for staff who send communications after an IRB review. This worksheet lists the letters that need to be prepared and sent within 30 business days after each review |
| IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee : | COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST |
| Approved protocol | Approval (HRP-510) |
| Acknowledged a protocol closure | Closure (HRP-511) |
| Required modifications to protocol to secure approval | Modifications Required to Secure Approval (HRP-512) |
| Determined that the activity is not Human Research | Non-Human Research (HRP-513) |
| Determined that the activity is Human Research in which the organization is not engaged | Non-Human Research (HRP-513) |
| With modifications the activity would not be Human Research | Modifications Required to Secure Determination (HRP-514) |
| Suspension or Termination of IRB Approval | Suspension or Termination of IRB Approval (HRP-515) |
| THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB |
| Deferred protocol | Deferral (HRP-516) |
| Disapproved protocol | Disapproval (HRP-517) |
| Reviewed an information item  | Information Item (HRP-519) |

**Paper-Based Letter Templates:**

|  |
| --- |
| The purpose of this worksheet is to provide support for staff who send communications after an IRB review or at the discretion of the IRB. |
| THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA) | Significant Risk Device (HRP-521) |
| Approved a waiver of the consent process for planned emergency research | OHRP Notification of Emergency Waiver (HRP-525) |
| **THE FOLLOWING NOTIFICATIONS ARE SENT AT THE IRB’S DISCRETION:**  |
| Tabled the protocol | Tabled (HRP-518) *Place on the agenda for the next IRB meeting* |
| Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency | External Report (HRP-520) |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA) | Significant Risk Device (HRP-521) |
| Approved research conducted or funded by DHHS involving prisoners as subjects | Certification of Prisoner Research (HRP-522) |
| Approved not otherwise approvable research involving children, pregnant women, or neonates | Not Otherwise Approvable Research (HRP-523) |
| Approved a waiver of the consent process for planned emergency research | OHRP Notification of Emergency Waiver (HRP-525) |
| Certification of approval of prisoner research for DOD research | Certification of approval of prisoner research (HRP-522) |
| Review of otherwise not approvable research to OHRP/FDA | Review of otherwise not approvable research (HRP-523) |
| Continuation of subjects in expired research | Continuation of subjects in expired research (HRP-532) |
| Investigator Quality Improvement assessment | Investigator Quality Improvement assessment (HRP-534)  |
| IRB Member Appointment | IRB Member Appointment (HRP-560) |
| IRB Member Thank You | IRB Member Thank You (HRP-561) |
| IRB Member Appreciation | IRB Member Appreciation (HRP-562) |
| Pre-Review of Emergency Use (Criteria Met) | Pre-Review of Emergency Use (Criteria Met) (HRP-570) |
| Pre-Review of Emergency Use (Criteria Not Met) | Pre-Review of Emergency Use (Criteria Not Met) (HRP-571) |
| Review of Emergency Use (Criteria Met) | Review of Emergency Use (Criteria Met) (HRP-572) |
| Review of Emergency Use (Criteria Not Met) | Review of Emergency Use (Criteria Not Met) (HRP-573) |
| Failure to Submit Emergency Use Report | Failure to Submit Emergency Use Report (HRP-551) |
| Failure to Submit Emergency Use Protocol | Failure to Submit Emergency Use Protocol (HRP-553) |