HRP-303 | 10/23/2024

**WORKSHEET: Communication of Review Results**

**System-Generated Letter Templates:**

The purpose of this worksheet is to provide support for staff who send communications after an IRB review.[[1]](#footnote-1)

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| **IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee:** | **COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST** |
| Approved protocol | HRP-510 - LETTER - Approval  HRP-510 - LETTER - Approval - CR NOT Req |
| Approved a participating site | HRP-870 - LETTER - Site Approval |
| Acknowledged a protocol closure | HRP-511 - LETTER - Closure |
| Required modifications to protocol to secure approval | HRP-512 - LETTER - Mods Req to Secure Approval |
| Required site modifications to secure approval | HRP-872 - LETTER - Site Modifications Required to Secure Approval |
| Determined a protocol to be exempt from regulation | HRP-514 - LETTER - Exemption |
| Determined that the activity is not Human Research | HRP-513 - LETTER - NHR Determination |
| Determined that the activity is Human Research in which the organization is not engaged | HRP-527 - LETTER - Not Engaged |
| Suspension or Termination of IRB Approval | HRP-515 - LETTER - Suspension or Termination |
| Agreed to provide IRB review for an external site engaged in a multi-site or collaborative study | HRP- 851 - LETTER - Invitation Decision |
| Agreed to cede IRB review to an external IRB | HRP-857 - LETTER - Acknowledge External IRB |
| Declined a request to serve as a sIRB | HRP-850- LETTER - Decline to Serve |
| Declined a request to cede review to an external IRB | HRP-856 - LETTER - Decline Reliance on an External IRB |
| Acknowledged study modifications approved by an external IRB | HRP-859 - LETTER - Acknowledge External IRB Update |

**THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB**

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| **IRB Determination** | COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST |
| Deferred protocol | HRP-516 - LETTER - Deferral |
| Deferred site | HRP-876 - LETTER - Site Deferral |
| Disapproved protocol | HRP-517 - LETTER - Disapproval |
| Disapproved site | HRP-877 - LETTER - Site Disapproval |
| Reviewed an information item | HRP-519 - LETTER - Information Item |
| Reviewed site information item | HRP-879 - LETTER - Review of Site Information Item |
| When a suspension is lifted | HRP-515a - LETTER - Lifting of Suspension |

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**

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| **IRB Determination** | **COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST** |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA) | HRP-521 - LETTER - SR NSR Device |
| Approved a waiver of the consent process for planned emergency research | HRP-525 - LETTER - OHRP Notif Emerg Waiver |

**THE FOLLOWING NOTIFICATIONS ARE SENT AT THE IRB’S DISCRETION**

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| **IRB Notification** | **COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST** |
| Tabled the protocol | HRP-518 - LETTER - Tabled *(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 and OHRP | HRP-520a - LETTER - External Report OHRP and Other Agencies and OHRP Incident Report Form[[2]](#footnote-2) |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA) | HRP-521 - LETTER - SR NSR Device |
| Approved research conducted or funded by DHHS involving prisoners as subjects | HRP-522 - LETTER - Cert Prisoner Research  [Subpart C Certification Formiii](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html) |
| Approved not otherwise approvable research involving children, pregnant women, or neonates | HRP-523 - LETTER - Not Otherwise Appro Research |
| Approved a waiver of the consent process for planned emergency research | HRP-525 - LETTER - OHRP Notif Emerg Waiver |
| Certification of approval of prisoner research for DOD research | HRP-522 - LETTER - Cert Prisoner Research |
| Review of otherwise not approvable research to OHRP/FDA | HRP-523 - LETTER - Not Otherwise Appro Research |
| Continuation of subjects in expired research | HRP-532 - LETTER - Conti Subj Expired Research |
| Investigator Quality Improvement assessment | HRP-534 - LETTER - Investigator QI Assessment |
| IRB Member Appointment | HRP-560 - LETTER - IRB Member Appointment |
| IRB Member Thank You | HRP-561 - LETTER - IRB Member Thank You |
| IRB Member Appreciation | HRP-562 - LETTER - IRB Member Appreciation |
| Pre-Review of Emergency Use (Criteria Met) | HRP-570 - LETTER - Pre-Rev EU - Crit Met |
| Pre-Review of Emergency Use (Criteria Not Met) | HRP-571 - LETTER - Pre-Rev EU - Crit Not Met |
| Review of Emergency Use (Criteria Met) | HRP-572 - LETTER - Review of EU - Crit Met |
| Review of Emergency Use (Criteria Not Met) | HRP-573 - LETTER - Review of EU - Crit Not Met |
| Failure to Submit Emergency Use Report | HRP-551 - LETTER - Failure to Submit EU Report |
| Failure to Submit Emergency Use Protocol | HRP-553 - LETTER - Failure to Submit EU Protocol |

1. This document satisfies AAHRPP elements I.1.A, I.5.D, I-9, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, III.2.D [↑](#footnote-ref-1)
2. See: <https://www.hhs.gov/sites/default/files/irpt-pra-incident-report-form.pdf> [↑](#footnote-ref-2)