HRP-303 | 3/29/2024

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]](#endnote-2) Additional notifications are auto-generated by ETHOS, including but not limited to submission reminders, lapse notifications, and annual approval date reminder for studies not required to complete continuing review.[[2]](#endnote-3)

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| IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee: | COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST |
| Approved protocol (initial approval) | HRP-510a - LETTER - Approval |
| Approved modification | HRP-510b - LETTER - Approval - MOD |
| Approved continuing review | HRP-510c - LETTER - Approval - CR |
| Approved modification-continuing review | HRP-510d - LETTER - Approval - MODCR |
| Acknowledged a protocol closure | HRP-511 - LETTER - Closure |
| Required modifications to protocol to secure approval | HRP-512 - LETTER - Mods Req to Secure Approval |
| 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 |
| Exempt Determination, including limited IRB review when applicable | HRP-514 - LETTER - Exemption |
| Suspension or Termination of IRB Approval | HRP-515 - LETTER - Suspension or Termination |
| IRB Review of QA Audit Reports | HRP-578- LETTER - IRB Review of QA Reports |
| **The following letters are used for sIRB and reliance related submissions in addition to the letters above as applicable:** |
| sIRB Approved protocol (initial approval) | HRP-510sa - LETTER - sIRB Approval  |
| sIRB Approved modification | HRP-510sm - LETTER - sIRB Approval - MOD |
| sIRB Approved continuing review | HRP-510sc - LETTER - sIRB Approval - CR |
| sIRB Approved modification-continuing review | HRP-510smc - LETTER - sIRB Approval - MODCR |
| sIRB Approved participating site | HRP-870 - LETTER - Site Approval |
| sIRB Required site modifications to secure approval  | HRP-872 - LETTER - Site Modifications Required to Secure Approval |
| Declined a request to serve as a sIRB | HRP-850- LETTER - Decline to Serve |
| Acknowledged study modifications approved by an external IRB (Ceded Research)  | HRP-859 - LETTER - Acknowledge External IRB Update |
| Notification regarding QA Audit Reports for ceded research or sIRB | HRP-579 - LETTER - Notification |

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB

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| **IRB Determination** | COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST |
| Deferred protocol | HRP-516 - LETTER - Deferral |
| sIRB Deferred site  | HRP-876 - LETTER - Site Deferral |
| Disapproved protocol | HRP-517 - LETTER - Disapproval |
| sIRB 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 FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB

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| **IRB Determination** | **COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST** |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA) | This determination is included in the approval letter. |
| 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 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 not including OHRP | HRP-520 - LETTER - External Report NOT Including OHRP |
| 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[[3]](#endnote-4) |
| 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 to DOD, or to DOD and OHRP  | HRP-526 - External Report to DOD |
| 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 - Certification for Prisoner Research[Subpart C Certification Form [[4]](#endnote-5)](https://www.hhs.gov/ohrp/regulations-and-policy/subpart-c-certification-request-to-ohrp/index.html) |
| Approved not otherwise approvable research involving children, pregnant women, or neonates | HRP-523 - LETTER - Not Otherwise Approvable 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 - Certification for Prisoner Research |
| Review of otherwise not approvable research to OHRP/FDA | HRP-523 - LETTER - Not Otherwise Approvable Research |
| Continuation of subjects in expired research | HRP-532 - LETTER – Continuation of Subjects in Expired Research |
| 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 [↑](#endnote-ref-2)
2. ETHOS has notifications built into the system that are triggered based on user and submission activity. A list of notifications can be made available upon request. [↑](#endnote-ref-3)
3. See: <https://www.hhs.gov/sites/default/files/irpt-pra-incident-report-form.pdf> [↑](#endnote-ref-4)
4. [OHRP Guidance: Prisoner Research Certification (2020)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-certification/index.html) requires institutions to submit the Subpart C Certification form when conducting research involving prisoners. OHRP encourages electronic submission of Subpart C certifications to subpartc@hhs.gov [↑](#endnote-ref-5)