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| The purpose of this worksheet is to provide support for staff who send communications after an IRB review. This worksheet may be used for guidance or as a training tool. | |
| 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 depending on the type of project (HRP-701, HRP-702, HRP-703, HRP-704, HRP-705) |
| Approved Short Form Consent | Short Form Consent Approval (HRP-730) |
| Acknowledged a protocol closure | Study Closure (HRP-718) |
| Required modifications to protocol to secure approval | Modifications Required to Secure Approval (HRP-706) |
| Required modifications to protocol to secure determination that the research activity is not Human Research | Modification Required to Secure Not Human Research Determination (HRP-710) |
| Required modifications to protocol to secure determination that the activity is Human Research in which the organization is not engaged | Modification Required to Secure Human Research Not Engaged Determination (HRP-708) |
| Determined that the activity is not Human Research | Non-Human Research (HRP-709) |
| Determined that the activity is Human Research in which the organization is not engaged | Human Research Not Engaged (HRP-707) |
| Agreed to cede IRB review to an external IRB | Acknowledgement of Reliance on External IRB (HRP-732) |
| Acknowledged study modifications approved by an external IRB | Acknowledgement of External IRB Update (HRP-733) |
| Reviewed a Reportable New Information Item | Reportable New Information Item (HRP-717) |
| THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB | |
| Deferred protocol | Deferral (HRP-712) |
| Disapproved protocol | Disapproval (HRP-714) |
| Reviewed a Reportable New Information Item | Reportable New Information Item (HRP-717) |
| Reviewed a Reportable New Information Item and determined that the information is one or more of the following: 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/or institutional officials | External Report (HRP-719);  External Report to OHRP (HRP-720); and/or  External Report Email Text - University Only Reports (HRP-1716) |
| Determined that a study submitted under the abbreviated requirements involved a significant risk device | Communicated through the minutes and to the PI through Deferral (HRP-712) or Modifications Required to Secure Approval (HRP-706) |
| Approved research conducted or funded by DHHS involving prisoners as subjects | Certification of Prisoner Research (HRP-722) |
| [Subpart C Certification Form](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html)[[1]](#footnote-1) |
| Approved not otherwise approvable research involving children, pregnant women, or neonates | Not Otherwise Approvable Research (HRP-723) |
| Approved a waiver of the consent process for planned emergency research | OHRP Notification of Emergency Waiver (HRP-724) |

1. [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](mailto:subpartc@hhs.gov) [↑](#footnote-ref-1)