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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) |
| 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) |
| THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB | |
| Deferred protocol | Deferral (HRP-712) |
| Disapproved protocol | Disapproval (HRP-714) |
| Reviewed an information item that is UPIRSO, Continued Non-Compliance, Serious Non-Compliance or Serious and Continuous Non-compliance. | Reportable New Information Item (HRP-717) |
| 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-719; if DOD: HRP-720) |
| 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) |
| 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) |