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| The purpose of this worksheet is to provide support for staff who send communications after an IRB 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) |
| Approved a participating site | Site Approval (HRP-870) |
| Acknowledged a protocol closure | Closure (HRP-511) |
| Required modifications to protocol to secure approval | Modifications Required to Secure Approval (HRP-512) |
| Required site modifications to secure approval | Site Modifications Required to Secure Approval (HRP-872) |
| 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) |
| Agreed to provide IRB review for an external site engaged in a multi-site or collaborative study | Invitation Decision (HRP – 851) |
| Agreed to cede IRB review to an external IRB | Acknowledgement of Reliance On An External IRB (HRP-857) |
| Acknowledged study modifications approved by an external IRB | Acknowledge External IRB Update (HRP-859) |
| **THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB** | |
| Deferred protocol | Deferral (HRP-516) |
| Deferred site | Site Deferral (HRP-876) |
| Disapproved protocol | Disapproval (HRP-517) |
| Disapproved site | Site Disapproval (HRP-877) |
| Tabled the protocol | Tabled (HRP-518) *Place on the agenda for the next IRB meeting* |
| Reviewed an information item | Information Item (HRP-519) |
| Reviewed site information item | Review of Site Information Item (HRP-879) |
| 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 HHS involving prisoners as subjects | Certification of Prisoner Research (HRP-522) |
| Approved not otherwise approvable research involving minors, 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) |