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| The purpose of this worksheet is to provide support for staff who send communications after an IRB review. This worksheet lists the letters that need to be prepared and sent after each review | |
| 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 | Approval of Protocol (HRP-510) |
| Acknowledged a protocol closure | Acknowledgement of Protocol Closure (HRP-511) |
| Required modifications to protocol to secure approval | Modifications Required to Secure Approval (HRP-512) |
| Determined that the activity is not Human Research | Non-Human Research Determination (HRP-513) |
| Determined that the activity is Human Research in which the institution is not engaged | Non-Human Research Determination (HRP-513) |
| With modifications the activity would not be Human Research | Modifications Required for Non-Human Research (HRP-514) |
| Reviewed an reportable new information item and a PI response is expected | Review of Information Item (HRP-519) |
| THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB | |
| Deferred protocol | Deferral of Protocol (HRP-516) |
| Disapproved protocol | Disapproval of Protocol (HRP-517) |
| Tabled the protocol | Tabled Protocol (HRP-518) *Place on the agenda for the next IRB meeting* |
| Reviewed an information item | Review of Information Item (HRP-519) |
| Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination of IRB Approval 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 Determination (HRP-521) |
| Approved research conducted or funded by DHHS involving prisoners as subjects | Certification of Approval of Prisoner Research (HRP-522) |
| Approved not otherwise approvable research involving children, pregnant women, or neonates | Review of Not Otherwise Approvable Research (HRP-523) |
| Approved a waiver of the consent process for planned emergency research | OHRP Notification of Emergency Waiver (HRP-525) |