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| The purpose of this worksheet is to provide support for HRPP staff conducting screening of submission materials. |
| 1. ALL REVIEWS |
| - Determine the laws that apply to the Human Research and indicate in the “Regulatory Oversight” section of “CHECKLIST: Pre-Review (HRP-401)”.  - Determine whether any investigators or research staff are Restricted. If so, list their names and the reasons in the “Restrictions” section of  “CHECKLIST: Pre-Review (HRP-401)”.  - Determine whether the Human Research has received all required ancillary reviews and approvals by the appropriate committees and officials.  - If the Human Research could be subject to EU GDPR, send for legal counsel review.  - If there is a HIPAA authorization, review using “WORKSHEET: HIPAA Authorization (HRP-330)”.  - If a HIPAA waiver of authorization is required, grant using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441).”  - Determine whether the submission is for a Single-Site Study, a Collaborative Study, or a Multi-Site Study. |
| **Note any missing materials necessary for review in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401)”.** |

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| * Completed “FORM: Basic Study Information (HRP-211)” including all appendices as applicable * Investigator Protocol * Consent document(s) or script(s) | | | * Data collection instruments * Written material to be seen or heard by subjects | | |
| * Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).” | | | | | |
| 1. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following): | | | | | |
| * If the research involves the use of a drug use the “WORKSHEET: Drugs (HRP-306).” * If the research involves the use of a device (including a humanitarian use device) use the “WORKSHEET: Devices (HRP-307).” * Note any special determinations that need to be made by the convened IRB or Designated Reviewer in the “Special Determinations” section. * If the device meets the abbreviated IDE requirements, note “Non-significant device determination” in the “Special Determinations” section. | | | | | |
| **Note any missing materials necessary for review in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”:** | | | | | |
| * Qualifications of the key personnel * Complete sponsor protocol (including HHS protocol) * HHS-approved sample consent document * Investigator brochure for investigational drug * Package insert for marketed drugs * Institutional Profile * Executed Reliance Agreement(s) | | * Product information for medical devices * For the Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA. | | | |
| **Note missing/inappropriately answered Investigator Protocol sections in the “Missing Materials” section of “CHECKLIST: Pre-Review (HRP-401)”:** | | | | | |
| - IRB Review History  - Objectives  - Background  - Setting  - Resources Available  - Prior Approvals  - Study Design  - Recruitment Methods | - Inclusion/Exclusion Criteria  - Compensation for Injury  - Local Number of Subjects  - Total Number of Subjects  - Study Timelines  - Study Endpoints  - Procedures Involved  - Data and Specimen Banking | | | - Data Management  - Confidentiality  - Provisions to Monitor Data  - Withdrawal of Subjects  - Risks to Subjects  - Potential Benefits to Subjects  - Provisions to Protect Privacy  - Economic Burden to Subjects | - Consent Process  - Consent Documentation  - Vulnerable Populations  - Drugs or Devices  - Multi-Site Research  - Community-Based Participatory Research  - Sharing of Results |
| **“Notes” section:** | | | | | |
| - Research is subject to regulations not overseen or conducted by the organization  - Positive financial declaration without a Conflict of Interest report  - Protocol information relates to an item in the list of institutional financial interests  - An IND is required and there is no IND  - An IND is required and there is insufficient documentation  - An IDE/HDE is required and there is no IDE/HDE  - An IDE/HDE is required and there is insufficient documentation  - There are inadequate provisions to control the drug(s) | | | | - There are inadequate provisions to control the device(s)  - There are inadequate provisions for an investigator held IND  - There are inadequate provisions for an investigator held IDE  - External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA)  - The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are legally authorized representatives (LAR) do not match.  - The research involves children and statements by the investigator and legal counsel regarding which persons do not match. | |
| 1. CONTINUING REVIEW | | | | | |
| - If continuing review is not required, ask the investigator to withdraw the submission.  - Note missing continuing review form in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401).” | | | | | |
| 1. MODIFICATION | | | | | |
| - Note missing modification form in the Missing Materials section of “CHECKLIST: Pre-Review (HRP-401).” | | | | | |
| 1. STUDY CLOSURE | | | | | |
| - Confirm that the research meets the criteria for closure and note in the Study Closure Section of “CHECKLIST: Pre-Review (HRP-401).” | | | | | |