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| The purpose of this checklist is to provide support for IRB 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 the Pre-Review Activity. * Determine whether any investigators or research staff are Restricted. If so, list their names and the reasons in the “Restrictions” section of the Pre-Review Activity. * Determine whether the Human Research has received all required ancillary reviews and approvals by the appropriate committees and officials. * 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)” |
| * **Note any missing materials necessary for review in the “Missing Materials” section of the Pre-Review Activity:** |

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| * Application & appendices A (external sites), B (drugs and devices) * 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 an 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 of the Pre-Review Activity. * If the device meets the abbreviated IDE requirements, note “Non significant device determination” in the “Special Determinations” section of the Pre-Review Activity. | | | | | |
| **Note any missing materials necessary for review in the “Missing Materials” section of the Pre-Review Activity:** | | | | | |
| * Qualifications of the key personnel * Grant application * Complete sponsor protocol (including DHHS protocol) * DHHS-approved sample consent document * Investigator brochure for investigational drug * Package insert for marketed drugs | | * Product information for medical devices * For the Department of Energy (DOE) research: “Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements” (<http://humansubjects.energy.gov/other-resources/documents/IRB-template-for-reviewing-PII-protocols-2010_ac.pdf>) * 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 the Pre-Review Activity:** | | | | | |
| * 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 |
| **“Final Contingencies” section of the Pre-Review Activity:** | | | | | |
| * 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 do not match. * The research involves children and statements by the investigator and legal counsel regarding which persons do not match. | |
| 1. CONTINUING REVIEW | | | | | |
| * Note missing Continuing review form in the “Missing Materials” section of the Pre-Review Activity. | | | | | |
| 1. MODIFICATION | | | | | |
| * Note missing modification form in the “Missing Materials” section of the Pre-Review Activity. | | | | | |
| 1. STUDY CLOSURE | | | | | |
| * Confirm that the research meets the criteria for closure and note in the Study Closure Section of the Pre-Review Activity. | | | | | |