|  |
| --- |
| 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:**
 |

|  |  |
| --- | --- |
| * 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.
 |