|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for IRB staff conducting screening of submission materials. | | | | |
| 1. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following) | | | | |
| * Determine the laws that apply to the Human Research and indicate these in the “Regulatory Oversight” section. * Determine whether the principal investigator is Restricted. If so, note in the “Restrictions” section. * Determine risk level of research and note in the “Risk Level” section. * 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)” * Determine whether any special determinations are required. If so, note in the “Special Determinations” section. * Determine whether any protocol tracking items apply. If so, note in the “Protocol Tracking” section. * If there is a HIPAA authorization, review using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)” * If a HIPAA waiver of authorization is required, grant using “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)” | | | | |
| **Note any missing materials necessary in the “Missing Materials” section:** | | | | |
| * Investigator Protocol * Point-by-point response * Evaluation of any Related Financial Interest. * Application form and appendices * Materials to meant to be seen or heard by subjects * Consent documents and scripts * Sponsor protocol * DHHS grant application, protocol, and sample consent | | * Investigator brochure for investigational drug * Package inserts 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” * For the Department of Education (ED) research letter attesting FERPA and PPRA compliance. | | |
| **Note missing/inappropriately answered Investigator Protocol sections in the “Missing Materials” section:** | | | | |
| * 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 |
| **Note any of the following in the “Final Contingencies” section:** | | | | |
| * The type of research is not conducted or overseen by the institution * The type of research is reviewed by an external IRB * 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 * If 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 getting federal funds from the institution does not have a federalwide assurance (FWA) * The research involves adults unable to consent and statements by the investigator and legal regarding which individuals are legally authorized representatives do not match. * The research involves children and statements by the investigator and legal regarding which persons do not match. | |
| 1. CONTINUING REVIEW or MODIFICATION | | | | |
| * Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).” * Note missing Continuing review form in the “Missing Materials” section: | | | | |
| 1. STUDY CLOSURE | | | | |
| * Confirm that the research meets the criteria for closure and note in the Study Closure Section. * Determine whether any new information has been provided. (For example, a new risk.) If so, follow “SOP: New Information (HRP-024).” | | | | |