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| --- | --- | --- | --- | --- | --- |
| The purpose of this worksheet is to provide support for IRB staff conducting screening of submission materials.[[1]](#footnote-2) | | | | | |
| 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 (per HRP-309 -WORKSHEET – Ancillary Review Matrix) 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 HRP-330 - WORKSHEET - HIPAA Authorization.  If a HIPAA waiver of authorization is required, grant using HRP-441 - CHECKLIST - HIPAA Waiver of Authorization.  Determine whether the submission is for a Single-Site Study, Collaborative Study, or Multi-Site Study. | | | | | |
| **Note any missing materials necessary for review in the “Missing Materials” section of the Pre-Review Activity:** | | | | | |
| Complete Huron IRB application  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 HRP-024 - SOP- New Information. | | | | | |
| 1. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following) | | | | | |
| If the research involves the use of a drug use HRP-306 - WORKSHEET - Drugs.  If the research involves the use of a device (including a humanitarian use device) use HRP-307 - WORKSHEET - Devices.  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  Complete sponsor protocol (including DHHS protocol)  DHHS-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 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 |
| **“Notes” 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 (LAR) do not match.  The research involves children and statements by the investigator and legal counsel regarding who can provide permission for the child if an individual is not a parent do not match. | |
| 1. INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB (when the modification affects one of the following) | | | | | |
| The site record includes all of the following:  Completed Basic Information Page  Completed Local Funding Sources Page (if relevant)  Site Informed Consent Document  All other documents required by the Study | | | | | |
| 1. CONTINUING REVIEW | | | | | |
| If Continuing review is not required, ask the investigator to discard the submission.  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. | | | | | |

1. This document satisfies AAHRPP elements I-9, II.2.C [↑](#footnote-ref-2)