|  |
| --- |
| 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)