HRP-308 | 2/2/2024

WORKSHEET: Pre-Review

The purpose of this worksheet is to provide support for IRB staff conducing screening submission materials.[1]

1. All Reviews

☐ Determine the Human Research laws that apply to the Human Research and indicate in the "Regulatory Oversight" 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 approval 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.

Note any missing materials necessary for review in the "Missing Materials" section of the Pre-Review Activity:

[1] This document satisfies AAHRPP elements I-9, II.2.C

☐ Completed 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)

2. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)

☐ If the submission includes a request to serve as the single IRB of record (sIRB) for a Cooperative Study or Multi-Site Study, determine if an authorization agreement is needed using HRP-801 - SOP - Establishing Authorization Agreements.

☐ For initial reviews, determine whether the principal investigator is Restricted. If so, list the principal investigator's name and the reasons in the "Restrictions" section of the Pre-Review Activity.

☐ If the research involves the use of a drug use the HRP-306 - WORKSHEET - Drugs.

☐ If the research involves the use of a device use the 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 risk device determination" in the "Special Determinations" section of the Pre-Review Activity.

☐ If the research is NIH-funded (regardless of whether the investigator has indicated the use of a Certificate of Confidentiality), note the presence of a Certificate of Confidentiality in the Protocol Tracking section of the Pre-Review Checklist.

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 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 provision 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.

3. INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB (when the modification affects one of the following)

☐ pSite Consent Process

☐ Protocol procedures are consistent with pSite age of majority state law as indicated in Institutional Profile.

☐ Protocol procedures are consistent with any pSite policies on assent as indicated in Institutional Profile.

☐ pSite Consent Documents

☐ Submission includes tracked version of the lead study approved version of consent document(s) (to ensure previously reviewed information and any modifications requested are present).

☐ pSite consent documents include pSite name and PI contact information.

☐ pSite consent documents contain any pSite required language (e.g., injury language, genetic testing/future use of genetic material, pregnancy reporting, barcode, logo) as indicated in Institutional Profile.

☐ HIPAA Authorization

☐ HIPAA authorization format is consistent with pSite requirement (e.g., separate or combined with consent)

☐ If HIPAA authorization language is included in the consent form, includes any pSite required language as indicated in HRP-815 - FORM - Institutional Profile (e.g., state law on expiration period).

☐ Privacy Board

☐ Determine if the IRB is serving as the Privacy Board (documented in HRP-830-Worksheet-Communication and Responsibilities in the Institutional Profile), for the study for purposes of review and approval of waivers of HIPAA authorization.

☐ HIPAA is not applicable to this study.

☐Recruitment and subject-facing materials

☐ Materials are consistent with the materials approved for the lead site.

☐ Materials are consistent with local pSite name/logo information.

☐ Protocol and/or Site Supplement and/or Basic Site Information Form

☐ Drug and Device Storage plan is present (if different from protocol) and consistent with pSite policy where indicated in Institutional Profile.

☐ If the drug/device storage plan is different from the parent protocol, use HRP-306 - WORKSHEET - Drugs and Biologics.

☐ Study procedures consider relevant tribal, state, or non-US laws, regulations, or policies (i.e., special populations, genetic testing, future use of genetic material) where indicated in Institutional Profile.

☐ Completed Local Funding Sources Page (if relevant)

☐ pSite Without an IRB/HRPP

☐ Qualifications and training of pSite key personnel have been provided (may request proof of human subjects and GCP training, confirmation of any special degrees or certifications needed for study procedures).

☐ If a possible conflict exists for pSite personnel is indicated in the submission materials, the COI office has been notified.

4. 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.

5. MODIFICATION

☐ Note missing modification form in the “Missing Materials” section of the Pre-Review Activity.

6. STUDY CLOSURE

☐ Confirm that the research meets the criteria for closure and note in the Study Closure Section the Pre-Review Activity.