HRP-308 | 10/6/2023

WORKSHEET: Pre-Review

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

1. ALL REVIEWS

☐ Determine the Human Research laws that apply to the Human Research and indicate in the "Regulatory Oversight" section of HRP-401 – CHECKLIST – Pre-Review.

☐ 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.

☐ Determine whether the submission is for a Single-Site Study, a Collaborative Study, or a Multi-Site Study.

Note any missing materials necessary for review in the "Missing Materials" section of HRP-401 – CHECKLIST – Pre-Review:

☐ Completed HRP-211 – FORM – Basic Study Information (including all appendices as applicable)

☐ 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)

☐ For initial reviews, determine whether the principal investigator is Restricted. If so, list the principal investigator's name and the reason in the "Restrictions" section of HRP-401 - CHECKLIST - Pre-Review.

☐ 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 HRP– 401 – CHECKLIST – Pre-Review.

☐ If the device meets the abbreviated IDE requirements, note "Non significant risk device determination" in the "Special Determinations" section of HRP– 401 – CHECKLIST – Pre-Review.

☐ 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 HRP-401 – CHECKLIST – Pre-Review:

☐ 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 HRP-401 – CHECKLIST – Pre-Review:

☐ 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:

☐ 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)

☐ The site submission includes all of the following:

- ☐ Completed HRP-811 – FORM – Basic Site Information
- ☐ Site Informed Consent Document
- ☐ All other documents required by the Study

4. CONTINUING REVIEW

☐ If Continuing review is not required, ask the investigator to withdraw the submission.

☐ Note missing Continuing review form in the “Missing Materials” section of HRP-401 – CHECKLIST – Pre-Review.

5. MODIFICATIONS

☐ Note missing modification form in the “Missing Materials” section of HRP-401 – CHECKLIST – Pre-Review.

6. STUDY CLOSURE

☐ Confirm that the research meets the criteria for closure and note in the Study Closure Section of HRP-401 – CHECKLIST – Pre-Review.

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