HRP-308 | 7/31/2024

WORKSHEET: Pre-Review

The purpose of this worksheet is to provide support for IRB staff conducing screening submission materials.[[1]](#endnote-2)

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 information for ancillary reviews (per HRP-309 – WORKSHEET – Ancillary Review Matrix) and if applicable, approval by the appropriate committees and officials prior to assigning the protocol. Please note that not all ancillary reviews need to be completed prior to routing.

Department Head/Chair: \_\_\_

MRI Safety Advisory Council

IBC

CoC

ADPH

IACUC

Correct version of the templates are used. (For all submissions, the current version date is 07/31/24)

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 the Pre-Review Activity:**

Completed Endeavor 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)

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 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

Secondary Use of Data Appendix

MRI Appendix

Anonymous Data Collection Assurance

**“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.

The study involved a clinical trial and the application does not include clinical trial registration information and/or required language in the consent form

The application involves secondary use of data and does not have HRP-900 uploaded.

The application involves MRI and does not have the MRI appendix attached and/or language in the consent form regarding incidental findings

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 the Pre-Review Activity.

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