RUTGERS UNIVERSITY
Office for Research

WORKSHEET: Pre-Review

NUMBER	DATE	PAGE
3.205 (HRP-308)	04.24.2024	1 of 1

The purpose of this worksheet is to provide support for IRB staff conducting initial review/continuing or progress review/modification of submission materials.

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 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 **6.205 (HRP-330) - WORKSHEET: HIPAA Authorization**
- ☐ If a HIPAA waiver of authorization is required, grant using **6.201 (HRP-441) - WORKSHEET: 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 eIRB+ 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 **10.001 (HRP-024) SOP: Reportable New Information**.

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

- ☐ If the research involves the use of a drug use the **8.202 (HRP-306) WORKSHEET: Drugs and Biologics**
- ☐ If the research involves the use of a device (including a humanitarian use device) use the **8.203 (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 which persons do not match.

3 STUDY CLOSURE

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