Pre-Review Checklist

Study Number:
Study Title:
Principal Investigator:

1. Regulatory oversight: (check all that apply)

	Federal Agency	Related Worksheet
☐	DOD (Department of Defense)	HRP-318
☐	DOE (Department of Energy)	HRP-318
☐	DOJ (Department of Justice)	HRP-318
☐	ED (Department of Education)	HRP-318
☐	EPA (Environmental Protection Agency)	HRP-318
☐	FDA (Food and Drug Administration)	
☐	HHS (Department of Health and Human Services)	
☐	ICH-GCP (International Center for Harmonization of Good Clinical Practice)	
☐	VA (Department of Veterans Affairs)	HRP-318

2. Special determinations and waivers: (check all that apply)

	Determination	Related Checklist
☐	Children	HRP-416
☐	Children who are wards of the state	HRP-416
☐	Neonates of uncertain viability	HRP-414
☐	Non-viable neonates	HRP-413
☐	Pregnant women	HRP-412
☐	Prisoners	HRP-415
☐	Cognitively impaired adults	HRP-417
☐	Students	
☐	Nonsignificant risk device (FDA)	HRP-418
☐	Waiver of consent documentation	HRP-411
☐	Waiver of consent for emergency research	HRP-419
☐	Waiver/alteration of the consent process	HRP-410
☐	Waiver of HIPAA authorization	HRP-441
☐	Waiver of Master Subject List (VA)	

3. * Risk level:

- ☐ No greater than minimal risk
- ☐ Greater than minimal risk

4. * Type of research: (check all that apply)

- ☐ Biomedical / clinical
- ☐ Social / behavioral / educational
- ☐ Other

5. Missing materials:

6. Final Contingencies:

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7. Other supporting documents:

	Protocol involves:	Related Worksheet
☐	Short Form of Consent Documentation	HRP-317
☐	Advertisements	HRP-315
☐	Payments	HRP-316
☐	Drugs	HRP-306
☐	Devices	HRP-307
☐	HUD	HRP-323
☐	FERPA Compliance	HRP-331
☐	HIPAA Authorization	HRP-330
☐	Emergency Use	HRP-322

HRPO Staff: _____ (Name) _____ (Email) _____ (Phone)

Pre-Review Checklist

The purpose of this checklist is to provide support for IRB staff conducting screening of submission materials.

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

- ☐ Determine the laws that apply to the Human Research and indicate these in the "Regulatory Oversight" section.
- ☐ Determine whether the principal investigator is Restricted. If so, note in the "Restrictions" section.
- ☐ Determine risk level of research and note in the "Risk Level" section.
- ☐ If the research involves the use of a drug use the "WORKSHEET: Drugs (HRP-306)."
- ☐ If the research involves the use of a device (including an humanitarian use device) use the "WORKSHEET: Devices (HRP-307)"
- ☐ Determine whether any special determinations are required. If so, note in the "Special Determinations" section.
- ☐ Determine whether any protocol tracking items apply. If so, note in the "Protocol Tracking" section.
- ☐ If there is a HIPAA authorization, review using "WORKSHEET: HIPAA Authorization (HRP-330)"
- ☐ If a HIPAA waiver of authorization is required, grant using "CHECKLIST: HIPAA Waiver of Authorization (HRP-441)"

Note any missing materials necessary in the "Missing Materials" section:

- ☐ Investigator Protocol
- ☐ Point-by-point response
- ☐ Evaluation of any Related Financial Interest.
- ☐ Application form and appendices
- ☐ Materials to meant to be seen or heard by subjects
- ☐ Consent documents and scripts
- ☐ Sponsor protocol
- ☐ DHHS grant application, protocol, and sample consent
- ☐ Investigator brochure for investigational drug
- ☐ Package inserts for marketed drugs
- ☐ Product information for medical devices
- ☐ For the Department of Energy (DOE) research: "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements"
- ☐ For the Department of Education (ED) research letter attesting FERPA and PPRA compliance.

Note missing/inappropriately answered Investigator Protocol sections in the "Missing Materials" section:

- ☐ 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

Note any of the following in the "Final Contingencies" section:

- ☐ The type of research is not conducted or overseen by the organization
- ☐ The type of research is reviewed by an external IRB
- ☐ 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
- ☐ If 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 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 regarding which individuals are legally authorized representatives do not match.
- ☐ The research involves children and statements by the investigator and legal regarding which persons do not match.

2 CONTINUING REVIEW or MODIFICATION

- ☐ Determine whether any new information has been provided. (For example, a new risk.) If so, follow "SOP: New Information (HRP-024)."
- ☐ Note missing Continuing review form in the "Missing Materials" section:

3 STUDY CLOSURE

- ☐ Confirm that the research meets the criteria for closure and note in the Study Closure Section.
- ☐ Determine whether any new information has been provided. (For example, a new risk.) If so, follow "SOP: New Information (HRP-024)."