HRP-401 | 9/25/2023

CHECKLIST: Pre-Review

The purpose of this checklist is to provide support for IRB Staff conducting Pre-review. This checklist is to be completed by the IRB staff, signed, dated, and retained.[i]

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.

Regulatory Oversight *(Check all that apply)*

☐ **Common Rule Requirements prior to January 21, 2019**

☐ **Common Rule Requirements as of January 21, 2019**

☐ **Applying equivalent protections**

☐ DHHS

☐ FDA

☐ OCR

☐ DOD

☐ DOE

☐ NSF

☐ DOJ

☐ ED / ED*

☐ Tribal Law

☐ EPA

☐ VA*

☐ EU GDPR

☐ Other Federal Agency

☐ ICH-GCP

☐ None

**The conduct of this research is disallowed by institutional policy per the HRPP Plan.*

Restrictions (Check if applicable)

☐ Principal Investigator is Restricted

Missing Materials

Click or tap here to enter text.

Special Determinations (Check all that apply)

☐ Children

☐ Wards

☐ Pregnant women

☐ Prisoners

☐ Students/Employees

☐ Not significant risk device (FDA)

☐ Non-viable neonates

☐ Neonates of uncertain viability

☐ Individuals with impaired decision-making capacity

☐ Waiver/alteration of the consent process

☐ Waiver of HIPAA authorization

☐ Waiver of consent documentation

☐ Waiver of consent for emergency research

☐ Broad Consent

Protocol Tracking (Check all that apply)

☐ Social/Behavioral/Education

☐ Single-Site Study

☐ Deception

☐ Certificate of Confidentiality

☐ Biomedical/Clinical

☐ Collaborative Study (Lead Site)

☐ Collaborative Study (Participating Site)

☐ Other

☐ Clinical Trial

☐ Multi-Site Study (Lead Site)

☐ Multi-Site Study (Participating Site)

Notes

Requesting DUA to be signed

STUDY CLOSURE

☐ Research can be closed.

Reviewer Signature

Date of Signature: Click or tap here to enter text.

[i] This document satisfies AAHRPP elements I.1.A, I.1.E, I.6.A, I.6.B, I.7.A, I.7.C. I-9, II.3.G, II.4.B, III.2.C