HRP-401 | 2/2/2024

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.[1]

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.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	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**

[1] 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

☐ 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

Click or tap here to enter text.

STUDY CLOSURE

☐ Research can be closed.

Reviewer Signature

X_____

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