HRP-401 | 02/01/2024

**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]](#footnote-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**

☐ DHHS

☐ FDA

☐ OCR

☐ DOD

☐ DOE

☐ NSF

☐ DOJ

☐ ED

☐ Tribal Law

☐ EPA

☐ VA

☐ EU GDPR

☐ Other Federal Agency

☐ ICH-GCP

☐ None

**Restrictions** (Check if applicable)

☐ Principal Investigator is Restricted

**Special Determinations** (Check all that apply)

☐ Children - HRP-416

☐ Wards - HRP-416

☐ Pregnant women - HRP-412

☐ Prisoners - HRP-415

☐ Students/Employees

☐ Not significant risk device (FDA) - HRP-418

☐ Non-viable neonates - HRP-413

☐ Neonates of uncertain viability - HRP-414

☐ Individuals with impaired decision-making capacity - HRP-417

☐ Waiver/alteration of the consent process - HRP-410

☐ Waiver of HIPAA authorization - HRP-441

☐ Waiver of consent documentation - HRP-411

☐ Waiver of consent for planned emergency research - HRP-419

**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**

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

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 [↑](#footnote-ref-1)