HRP-401 | 7/31/2024

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]](#endnote-2)

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. |

Correct version of the templates are used. (For all submissions, the current version date is 07/31/24)

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 / 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.*

Ancillary Reviews Required

Department Head/Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MRI Safety Advisory Council

IBC

CoC

ADPH

IACUC

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)

MRI Study (Requires Appendix)

Secondary Use of Data (Requires Appendix)

Developmental Approval (118 Determination)

Non-Human Subjects Research Determination

Anonymous Data Collection Assurance

Ceded Review

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 [↑](#endnote-ref-2)