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)