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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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-2) | | | | | | | | | | | | | | | | | | | | | | | | | |
| **IRB Number:** | | | | |  | | | | | | | | | | | | | | | | | | | | |
| **Study Title:** | | | | |  | | | | | | | | | | | | | | | | | | | | |
| **Short Title:** | | | | |  | | | | | | | | | | | | | | | | | | | | |
| **Investigator:** | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Type of Review** | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Initial Review | | | | | |  | | Modification | | |  | | RNI | | | | | | | | | | |
|  | Continuing Review | | | | | |  | | Closure | | |  | | Request for Human Research or Engagement Determination | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Regulatory Oversight** *(Check all that apply)* | | | | | | | | | | | | | | | | | | | | | | | | |
|  | **Common Rule Requirements prior to January 21, 2019** | | | | | | | | | | | |  | | **Common Rule Requirements as of January 21, 2019** | | | | | | | | | |
|  | DHHS | | |  | | DOD | | | |  | DOJ | | | | |  | | EPA | | | |  | | Other Federal Agency |
|  | FDA | | |  | | DOE | | | |  | ED | | | | |  | | VA\* | | | |  | | ICH-GCP |
|  | OCR | | |  | | NSF | | | |  | Tribal Law | | | | |  | | EU GDPR | | | |  | | None |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Restrictions (**Check if applicable) | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Principal investigator is Restricted. | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Missing Materials[[2]](#footnote-3)** | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Special Determ**in**ations (**Check all that apply) | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Children | | | | | | |  | Not significant risk device (FDA) | | | | | | | |  | | Waiver/alteration of the consent process | | | | | |
|  | Wards | | | | | | |  | Non-viable neonates | | | | | | | |  | | Waiver of HIPAA authorization | | | | | |
|  | Pregnant women | | | | | | |  | Neonates of uncertain viability | | | | | | | |  | | Waiver of consent documentation | | | | | |
|  | Prisoners | | | | | | |  | Individuals with impaired decision-making capacity | | | | | | | |  | | Waiver of consent for emergency research | | | | | |
|  | Students/Employees | | | | | | |  |  | | | | | | | |  | | Broad Consent | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Protocol Tracking (**Check all that apply) | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Social/ Behavioral/ Education | | | | | |  | Biomedical/Clinical | | | | | | | |  | | | Clinical Trial | | | | |
|  | | Single-Site Study | | | | | |  | Collaborative Study (Lead Site) | | | | | | | |  | | | Multi-Site Study (Lead Site) | | | | |
|  | | Deception | | | | | |  | Collaborative Study (Participating Site) | | | | | | | |  | | | Multi-Site Study (Participating Site) | | | | |
|  | | Certificate of Confidentiality | | | | | |  | Other | | | | | | | |  | | |  | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **Notes** | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **STUDY CLOSURE** | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Research can be closed. | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| Sign | | |  | | | | | | | | | | | | | | | | | | Date | |  | |

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

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-2)
2. If the submission is a request for Continuing Review, ensure minor deviation log is provided for IRB review. [↑](#footnote-ref-3)