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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for HRPP staff conducting Pre-review. This checklist is to be completed by the HRPP staff, signed, dated, and retained. | | | | | | | | | | | | | | | | | | | | | | | |
| **IRB Number:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Study Title:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Short Title:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Investigator:** | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **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 (this will be rare) | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Missing Materials** | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Special Determ**in**ations (**Check all that apply; items that are grayed out are not in use at this time) | | | | | | | | | | | | | | | | | | | | | | |
|  | 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 | |  | |