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| **Version** | **Date** | **Revisions** |
| R00 | 3/25/14 | Original Issue |
| R01 | 1/21/19 | Revised Common Rule |
| R01 | 12/18/2020 | Annual review, update logo |
| R01 | 1/14/22 | Annual review, no changes |
| R01 | 11/29/22 | Annual review, no changes |
| R01 | 11/30/23 | Annual review, no changes |

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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. | | | | | | | | | | | | | | | | | | | | | | | |
| **IRB Number:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Study Title:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Short Title:** | | | | | |  | | | | | | | | | | | | | | | | | |
| **Investigator:** | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Regulatory Oversight** *(Check all that apply)* | | | | | | | | | | | | | | | | | | | | | | |
|  | | **Common Rule Requirements prior to January 19, 2018** | | | | | | | | | |  | **Common Rule Requirements as of January 19, 2018** | | | | | | | | | |
|  | DHHS | | | |  | | DOD | | |  | DOJ | | |  | | EPA | | | |  | | ICH-GCP |
|  | FDA | | | |  | | DOE | | |  | ED | | |  | | EU GDPR | | | |  | | None |
|  | OCR | | | |  | | NSF | | |  | Tribal Law | | |  | | Other Federal Agency | | | |  | |  |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Restrictions (**Check if applicable) | | | | | | | | | | | | | | | | | | | | | | |
|  | | | Principal investigator is Restricted | | | | | | | | | | | | | | | | | | | |
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| **Missing Materials** | | | | | | | | | | | | | | | | | | | | | | |
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| **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 | | | | | |  | | |  | | | | |
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| **Notes** | | | | | | | | | | | | | | | | | | | | | | |
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| **STUDY CLOSURE** | | | | | | | | | | | | | | | | | | | | | | |
|  | | | Research can be closed. | | | | | | | | | | | | | | | | | | | |
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| Sign | | | |  | | | | | | | | | | | | | | |  | |  | |