|  |
| --- |
| 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. This worksheet is in the eIRB system. |
| **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 |
|  |
| **Missing Materials** |
|        |
|  |
| **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 – not being utilized  |
|  |  |  |  |  |  |
|  |
| **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 |[ ]  FWA required for other sites for federally supported research when RU is the prime awardee |[ ]  Other |
|  |
| **Notes** |
|       |
|  |
| **STUDY CLOSURE** |
|[ ]  Research can be closed. |
|  |
| Sign |       | Date |       |