|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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:** | | | | |  | | | | | | | | | | | | | |
| **Protocol Name:** | | | | |  | | | | | | | | | | | | | |
| **Investigator:** | | | | |  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **Regulatory Oversight** *(Check all that apply)* | | | | | | | | | | | | | | | | | |
|  | DHHS | | |  | | DOD | | |  | DOJ |  | | Other Federal Agency | | | |
|  | FDA | | |  | | DOE | | |  | ED |  | | ICH-GCP | | | |
|  | OCR | | |  | | None | | |  | EPA |  | |  | | | |
|  | | | | | | | | | | | | | | | | | |
| **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 | | | | | |  | Cognitively impaired adults | | | |  | | Waiver of consent for emergency research | | | |
|  | Pregnant women | | | | | |  | Waiver of HIPAA authorization | | | |  | | | | | |
|  | Prisoners | | | | | |  | Waiver of consent documentation | | | |
|  | | | | | | | | | | | | | | | | | |
| **Protocol Tracking (**Check all that apply) | | | | | | | | | | | | | | | | | |
|  | | Social/Behavioral/Education | | | | |  | Biomedical/Clinical | | | |  | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **Final Contingencies** | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **STUDY CLOSURE** | | | | | | | | | | | | | | | | | |
|  | | Research can be closed. | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| Sign | | |  | | | | | | | | | | | | Date |  | |