|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for IRB staff conducting Pre-review. This checklist or equivalent 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) |  | | (EPA) | |  | Other Federal Agency |
|  | (FDA) | | |  | | (DOE) | | |  | (ED) |  | | (VA) | |  | ICH-GCP |
|  | | | | | | | | | | | | | | | | |
| **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[[1]](#endnote-1) | | | | | |  | Neonates of uncertain viability | | | |  | | Waiver of consent documentation | | |
|  | Prisoners | | | | | |  | Cognitively impaired adults | | | |  | | Waiver of consent for emergency research | | |
|  | | | | | | | | | | | | | | | | |
| **Risk Level** (Check one) | | | | | | | | | | | | | | | | |
|  | | More than minimal risk to subjects | | | | |  | No more than minimal risk to subjects | | | |  | | | | |
|  | | | | | | | | | | | | | | | | |
| **Protocol Tracking (**Check all that apply) | | | | | | | | | | | | | | | | |
|  | | Social/Behavioral/Education | | | | |  | Biomedical/Clinical | | | |  | | | | |
|  | | | | | | | | | | | | | | | | |
| **F**in**al Cont**in**gencies** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **STUDY CLOSURE** | | | | | | | | | | | | | | | | |
|  | | Research can be closed. | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Sign | | |  | | | | | | | | | | | Date |  | |

1. Applicable for research that is funded by HHS or Homeland Security and includes pregnant women. Research involving intentional exposure of pregnant woman and/or children to insecticides is not approvable. [↑](#endnote-ref-1)