|  |
| --- |
| 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)