The purpose of this checklist is to provide support for Office of IRB Administration (OIA) staff conducting pre-review. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

<table>
<thead>
<tr>
<th>IRB Number:</th>
<th>Protocol Name:</th>
<th>Investigator:</th>
</tr>
</thead>
</table>

### Regulatory Oversight (Check all that apply)
- [ ] (DHHS)
- [ ] (DOD)
- [ ] (DOJ)
- [ ] (EPA)
- [ ] (FDA)
- [ ] (DOE)
- [ ] (ED)
- [ ] (VA)
- [ ] Other Federal Agency:
- [ ] ICH-GCP

### Restrictions (Check if applicable)
- [ ] Principal investigator is restricted

### Missing Materials

### Special Determinations (Check all that apply)
- [ ] Children
- [ ] Not significant risk device
- [ ] Waiver/alteration of the consent process
- [ ] Wards
- [ ] Non-viable neonates
- [ ] Waiver of HIPAA authorization

### Missing Materials

### Special Determinations (Check all that apply)
- [ ] Children
- [ ] Not significant risk device
- [ ] Waiver/alteration of the consent process
- [ ] Wards
- [ ] Non-viable neonates
- [ ] Waiver of HIPAA authorization

### 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

### Final Contingencies

### STUDY CLOSURE
- [ ] Research can be closed.

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1 Applicable for research that is funded by Health and Human Services (HHS) or Homeland Security and includes pregnant subjects. Research involving intentional exposure of pregnant subjects and/or children to insecticides is not approvable.