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.

<table>
<thead>
<tr>
<th>IRB Number:</th>
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<td>Protocol Name:</td>
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<tr>
<td>Investigator:</td>
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**Regulatory Oversight (Check all that apply)**

- [ ] DHHS
- [ ] DOD
- [ ] DOJ
- [ ] ICH-GCP
- [ ] FDA
- [ ] DOE
- [ ] ED
- [ ] Other Federal Agency
- [ ] None
- [ ] EPA

**Restrictions (Check if applicable)**

- [ ] Principal investigator is Restricted

**Missing Materials**

**Special Determinations (Check all that apply)**

- [ ] Children
- [ ] Wards
- [ ] Pregnant women
- [ ] Prisoners
- [ ] Not significant risk device (FDA)
- [ ] Waiver of consent documentation
- [ ] Waiver of consent for emergency research
- [ ] Waiver/alteration of the consent process
- [ ] Cognitively impaired adults

**Protocol Tracking (Check all that apply)**

- [ ] Social/Behavioral/Education
- [ ] Biomedical/Clinical

**Notes**

**STUDY CLOSURE**

- [ ] Research can be closed.

**Sign**