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

#### Type of Review
- [ ] Initial Review
- [ ] Modification
- [ ] RNI
- [ ] Continuing Review*
- [ ] Closure
- [ ] Request for Human Research or Engagement Determination

#### Regulatory Oversight (Check all that apply)
- [ ] DHHS
- [ ] DOD
- [ ] DOJ
- [ ] EPA
- [ ] Other Federal Agency
- [ ] FDA
- [ ] DOE
- [ ] ED
- [ ] VA
- [ ] ICH-GCP
- [ ] OCR
- [ ] None

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

#### Missing Materials

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*Note: If Continuing Review, ensure minor deviation log is provided for IRB review.

#### Special Determinations (Check all that apply)
- [ ] Children
- [ ] Wards
- [ ] Prisoners
- [ ] Pregnant women
- [ ] Children, Non-viable neonates
- [ ] Neonates of uncertain viability
- [ ] Cognitively impaired adults
- [ ] Children, Non-viable neonates
- [ ] Neonates of uncertain viability
- [ ] Cognitively impaired adults
- [ ] Wards, Non-viable neonates
- [ ] Neonates of uncertain viability
- [ ] Cognitively impaired adults
- [ ] Pregnant women, Non-viable neonates
- [ ] Neonates of uncertain viability
- [ ] Cognitively impaired adults
- [ ] Pregnant women and children for outcome data only

#### Protocol Tracking (Check all that apply)
- [ ] Social/Behavioral/Education
- [ ] Biomedical/Clinical

#### Final Contingencies

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### STUDY CLOSURE

- [ ] Research can be closed.

**Sign**

**Date**