**AUDIT CHECKLIST FOR INVESTIGATORS**

**\*PLEASE provide the IRB with a brief (2 to 3 sentence) description of the research staff (key personnel) involved in this project. This information MUST be received AT LEAST ONE WEEK PRIOR to the site visit.**

**Review your research-related materials for the following, *as applicable* to the research:**

Most recent, IRB approved protocol

Recruitment materials

Consent documentation

Parental permission documents

Assent documentation

Additional consent material – audio/video, consent to collect specimens, etc.

Waiver or modification of consent

HIPAA authorization

Amendment application(s)

Continuing review application(s)

Grant applications and/or funding sources

Conflict of Interest/Financial Conflict of Interest documentation

All signed contracts, agreements, approval letters, etc.

Adverse event reports

Serious adverse event reports

Protocol deviations

Data safety monitoring board (DSMB) reports

**Potential Interview Topics:**

Research team

Procedures

Recruitment

Consent process

Record keeping

Adverse events

Data safety monitoring

Other protocol specific questions