**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