**IRB Analyst Review Checklist**

**AMENDMENTS**

Prior to forwarding an action for IRB review, all actions should undergo an Analyst review. This Analyst review is NOT meant to be an ethical IRB review. The purpose is to ensure that the submission being forwarded for review is complete and appropriate.

**Amendments**

eIRB Amendment Application is correctly completed

eIRB Main Study Application has been updated to be consistent with the changes requested in the amendment

**Attachments**

A listing of all changes is submitted (cover letter or other document).

Conflict of Interest forms (with original signatures) are submitted for new study staff (if applicable).

Both a tracked-changes copy and clean copy of protocol (if applicable).

Both tracked-changes copy and clean copy of Informed Consent Form (if applicable).

Both Tracked changes copy and clean copy of any other documents (e.g., IB, recruitment material, if applicable).

**Review Category**

See Appendix A and B of IRB SOP 401 for a detailed explanation of changes approvable using expedited procedures

If proposed changes are both minimal risk and qualify as no more than a minor change the study can be reviewed by expedited measures.

If proposed changes meet any of the following criteria, the study will be reviewed at the full Board:

* Major change in study design (full Board reviewed studies)
* Addition of procedure(s) not approvable using expedited review procedures (e.g., ionizing radiation)
* Changes that adversely affect risk to subjects (e.g., increase in risk or discomfort to subjects)
* Broadening of the exclusion criteria/narrowing of the inclusion criteria (full Board reviewed studies)