**To be accepted for IRB processing, your submission must include:**

AURA-IRB submission contains link to funding source, if externally funded

If study involves clinical/research billing, the Medicare Coverage Analysis (MCA)/ completed schema review memo and signed schema have been submitted to OCR-ROC and OCR-ROC has indicated that documents are substantially complete

Completed AURA-IRB protocol submission form

Protocol narrative document uploaded in view 8.1, question 1

Sponsor protocol should be provided unless study is investigator-initiated, in which case a protocol should be written and uploaded.

See the IRB website for a sample outline of a protocol narrative document:

<http://bsdirb.bsd.uchicago.edu/forms-guidelines/documents/detailed-protocol-narrative.pdf>

If consent will be obtained, consent script(s) and/or forms uploaded in view 7.4

See the IRB website for a sample consent/authorization form:

<http://bsdirb.bsd.uchicago.edu/forms-guidelines/index.html#consent>

IB or package insert for each drug given as part of the study

Device manual for any investigational device

If CTRC review is required, CTRC approval or approved with revisions letter