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

PI must be in compliance with CR\_Policy 110, “Faculty and Staff Training Requirements for the Conduct of Clinical Research”

<https://voices.uchicago.edu/ocr/clinical-research-policies/> *(must be on intranet to access link)*

AURA-IRB submission identifies primary funding source, including identifying any external funding source(s)

If applicable, the Medicare Coverage Analysis (MCA) has been submitted to OCR and OCR has indicated that MCA documents are substantially complete (See CR\_ Policy 105, “Medicare Coverage Analysis requirement - Identification & Distinction of Clinical Trial Participant Charges”

<https://voices.uchicago.edu/ocr/clinical-research-policies/> *(must be on intranet to access link)*

If the study involves prospective written consent, an OnCore record has been created

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:

<https://biologicalsciences.uchicago.edu/irb-forms-and-templates>

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 and guidance on modifying sponsor templates:

<https://biologicalsciences.uchicago.edu/irb-forms-and-templates>

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

Device manual for any investigational device

If FDA regulated and UChicago is the sponsor, FDA documentation has been uploaded

e.g. IND letter, IDE letter, notice of NSR determination by FDA for a device or documentation to support NSR determination by IRB), etc.

If PRMC (CTRC) review is required, PRMC approval or approved with revisions letter \*

\**If the study is a phase 1, 2, or 3, industry-sponsored study, this requirement may be waived. PRMC approval will still be required prior to IRB Committee review.*

If this is a resubmission, and the previous submission received a pending conditional or deferral letter from the IRB, response to all IRB Committee comments has been provided

All documents noted above are able to be opened, i.e. not password-protected, corrupted, etc.