**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.