Commercial IRB Submission Checklist

This checklist should be used for all Commercial IRB submissions to determine the documents required to be uploaded into IRBIS for review to obtain a Commercial IRB Cover Page and Permission to Register Letter:

- ◯ External IRB approval letter with date of expiration for the overall study/protocol provided by the sponsor*
- ◯ Current Master Protocol
- ◯ Sponsor's Model Consent Forms
- ◯ UNC Standalone HIPAA Authorization (if applicable)
- ◯ Recruitment materials, only for MyChart/Research for Me Recruitment Listing
- ◯ Documentation of the approved Subject Injury Language from OIC/Christine Nelson
- ◯ Documentation of any applicable ancillary review, as well as any resulting language requirements (IDS, radiation safety, PRC, IBC, etc.)
- ◯ Completed Conflict of Interest Review. The standard UNC process for COI disclosures still applies. Registration with the Commercial IRB cannot occur until the UNC COI process has been completed for all applicable members of the research team.
- ◯ Confirmation of required ethics training for all UNC personnel

*If the commercial IRB is acting as a single IRB of record then the approval letter can be provided by the sponsor. If UNC is a standalone site there will be no existing approval letter and can be noted in the IRBIS submission using a Cover Memo.

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