

What do I include with a new protocol submission?

When submitting a new protocol to the IRB, please include the following items in your submission packet. Please note that if one or more of these items is applicable and not submitted, the IRB may return the incomplete protocol submission to the PI.

1. Completed Protocol Submission Form (<http://bsdirb.bsd.uchicago.edu/forms-guidelines/documents/new-protocol-submission.pdf>)
2. Protocol narrative (see the following link for guidance: <http://bsdirb.bsd.uchicago.edu/forms-guidelines/documents/detailed-protocol-narrative.pdf>)
3. Literature search assessing the risks/benefits/alternatives to participation of the study
4. Any consent forms to be used on this study, including the consent script if oral consent is being requested (for written consent forms, please utilize the IRB consent form template: <http://bsdirb.bsd.uchicago.edu/forms-guidelines/new-protocol.html#forms>)
5. Any recruitment materials (advertisements, letter to subjects, text of webpages)
6. Supplemental forms (A, B, C, D, E, F, G, H, I, J, K, N, O, P, Q, R, and/or W, as applicable: <http://bsdirb.bsd.uchicago.edu/forms-guidelines/new-protocol.html#forms>)
7. Grant proposal (if study is funded by a grant)
8. Investigator's Brochure (for investigational drugs or devices)
9. Package insert (for approved drugs)
10. Any questionnaires to be used
11. Approval letters from IRBs at any outside sites at which research is being conducted under the direction of the U of C PI or U of C co-investigator
12. Approval letters from other committees at the U of C by which this study requires review
13. Statement regarding any applicable conflict of interest
14. If the study is internet-based or uses web pages for recruitment, printouts of all web pages subjects may see