What do I include with a new protocol submission?

When submitting a new protocol to the IRB, please include the following items in your online submission. 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. Not all items below are applicable to all studies. Offline, please ensure that appropriate concurrent routing materials are submitted to OCR.

1. Complete the Online Protocol Submission questions (at http://aura.uchicago.edu select “Create Study” under My Activities)

2. Identify the main purpose of the study and specify all study activities in view 2.2

3. Upload a protocol narrative in view 8.1 (see the following link for guidance: http://bsdirbbsd.uchicago.edu/forms-guidelines/documents/detailed-protocol-narrative.pdf)

4. Provide a literature search assessing the risks/benefits/alternatives to participation of the study

5. Upload any consent forms to be used on this study in view 7.4, including the consent script if oral consent is being requested (for written consent forms, please utilize the IRB consent form template: http://bsdirbbsd.uchicago.edu/forms-guidelines/new-protocol.html#forms)

6. Upload any recruitment materials (advertisements, letter to subjects, text of webpages) in view 3.1

7. Identify vulnerable populations in view 4.1 and answer following questions about this populations

8. Upload grant proposal(s) (if study is funded by a grant or grants) in view 1.4 or by using the “Upload Grant Application” option under “My Activities” on the main protocol page

9. Upload Investigator’s Brochure(s) (for investigational drugs or devices) in view 3.2

10. Upload Package Insert(s) (for approved drugs given on study) in view 3.2

11. Upload any questionnaires to be used in view 3.7

12. Upload 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 in view 1.5

13. Provide a statement regarding any applicable conflict of interest in view 8.1