Steps to Request the University of Chicago Rely Upon an External Reviewing* IRB

The University of Chicago BSD IRB has the responsibility to review multi-center research projects that request the BSD IRB to rely upon an external reviewing IRB prior to completing a reliance agreement. In these cases, the BSD IRB may review the following documentation and/or appropriate information including, but not limited to: external IRB's Institutional information, regulatory requirements, protocol document, and consent form document. The following document provides a guideline of steps to consider when requesting a reliance agreement with an external IRB. Please note Institutional sign-off will be needed prior to the start of the research activities at the University of Chicago.

* It has been noted the terms external IRB, reviewing IRB, and central IRB are used interchangeably. This guidance document can be used for reliance agreements using any one of these terms when requesting reliance from UChicago.

1) Is Reliance optional or mandatory for participation in the project?
    a. If required – proceed to step 2
    b. If optional- email IRBReliance@bsd.uchicago.edu and provide an explanation as to why reliance is being sought. For example, a study network that anticipates more than one protocol focused on a specific disease/condition conducted at predetermined study locations.

2) Ensure that our institution is "engaged" in research. For example, these activities would *not* constitute as engagement in research:
    a. Inform prospective subjects about the availability of the research
    b. Provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators
    c. Provide prospective subjects with information about contacting investigators for information or enrollment

    For further guidance, please refer to the OHRP website: https://www.hhs.gov/ohrp/regulations and-policy/guidance/guidance-on-engagement-of-institutions/index.html
    The Office of Human Research Protections (OHRP) Decision guide may also be used for further clarification: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

    Any additional questions may be routed to IRBReliance@bsd.uchicago.edu.

3) Review external reviewing IRBs Standard Operating Procedures (SOP) to ensure that the site (UChicago study team) has set appropriate procedures in place to adhere to these policies.

4) Determine whether we have an agreement with the "Reviewing" (or "External" IRB).
    As of 11/1/2018, the BSD IRB has reliance agreements with:
    a. **NCI CIRB** (The National Cancer Institute (NCI) funds an extensive national program of cancer research, including pilot, phase 1, phase 2, and phase 3 clinical trials in adults and children focused on cancer prevention, cancer care and delivery, and treatment. The NCI

CIRB is an independent organization that provides reviews of NCI-funded clinical studies.)

b. **CHAIRb** (Chicago Area IRB for studies funded and/or sponsored by Chicago PCORI CAPRICORN group). The Chicago Area Institutional Review Board (CHAIRb) is the IRB of record for all CAPriCORN research. CHAIRb is made up of experienced IRB members from all of the CAPriCORN institutions.

c. **SMARTIRB** (An authorization agreement established by the NIH National Center for Advancing Translational Sciences (NCATS) that allows institutions to rely upon each other under one agreement). Please go to https://smartirb.org/ to determine if the reviewing IRB is a part of SMART IRB: https://smartirb.org/participating-institutions/.

   i. If the reviewing IRB has additional forms that require institutional certification for reliance, please email IRBReliance@bsd.uchicago.edu for assistance in completing these documents.

   ii. Alternatively, or in addition, the study may be routed through the SMART IRB Reliance system (https://smartirb.org/reliance/). The IRB office will be notified from the SMART IRB system that there is a request for reliance pending and will take appropriate action.

      1. *If using the SMARTIRB pathway, the UChicago PI/research team will need to enter the protocol information into the SMARTIRB Reliance platform. Please see https://smartirb.org/. If using SMARTIRB for the first time, access will need to be requested on the website portal. The UChicago IRB will be notified when a request is made.*

d. If the Reviewing IRB we are being asked to rely upon is not listed above *and* the institution is NOT part of SMART IRB, an authorization agreement will need to be established with that institution. Please email IRBReliance@bsd.uchicago.edu for further assistance.

5) Once the authorization agreement issues have been resolved, the protocol should be entered into AURA-IRB by using the "Create CIRB study" button on the main AURA-IRB page. The CIRB form is designed to collect information that the Institution will utilize to make appropriate reliance determinations. The CIRB form also collects information to be utilized by multiple clinical research operational systems, many of which extract data directly from the AURA-IRB system. For example, data feeds into EPIC, Pharmacy, etc.

   a. In View 1.0a, question 1, requests the name of the organization/IRB that is requesting to serve as the IRB of record. Please note: If the organization/IRB is not listed in the drop down list, please contact the AURA Help Desk at AURA-Help@uchicago.edu to request that this institution be added.

   b. In View 1.0a, question 4, requests a copy of the IRB approval letter. The Central IRB (Reviewing IRB) approval letter for the study should be uploaded in response to this query.

      i. The addition of University of Chicago as a study site may be documented in a subsequent approval and if so, that correspondence will need to be uploaded at a later date.

c. The remainder of the CIRB form will reflect a subset of the same questions on the standard AURA-IRB submission form.
d. In section 17.1, question 2, please upload attestation from the Principal Investigator indicating his/her awareness and compliance with the Reviewing IRBs Policies and Procedures (SOPS).
e. Upon completion of the form and attachment of all required documents, please perform the activity "Submit to the IRB." (*Please note: Submission of a Central IRB protocol does not require routing to the Principal Investigator for approval.)*
f. As needed, budget and contract/agreement documentation should be submitted by the department in accordance with the concurrent routing guidelines. Please see guidance on concurrent routing available at: http://bsdocr.bsd.uchicago.edu/fac-staff/reg-affairs/routing/index.html.

6) Upon receipt of the CIRB submission, the Office of Clinical Research (OCR) will route the submission to:
   a. OCR Research Operations and Conduct (ROC)
   b. IRB staff member to determine any HIPAA Privacy Board concerns and confirm consistency with institutional policies on research related injury, recruitment and other issues that need further clarification or revision.
   c. If any issues from the ROC or IRB staff member review require revisions, an email will be sent to the primary contact for revisions/clarification.
   d. Once all Institutional issues are addressed, an Institutional acknowledgement letter will be generated and the research may begin at the institution (once contract and other issues have been addressed). When there is an external agreement (master or study specific), institutional acknowledgement is dependent upon final execution of agreement. (*Exceptions may be granted on a case by case basis.)*

7) After institutional acknowledgement is granted, UChicago (as the institution) will still be required to review the following:
   a. Unanticipated Problems – Submit using the "Unanticipated Problem" button under "My activities." Please ensure that the Unanticipated Problem has been reported to the Reviewing IRB consistent with their SOPs.
   b. Personnel Changes (Changes in faculty/staff involved in the research) – University of Chicago remains responsible for ensuring compliance with institutional human subjects' training requirement and conflict of interest. Submit changes to personnel using the "Personnel Amendment" button under "My activities."
      i. Please note, AURA-IRB personnel lists also control research staff access within EPIC.
   c. In addition, to ensure that the Institution retains a copy of the currently approved documents, changes to the smart form, consent form, protocol, advertisements, investigator's brochure, etc. should be uploaded to the AURA-IRB submission when approved by the Reviewing IRB. The "Update CIRB" button allows the acknowledged submission to be edited and to upload revised documents. Once all changes have been

entered, the button “CIRB Updates Completed” should be checked to return the submission to its acknowledged state.

   i. Please note, if changes to the consent form document impacts any procedures or costs related to the study, the Research Operations and Conduct office will need to be informed as such in order to ensure billing documentation is updated.

d. Upon termination of the study by the Reviewing IRB, the button “Terminate CIRB study” should be checked. AURA-IRB will prompt you to upload the termination/closure notice from the Reviewing IRB.