Purpose of form: When the UChicago BSD IRB is intended to serve as IRB of Record for relying site(s), this document can be used to provide the UChicago local study team with guidance regarding the reliance process. Please contact IRBReliance@bsd.uchicago.edu for any questions related to single-IRB.

Steps to Request the University of Chicago serve as the IRB of Record for an External Site

Prior to completing a reliance agreement, the University of Chicago BSD IRB has the responsibility to review multi-center research projects that request the BSD IRB to serve as the Reviewing IRB*. In these cases, the BSD IRB may review the following documentation and/or appropriate information including, but not limited to: relying 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 site or outside individual. Please note Institutional sign- off will be needed prior to the start of the research activities at the any relying sites.

The Common Rule's sIRB mandate states organizations engaged in cooperative research must rely upon approval by a single IRB for that portion of the research conducted in the U.S. Cooperative research is defined as projects covered by this policy involving more than one institution.

The University of Chicago BSD IRB will serve as the IRB of record in instances where mandated by regulation or policy.

* It has been noted the terms IRB of Record, reviewing IRB, and central IRB are used interchangeably. In this document, the IRB of Record is in reference to the UChicago BSD-IRB. Relying Site/Individual is in reference to the site or individual ceding IRB review to the UChicago BSD- IRB.

Step 1: Determining if proposed activities fit the definition of research

Ensure that the relying site is 'engaged' in research. For example, the following activities would not constitute as engagement in research:

a. Inform prospective subjects about the availability of research
b. Provide prospective subjects with information about the research (which may include a copy of the relevant consent document and other 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

If the external site is not engaged in research, a reliance agreement is not needed. It is the responsibility of the relying site to make the determination whether their site is engaged in the research.

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

Step 2: Proposing UChicago Serve as the IRB of Record

The initial request for the University of Chicago BSD IRB to serve as the IRB of Record should be made at the time of new submission and sites should be submitted through an amendment.

Before proceeding, please consider the two following points in regards to the Reliance request process.

- It is the preference of the University of Chicago BSD IRB, to utilize the SMART IRB cede letter to document reliance. If the Relying site is requesting to use the SMARTIRB system, 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. Documentation that Relying site is a member of SMARTIRB will be needed (This form will require a list of all personnel at the Relying site, as well as documentation of Human Subjects Protection training). The SMARTIRB process can be conducted simultaneously with the following procedures. Please contact the reliance team if a relying site is requesting to only utilize the SMART IRB system (and will not utilize the cede letter).

- Effective January 25, 2018, federally funded research by the National Institute of Health is required to use a single Institutional Review Board (central IRB) to conduct the ethical review required for the protection of human subjects. For more information please see: https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm
- In addition, all participating sites must have a Federalwide Assurance. For more information, please see the following link:

https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html

Step 3: For external sites requesting UChicago serve as the IRB of record

- Please indicate this is a multisite study in the AURA-IRB submission form, view 1.5 question 2.
- Please indicate that another site is requesting UChicago IRB to serve as the IRB of record in the AURA-IRB submission form, view 1.5 question 5.
- Please revise the AURA-IRB submission form, view 1.5 question 5a to specific what site(s) are requesting that UChicago be the IRB of record.
    - In View 1.5 question 5b, state that an amendment will be submitted when sites are ready to be approved/after approval of the study at the University of Chicago.
    - In View 1.5 question 5c, upload a memo stating that [sites(s)] are requesting to rely on the University of Chicago IRB, an amendment will be submitted after approval of the study at the University of Chicago.
- When a submission is received by the IRB during the pre-review process, IRB staff will notify the Assistant Director for IRB Reliance about the request.
- The Assistant Director for IRB Reliance will contact the primary contact/principal investigator to determine what sites will be relying and whether reliance is appropriate.
    - A meeting may be scheduled to discuss the amendment process for adding sites.
    - The Assistant Director for IRB reliance will request the study team complete the sIRB tracking spreadsheet for the sites requesting to rely. This will include the name of the site, their role, and site study team contact information.

- Once the UChicago study team receives approval for the overall study, the Assistant Director for IRB reliance will email the relying sites copying the local University of Chicago study contact and principal investigator, with instructions for reliance, the required reliance documents to be completed by the relying sites and if applicable the currently approved consent form.

- When the relying sites provide the completed reliance materials back to the University of Chicago study team, the team should submit an amendment to obtain approval for the site.
    - The amendment should only include information about reliance, no other changes should be submitted at the same time.

Step 4: Submitting the Amendment to add the relying sites

- When submitting the amendment, under view 1.2 Nature of the Amendment question 1, please be sure to select all changes that are applicable to the reliance request:
    - Change to protocol document(s)
    - Changes to consent form(s)
    - Change to study sites
    - In the brief summary of changes please include the following: *The purpose of this amendment is to request the University of Chicago BSD IRB serve as the IRB of record for [list site(s)]. The IRB authorization agreement/SMART IRB cede letter, local context and communication form, participating site application, relying site master personnel list, human subjects training for personnel and consent form (if applicable) have been provided.*
- Please revise view 1.5 question 5b to provide a brief summary of the activities to be performed by the site, such as all protocol activities, limited activities, data analysis, etc.
- Please attach the following documents that were provided to the relying site by the IRB via email to view 1.5 question 5c:
    - Local Context and Communication Plan
    - Participating Site Application
    - IRB authorization agreement or SMART IRB Cede Letter
        - **Please do not request the UChicago Institutional Official sign these documents, the IRB office will route the form for signature.**
    - Relying Site Master Personnel List
    - Relying Site Human Subjects Training for the individuals listed on the personnel list (as a single PDF document).

- These documents can also be found on the UChicago BSD IRB website under the reliance section: https://biologicalsciences.uchicago.edu/irb/irb-reliance-university-chicago-serving-irb-record

- Please attach the tracked changes version of the site specific consent form (if applicable) in section 7.4.
  - The following sections of the consent can be altered/changed: Cost, injury, payment, HIPAA and contact information.
  - Other changes may be reviewed on a case by case basis
- Once the amendment is submitted, the standard IRB process will take place.
- Upon review and approval of the amendment, the signed and final reliance agreement will be emailed to the Principal Investigator and study contact and uploaded as a public comment within AURA-IRB. The study team is responsible for sharing the completed document/approved material with the relying site.

Step 5: Submitting a request to serve as the IRB of record for an already approved study

- The request for the University of Chicago BSD IRB can also be submitted through an amendment.
- The same process should be followed, except at the time of the amendment, View 1.5 questions 1-5 will also need to be updated to reflect the addition of relying sites.
- **You will not need to include the following**:
  - In View 1.5 question 5b, state that an amendment will be submitted when sites are ready to be approved/after approval of the study at the University of Chicago.
  - In View 1.5 question 5c, upload a memo stating that [sites(s)] are requesting to rely on the University of Chicago IRB, an amendment will be submitted after approval of the study at the University of Chicago.

Key Terms:

- **Reliance agreement-** allows for an institution to rely on an IRB outside of their institution for a study or group of studies
- **IRB authorization agreement-** an agreement signed between the relying institution and IRB of record to document reliance for a study or group of studies.
- **SMART IRB Cede letter:** an agreement signed by institutions that participate in SMART IRB to document reliance for a study.
- **Single IRB (sIRB)-** IRB review of multisite research by a single IRB. This IRB provides the regulatory review of the research.

- **IRB of Record (Reviewing IRB)-** The IRB that is providing the IRB review for more than one institution. Also referred to as the Reviewing IRB or Central IRB.
- **Relying Institution-** The institution that is ceding review to an external IRB of record or reviewing IRB. Note the institution cedes review- not the IRB
- **Local Context-** there is not a regulatory definition of local context, but it is viewed as the regulations, laws or customs of the area that the relying institution must provide to the IRB of record.