Purpose of form: When the UChicago BSD IRB is intended to serve as IRB of Record for an individual(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 Individual Investigator

Prior to completing a reliance agreement, the University of Chicago BSD IRB has the responsibility to review research projects that request the BSD IRB to serve as the Reviewing IRB* for an individual. In these cases, the BSD IRB may review the following documentation and/or appropriate information including, but not limited to: protocol, individual's CV/resume and training qualifications. The following document provides a guideline of steps to consider when requesting a reliance agreement with an outside individual. Please note Institutional sign-off will be needed prior to the start of the research activities by the Individual Investigator.

* 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 individual is 'engaged' in the research. For example, the following 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

If the external individual is not engaged in research, a reliance agreement is not needed.

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

Step 2: Proposing UChicago serve as the IRB of Record

The request for UChicago to serve as the IRB for a relying individual will be considered on a case-by-case basis. The request for UChicago to serve as the IRB of Record can be made during the pre-review process or with an amendment. *Please note, if you are adding more than one individual, all documents, including agreements must be completed for each individual*.

1. If the study is currently in pre-review or pre-submission status, please follow the instructions below:
    A. In view 1.5 question 2 in the AURA-IRB submission form, please indicate this is a multi- site study.
    B. In view 1.5 question 5 in the AURA-IRB submission form, please indicate another individual is requesting UChicago IRB is being asked to serve as the IRB of record.
    C. In view 1.5 question 5a in the AURA-IRB submission form, please name the individual(s) that are requesting that UChicago be their IRB of Record.
    D. In view 1.5 question 5b in the AURA-IRB submission form, please describe research activities being conducted by the individual(s). If the activities are the same as those conducted by UChicago researchers, please simply state as such. If activities will differ, please specify how they will differ for each individual (e.g. consent, recruitment, data analysis).
    E. The following documentation is needed for consideration:
        i. **Memo from the PI requesting that UChicago serve as the IRB and justification for adding the individual:** Please provide documentation from the PI requesting that UChicago serve as the IRB of record for the individual and a statement for why the individual is being added.
        ii. **Individual Investigator Agreement**: Please fill out the IRB Authorization Agreement and send to Relying individual(s) for signature of their Institutional Official. If they do not have an Institutional Official, he/she can sign the agreement themselves. Please attach to view 1.5 question 5c. ***Please do not route to the UChicago Institutional Official for sign-off. The IRB office will route the form after review.***
        iii. **Individual Investigator Information Sheet**: Please fill out and attach to view 1.5 question 5c.
        iv. **Confidentiality Agreement**: If the individual will be accessing identifiable data, a confidentiality agreement should be singed by the individual and attached to view 1.5 question 5c.
        v. **Resume/CV**- A copy of the individual's current resume or CV should be

attached to view 1.5 question 5c.

vi. Please provide a copy of human subjects protections training for each individual to view 1.5 question 5c. *If several human subject training certificates will be provided, please consider combining the PDFs into one document for review.*

In the rare case that a Relying individual-specific consent form is needed, please reach out to the IRB for guidance.

F. The UChicago IRB recognizes that a Sponsored protocol cannot be readily revised to reflect a Reliance request. However, if the protocol document is an UChicago authored document, please revise the protocol document within the AURA-IRB submission form to include the Reliance request information. Please be sure to provide a CLEAN and TRACKED version to view 8.1.

G. Once the IRB administrator has confirmed the pre-review process is completed (including all reliance documentation/information), the study will be scheduled for review.

H. The IRB staff will obtain the institutional official sign off on the Individual Investigator agreement and provide the signed copy back to the PI and study contact listed in AURA and upload the signed document as a public comment in AURA. It is the responsibility of the study team to provide the completed document back to the individual.

2. If an *individual(s)* is requesting UChicago to serve as their IRB of Record and the study is currently approved, please follow the instructions below. When submitting an amendment to add an individual investigator, the only changes that should be submitted with the amendment should pertain to the individual.

   A. When submitting the amendment, under view 1.2 (Nature of Amendment) question 1, please be sure to select *all* changes that are *applicable* to the Reliance request:

      i. Change to Protocol Document(s)
      ii. Changes to Consent Form(s)
      iii. Change to Study Sites
      iv. For question view 1.2 question 3 (Nature of Amendment), the following suggested language may be used in the brief summary of changes:

         1. *The purpose of this amendment is to request UChicago IRB serve as the IRB of Record for ([list individual(s)]. The following documents have been uploaded for review: individual investigator agreement, individual investigator information sheet, memo from the PI, human subjects training, CV/Resume and (if applicable confidentiality agreement).*

   B. Please also make the additional changes to the application as described in steps 1A-H above.