Steps to Request the University of Chicago Serve as the IRB of Record

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 University of Chicago.

* 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 relying site/individual is "engaged" in 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 site 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 site/individual will be considered at a fully convened IRB meeting for both minimal and more than minimal risk research. 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 the following instructions have been separated depending on the *type* of reliance request and *current status* of the protocol.

-If an *external site* is requesting UChicago to serve as the IRB of Record and the study is currently in pre-submission/pre-review status, please see instructions under number 1.

-If an *external site* is requesting UChicago to serve as the IRB of Record and the study is currently approved, please see instructions under number 2.

-If an *individual(s)* is requesting UChicago to serve as their IRB of Record and the study is currently in -pre-submission/pre-review status, please see instructions under number 3.

-If an *individual(s)* is requesting UChicago to serve as their IRB of Record and the study is currently approved, please see instructions under number 4.

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

- If the Relying site is requesting to use 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. 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.

- 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

1. **If an *external site* is requesting UChicago to serve as the IRB of Record and the study is currently in pre-submission/pre-review status, please follow the instructions below.**
   A. Please indicate this is a multi-site study in the AURA-IRB submission form, view 1.5 question 2.
   B. Please indicate another site is requesting UChicago IRB is being asked to serve as the IRB of record in the AURA-IRB submission form, view 1.5 question 5.
   C. Please revise the AURA-IRB submission form, view 1.5 question 5a, to specify what site(s) are requesting that UChicago be the IRB of Record.
   D. Please describe research activities being conducted at all sites in the AURA-IRB submission form, view 1.5 question 5b. If the activities are the same as those conducted at UChicago, please simply state as such. If activities will differ, please specify how they will differ for each site/individual (e.g. consent, recruitment, data analysis).
   E. The following documentation is needed for consideration. Links have been provided for the appropriate documents.

i. Request to Serve as IRB Please provide documentation from the relying site formally requesting UChicago serve as the IRB of Record. Please attach this memo to view 1.5 question 5c in AURA-IRB.
ii. IRB Authorization Agreement Please fill out the IRB Authorization Agreement and send to Relying site for signature of their Institutional Official. 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. Local Site Context Form Please fill out and attach to view 1.5 question 5c.
iv. Please provide a copy of human subjects protections training to view 1.5 question 5c. *If several human subject training certificates will be provided, please consider combining the PDF's into one document for review.*

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 provide the protocol in view 8.1.

Please note, during the initial submission of the study the consent form document provided for the main study will only be considered. Therefore, please do not upload a relying site consent form. Due to potential for changes during the IRB process, we ask that relying site consent forms be submitted with an amendment to limit the back and forth between the institutions. Please see the steps to follow.

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 at a fully convened IRB meeting. During the review of the protocol, the BSD IRB Committee will consider the reliance request. The Committee's decision will be communicated as part of the IRB official correspondence (e.g. Approval letter, Pending Conditional letter).
    i. If the main study was approved please proceed to step H to complete the reliance process.
    ii. If the main study was not approved (e.g. pending conditional, deferral), the Committee's decision to serve as the IRB of Record will be communicated within the letter (e.g. pending conditional letter, deferral letter). The Reliance process will need to be completed once the main study has been approved. Once this takes place, please see step H to complete the process.
    iii. If the IRB does not agree to serve as the IRB of Record, this will be communicated with official correspondence.
H. If the Committee agreed to serve as the IRB of Record, the Reliance Manager will send the UChicago IRB Authorization Agreement to the Institutional Official for sign-off. Once the document is signed and the agreement has been obtained, the agreement will be emailed to the Principal Investigator and Study contact. The document will then be uploaded as a public comment in the AURA-IRB submission form. The study team is responsible for sharing with the Relying site.

If there is no need for a Relying site-specific consent form document, the Reliance process is complete. If a Relying site-specific consent form document is needed please move on to step I-K.

I. To submit the Relying site-specific consent form document, please submit an amendment with the AURA-IRB submission form. Please upload a site specific consent form document with track changes to include institutional specific language (e.g. site PI, injury language, HIPAA language, etc.). Please attach the clean and tracked documents to view 7.4 in the AURA-IRB submission form. A template of relying site consent form document can be found **here**. The sections that require review have been highlighted. If a section is not applicable, please leave as is. *If the study is minimal risk, injury language is not required.*

J. The standard IRB review process will take place which may include pre-review comments. Once the pre-review process is complete, the amendment will be scheduled for review at a fully convened meeting.

K. At the fully convened meeting, the Committee will review the proposed consent form document and if no further revisions are requested (e.g. pending conditional), the consent form documents will be stamped during the approval of the amendment.

2. If an *external site* is requesting UChicago to serve as the IRB of Record and the study is currently approved, please submit an amendment in AURA-IRB.

The following steps have been separated based on the AURA submission Smartform version that was used during the protocol's *initial* submission. To find the AURA submission Smartform version of the protocol, please go to the main page of the study workspace, as shown below.

If the Smartform Version is blank, this indicates Version 1. Please follow steps A and C.
If the Smartform Version is 2 or 3, please follow steps B and C.

A. AURA-IRB Smartform Version 1 Instructions
   i. 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:
   Change to Protocol Document(s)

Changes to Consent Form(s)
Change to Study Sites

ii. For question view 1.2 question 3 (Nature of Amendment), the following suggested language may be used in the brief summary of Changes:
*The purpose of this amendment is to request the UChicago IRB serve as the IRB of Record for (**list sites**). Appropriate Authorization Agreement/Individual investigator agreement and Local Site Context form have been provided.*

iii. In the modified study smart form, please revise question 4 of view 2.2 to include a paragraph stating which site is requesting to rely and detailing what research procedures will take place at the relying site.

iv. In the modified study smart form, please revise question 7 of view 2.2 to select "yes," another site is requesting that the UChicago be the IRB of record.

v. The following documentation is needed for consideration. Links have been provided for appropriate documents.
    1. Request to Serve as IRB Please provide documentation from the relying site formally requesting UChicago serve as the IRB of Record. Please attach this memo to view 17.1 question 2 in AURA-IRB.
    2. IRB Authorization Agreement Please fill out the IRB Authorization Agreement and send to Relying site for signature of their Institutional Official. Please attach to view 17.1 question 2. ***Please do not route to the UChicago Institutional Official for sign-off. The IRB office will route the form after review.***
    3. Local Site Context Form Please fill out and attach to view 17.1 question 2.
    4. Please provide a copy of human subjects protections training to view 17.1 question 2. *If several human subject training certificates will be provided, please consider combining the PDFs into one document for review.*

vi. If a relying site-specific consent form document will be needed, the UChicago consent form template may be used. A template of relying site consent form document can be found **here.** The sections that require review have been highlighted. If a section is not applicable, please leave as is. Please upload to view 16.8.

vii. If the currently approved consent form document needs to be updated (e.g. to disclose sharing data with an outside site/individual), please provide a CLEAN and TRACKED version of the consent form document to view 16.8.

viii. The UChicago IRB recognizes that a Sponsored protocol cannot be readily revised to reflect a Reliance request. However, if the protocol document is a 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 in view 17.1, question 1.

Please proceed to step C.

B. AURA-IRB Smartform Version 2 and 3 Instructions

i. 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:
Change to Protocol Document(s)
Changes to Consent Form(s)
Change to Study Sites

ii. For question view 1.2 question 3(Nature of Amendment), the following suggested language may be used in the brief summary of changes:
The purpose of this amendment is to request UChicago IRB serve as the IRB of Record for (list sites). Appropriate Authorization Agreement/Individual investigator agreement and Local Site Context form have been provided.

iii. In the modified study smart form, please revise the AURA-IRB submission form, view 1.5 question 2, to indicate this is a multi-site study.

iv. In the modified study smart form, please revise view 1.5 question 5, to indicate another site is requesting UChicago IRB is being asked to serve as the IRB of record.

v. In the modified study smart form, please revise view 1.5 question 5a to specify what site(s) are requesting that UChicago be the IRB of Record for.

vi. In the modified study smart form, please revise view 1.5 question 5b to describe research activities being conducted at all sites. If the activities are the same as those conducted at UChicago, please simply state as such. If activities will differ, please specify how they will differ for each site (e.g. consent, recruitment, data analysis).

vii. (*If applicable*) Using the IRB approved UChicago site consent form template, please upload a site specific consent form document with track changes to include institutional specific language (e.g. site PI, injury language, HIPAA language, etc.). Please attach the clean and tracked documents to view 7.4 in the modified AURA-IRB submission form. *If the study is minimal risk, injury language is not required.*

viii. The following documentation is needed for consideration. Links have been provided for appropriate documents.

1. Request to Serve as IRB Please provide documentation from the relying site formally requesting UChicago serve as the IRB of Record. Please attach this memo to view 1.5 question 5c.
2. UChicago IRB Authorization Agreement Please fill out the IRB Authorization Agreement and send to Relying site for signature of their Institutional Official. 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.***
3. Local Context Form Please fill out and attach to view 1.5 question 5c.
4. Please provide a copy of human subjects protections training 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.

ix. If a relying site specific consent form document will be needed, the UChicago consent form template may be used. A template of relying site consent form document can be found **here.** The sections that require review have been highlighted. If a section is not applicable, please leave as is. Please upload to 7.4.

x. If the currently approved consent form document needs to be updated (e.g. to disclose sharing data with an outside site/individual), please provide a CLEAN and TRACKED version of the consent form document to view 7.4.

xi. 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 in view 8.1.

Please proceed to step C.

C. After amendment submission

i. The standard IRB review process will take place which may include pre-review comments. Once the pre-review process is complete, the amendment will be scheduled for review at a fully convened meeting.

ii. At the fully convened meeting, the Committee will review the proposed consent form document and if no further revisions are requested (e.g. pending conditional), the consent form documents will be stamped during the approval of the amendment.

iii. If the Committee agreed to serve as the IRB of Record, the Reliance Manager will send the UChicago IRB Authorization Agreement to the Institutional Official for sign-off. Once the signed and final agreement has been obtained, the agreement will be emailed to the Principal Investigator and Study contact. The document will then be uploaded as a public comment in the AURA-IRB submission form. The study team is responsible for sharing with the Relying site.

3. If an *individual(s)* is requesting UChicago to serve as their IRB of Record and the study is currently in pre-submission/pre-review status, please follow the instructions below. *Please note, separate agreements will be needed for each individual.*

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. Links have been provided for appropriate documents.
    i. Request to Serve as IRB Please provide documentation from the individual(s) formally requesting UChicago serve as the IRB of Record. Please attach this memo(s) to view 1.5 question 5c in AURA-IRB.
    ii. UChicago 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. Local Context Form Please fill out and attach to view 1.5 question 5c.
    iv. 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 at a fully convened IRB meeting. During the review of the protocol, the BSD IRB Committee will consider the reliance request. The Committee's decision will be communicated as part of the IRB official correspondence (e.g. Approval letter, Pending Conditional letter).
    i. If the main study was approved and the Committee agreed to serve as the IRB of Record please proceed to step H to complete the reliance process.
    ii. If the main study was not approved (e.g. pending conditional, deferral), the Committee's decision to serve as the IRB of Record will be communicated within the letter (e.g. pending conditional letter, deferral letter). The Reliance process will need to be completed once the main study has been approved. Once this takes place, please see step H to complete the process.
    iii. If the IRB does not agree to serve as the IRB of Record, this will be communicated with official correspondence.

H. If the Committee agreed to serve as the IRB of Record, the Reliance Manager will send the UChicago IRB Individual Investigator Agreement to the Institutional Official for sign-off. Once the signed and final agreement has been obtained, the agreement will be emailed to the Principal Investigator and Study contact. The document will then be

uploaded as a public comment in the AURA-IRB submission form. The study team is responsible for sharing with the Relying Individual.

4. 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.

The following steps have been separated based on the AURA submission Smartform version that was used during the protocol's *initial* submission. To find the AURA submission Smartform version of the protocol, please go to the main page of the study workspace, as shown below.

If the Smartform Version is blank, this indicates Version 1. Please follow steps A and C.
If the Smartform Version is 2 or 3, please follow steps B.

A. AURA-IRB Version 1 Instructions
   i. 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:
      Change to Protocol Document(s)
      Changes to Consent Form(s)
      Change to Study Sites
   ii. For question view 1.2 question 3(Nature of Amendment), the following suggested language has been provided to include in the brief summary of Changes:
      *The purpose of this amendment is to request the UChicago IRB serve as the IRB of Record for (**list individuals**). Appropriate Authorization Agreement/Individual investigator agreement and Local Site Context form have been provided.*
   iii. In the modified study smart form, please revise question 4 of view 2.2 to include a paragraph stating which site is requesting to rely and detailing what research procedures will take place at the relying site.
   iv. Please revise question 7 of view 2.2 to select "yes," another site is requesting that the UChicago be the IRB of record.
   v. (*If applicable*) Using the IRB approved UChicago site consent form template, please upload a site specific consent form document with track changes to include institutional specific language (e.g. site PI, injury language, HIPAA

language, etc.). Please attach the clean and tracked documents to view 16.8 in the AURA-IRB submission form. *If the study is minimal risk, injury language is not required.*

vi. The following documentation is needed for consideration. Links have been provided for appropriate documents.
    1. Request to Serve as IRB Please provide documentation from the relying site formally requesting UChicago serve as the IRB of Record. Please attach this memo to view 17.1 question 2 in AURA-IRB.
    2. UChicago 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 17.1 question 2. ***Please do not route to the UChicago Institutional Official for sign-off. The IRB office will route the form after review.***
    3. Local Context Form Please fill out and attach to view 17.1 question 2.
    4. Please provide a copy of human subjects protections training to view 17.1 question 2. *If several human subject training certificates will be provided, please consider combining the PDF's into one document for review*.

vii. If the currently approved consent form document needs to be updated (e.g. to disclose sharing data with an individual), please provide a CLEAN and TRACKED version of the consent form document to view 16.8.

viii. The UChicago IRB recognizes that a Sponsored protocol cannot be readily revised to reflect a Reliance request. However, if the protocol document is a 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 in view 17.1.

Please proceed to step C.

B. AURA-IRB Version 2 and 3 Instructions

i. 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:
Change to Protocol Document(s)
Changes to Consent Form(s)
Change to Study Sites

ii. For question view 1.2 question 3 (Nature of Amendment), the following suggested language may be used in the brief summary of changes:
The purpose of this amendment is to request UChicago IRB serve as the IRB of Record for (list individuals). Appropriate Authorization Agreement/Individual investigator agreement and Local Site Context form have been provided.

iii. In the modified study smart form, please revise view 1.5 question 2 to indicate this is a multi-site study.

iv. Please revise view 1.5 question 5 to indicate another site is requesting UChicago IRB is being asked to serve as the IRB of record.
v. Please revise view 1.5 question 5a to name the individual(s) that are requesting that UChicago be their IRB of Record.
vi. Please revise view 1.5 question 5b to 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).
vii. (*If applicable*) Using the IRB approved UChicago site consent form template, please upload an individual-specific consent form document with track changes to include specific language (e.g. site PI, injury language, HIPAA language, etc.). Please attach the clean and tracked documents to view 7.4 in the AURA-IRB submission form. *If the study is minimal risk, injury language is not required.*
viii. The following documentation is needed for consideration. Links have been provided for appropriate documents.
    1. Request to Serve as IRB Please provide documentation from the relying individual formally requesting UChicago serve as the IRB of Record. Please attach this memo to view 1.5 question 5c in AURA-IRB.
    2. UChicago 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 do not route to the UChicago Institutional Official for sign-off. The IRB office will route the form after review.***
    3. Local Context Form Please fill out and attach to view 1.5 question 5c.
    4. Please provide a copy of human subjects training to view 1.5 question 5c. *If several human subject training certificates will be provided, please consider combining the PDF's into one document for review.*
ix. If the currently approved consent form document needs to be updated (e.g. to disclose sharing data with an individual), please provide a CLEAN and TRACKED version of the consent form document to view 7.4.
x. The UChicago IRB recognizes that a Sponsored protocol cannot be readily revised to reflect a Reliance request. However, if the protocol document is a 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 in view 8.1.

C. After amendment submission
    i. The standard IRB review process will take place which may include pre-review comments. Once the pre-review process is complete, the amendment will be scheduled for review at a fully convened meeting.
    ii. At the fully convened meeting, the Committee will review the request and the proposed consent form document. If no further revisions are requested (e.g.

pending conditional), the consent form documents will be stamped during the approval of the amendment.

iii. If the Committee agreed to serve as the IRB of Record, the Reliance Manager will send the UChicago IRB Individual Investigator Agreement to the Institutional Official for sign-off. Once the signed and final agreement has been obtained, the agreement will be emailed to the Principal Investigator and Study contact. The document will then be uploaded as a public comment in the AURA-IRB submission form. The study team is responsible for sharing with the Relying Individual.