**POLICY STATEMENT:**

The purpose of this policy is to define the procedures and standards the University of Chicago follows for determining when to accept the review of an external IRB for a human subject research project in which University of Chicago faculty, staff or students are engaged and when to permit a domestic external institution or an unaffiliated researcher to rely upon the review of  the University of Chicago BSD IRB for a non-exempt human subject research project.

**PROCEDURES:**

**Reliance on an External IRB for University of Chicago Research**

University of Chicagoinstitutions may rely on another IRB (e.g. an independent IRB or another academic IRB) for research conducted at the University of Chicago. The University of Chicago Vice President of Research or their designee(s) is responsible for making determinations regarding whether relying on an external IRB is appropriate, given the nature of the research, applicable regulations, funding agency and other factors.

The decision to rely is based on a number of factors, including but not limited to:

* Whether the use of a single IRB has been mandated by the study sponsor or funding agency;
* The number of proposed sites and/or studies involved in the collaboration;
* The anticipated level of risk associated with the proposed study;
* Whether the reviewing IRB's policies and procedures meet University of Chicago HRPP standards.
* The location in which the majority of study procedures will take place;
* The Principal Investigator's eligibility to serve as the PI and their role in the overall research;
* The ability of the reviewing IRB to be sufficiently informed about local context issues, including local laws and regulations; and
* The terms and conditions of the proposed IRB reliance agreement.

Reliance on an external IRB requires a reliance agreement with the proposed reviewing IRB, which outlines roles and responsibilities and documents the agreement of both parties.

Additionally, University of Chicago investigators seeking to rely on an external IRB must submit a cede application in AURA IRB, which is administratively reviewed by the University of Chicago HRPP to ensure compliance with University of Chicago institutional policies as well as University of Chicago HRPP policies and procedures. The HRPP may request input from a physician IRB member for clinical trials to ensure compliance with relevant institutional policies and current medical practices.

When the University of Chicago cedes the IRB review of research to another organization, University of Chicago remains responsible for the oversight of the research and remains responsible for maintaining a human research protection plan, including but not limited to:

* Safeguarding the rights and welfare of human subjects within the local context. The University of Chicago IRB retains the responsibility to maintain oversight for local unanticipated problems involving risks to participants or others and local non-compliance.
* Conducting audits to ensure compliance.
* Conducting conflict of interest review for University of Chicago investigators.
* Conducting ancillary reviews (e.g. PRMC, RADRAC, HIRO, IBC, Conflicts of Interest, etc) to ensure the research is conducted in compliance with University of Chicago policies and procedures.
* Educating members of the University of Chicago research community to establish and maintain compliance of federal regulations and institutional policies relevant to human subjects research.
* Implementing appropriate oversight mechanisms to ensure compliance with the determinations of the reviewing IRB.

**University of Chicago IRB Serving as the IRB of Record**

The University of Chicago IRB may serve as the IRB of record for multi-site research. The University of Chicago IRB adheres to the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research as well as 45 CFR 46.114. As such, the University of Chicago IRB may serve as the reviewing IRB for domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research or for domestic sites of Common Rule agency-funded cooperative research.

When the University of Chicago IRB provides IRB review for external institutions, the University of Chicago IRB will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. When the University of Chicago IRB is serving as the single IRB (slRB), all reviews of the research, including initial review, continuing review and review of proposed changes to the research, are done in accordance with applicable regulations and University of Chicago IRB policies and procedures.

Additionally, when providing IRB review for external institutions, the University of Chicago IRB requires the completion of a participating site application which outlines the research to be conducted at the site and the completion of a local context and communication plan by the local IRB which documents any local considerations the reviewing IRB needs to factor into the review.

Whether the University of Chicago IRB will provide review for another institution is determined by the Vice President of Research (or designee(s)) based on a number of factors, including but not limited to:

* Whether a University of Chicago institution is the prime awardee of the funds;
* Whether single IRB review is required by the sponsor or regulation;
* The time and resources required to accept review;
* The number of proposed sites involved in the collaboration;
* The anticipated level of risk associated with the proposed study;
* The location in which the majority of study procedures will take place; and
* The Principal Investigator's eligibility to serve as the PI and their role in the overall research.

**Establishing Reliance Agreements**

When sites are relying on the University of Chicago IRB, a reliance agreement is required. When individual investigators (i.e. investigators not acting as agents of an external institution) are relying on the University of Chicago IRB, an individual investigator agreement is required.

University of Chicago lead study teams are encouraged to identify an individual on their team who can serve as the slRB liaison, facilitating communication between external sites and the University of Chicago IRB. University of Chicago lead study teams are responsible for submitting applications on behalf of sites (e.g. to obtain initial approval, amendments and continuing reviews) to the University of Chicago IRB and for communicating University of Chicago IRB determinations to sites.

Reliance agreements established for the purposes of single IRB review are signed by University of Chicago Institutional Officials or their designees. Reliance agreements set forth the following basic information: the University of Chicago institution's FWA and the FWA of the other party to the agreement; the names of the PIs and the scope of the agreement (e.g. study(ies) that fall under the agreement). The agreement must also specify which party is relying on the other for IRB review and how the relying institution will be kept informed of the reviewing IRB's actions.

Regardless of whether a University of Chicago institution is ceding review to an external IRB or the University of Chicago is agreeing to serving as the reviewing IRB, the reliance agreement will include sufficient information to ascertain which party is responsible for the following:

* Providing education to researchers and research staff;
* Conducting scientific review;
* Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits;
* Identifying which organization is responsible for deciding whether allegations of non-compliance has a basis in fact;
* Identifying which organization's process is used to decide whether incidents of non-compliance are serious or continuing;
* Obtaining management plans for researcher and research staff conflicts of interest. If the relying organization maintains responsibility for this issue, the management plan must be provided to the IRB of record in a timely manner prior to the IRB's determination;
* Managing institutional conflicts of interest related to the research; and
* Ensuring that, should the reliance agreement be terminated, one of the parties is clearly responsible for continued oversight of actives studies until closure or a mutually agreed upon transfer of the studies.

**Conditions for External Researcher without Institutional Affiliation (Individual Investigator Agreements)**

Researchers that will be engaged in human subject research that do not have an affiliated IRB will be permitted to rely on the University of Chicago BSD IRB through the use of an Individual Investigator Agreement. The execution of this agreement will be handled through an amendment to the AURA IRB application and the University of Chicago IRB staff and the Vice President of Research will review the documentation for appropriateness for oversight.

The following documentation will be requested to determine whether the institution will take oversight of the engaged individual:

* Letter of support from the University of Chicago PI, describing the individual’s role and why the request for oversight is being sought.
* A signed Individual Investigator Agreement (IIA)
* CV or Biosketch
* Human Subjects Training
* A completed IIA Information Sheet

**KEY TERMS:**

**IRB**  An Institutional Review Board is a committee charged with providing regulatory oversight for research involving human subjects.

**sIRB** A single IRB, also termed “central” IRB. An IRB that provides IRB review and oversight for two or more participating sites in multi-site research. The IRB may be associated with an academic, private, non-profit, or commercial entity.

**Reliance Agreement** A written agreement between entities participating in multi-site research. The agreement contains terms that describe what each entity is responsible for in the review, oversight, and conduct of the research including responsibilities related to local requirements, state law, and federal regulations. Previously these were referred to as IAAs or “IRB Authorization Agreements.”

**Reviewing IRB** A term used in Reliance Agreements to identify the party to the agreement that acts as the sIRB in providing IRB review for all sites participating in the conduct of the same multi-site protocol.

**Relying Institution** A term used in Reliance Agreements to identify the party to the agreement that will rely on an IRB outside of its own entity. This is sometimes termed the Relying Institution or Relying Site or Participating Site.