Human Research Protection Program Procedure

REVIEW OF RESEARCH INVOLVING A RELIANCE AGREEMENT

DESCRIPTION

University of Cincinnati (UC) researchers may ask the UC Institutional Review Board (IRB) to enter into a reliance agreement whereby

1. the UC IRB will be considered the IRB of Record and the external IRB will rely upon UC's IRB for oversight of the research, or
2. the external IRB will be considered the IRB of Record and UC's IRB will rely upon the external IRB for oversight of the research.

The request may be for a single research study, for multiple studies, or for a period of time. Each request will be evaluated individually by the UC IRB. The UC IRB may determine that reliance is not appropriate for a given study and that oversight of each institution's research is needed by the respective IRBs.

RESPONSIBILITY

The UC IRB retains responsibility for ensuring protection of research participants at UC, even if the UC IRB is relying on an external IRB as the IRB of Record. The UC IRB Chair (or designee) is responsible for determining whether or not the research qualifies for a reliance agreement with another IRB.

1. If the study is federally funded, the other institution must have a current Federalwide Assurance (FWA).
2. Reliance on an external IRB may be appropriate if a UC faculty member, employee, or student will be conducting the research at the non-UC institution.
3. Reliance on an external IRB may be appropriate if a non-UC researcher will be using UC facilities for part of their research.
4. Pertinent local factors will be considered, including:
    a. Whether UC and the external IRB draw from culturally dissimilar patient populations;
    b. Whether UC and the external IRB are located in different states or other geographical subdivisions with conflicting legal or regulatory constraints; and
    c. Whether UC and the external IRB have conflicting operational policies, constraints, procedures, or commitments.
5. UC's IRB shall only rely on another IRB if the external IRB conforms to applicable human research protection regulations.

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DEFINITIONS

IRB Authorization Agreement (IAA): Any designation under the FWA of the IRB of another institution or organization must be documented by a written agreement between the Institution holding the FWA and the IRB organization, outlining their relationship and incorporating a commitment that the designated IRB will adhere to the requirements of the FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. If a Memorandum of Understanding (MOU) has been established and indicates that the involved IRBs may rely on each other for review then an additional agreement is not required.

PROCESS

UC IRB AS THE IRB OF RECORD (Institution A for a single study)

Usually, the UC IRB is expected to be the IRB of Record if the PI of the study is a faculty member, staff or student at UC, the research will utilize UC resources, or the research will use identifiable, non-public information from UC faculty, staff or students.

The UC researcher must submit a standard research proposal to the UC IRB as described in UC HHRP policies and procedures. The submission must include discussion of the need for an external IRB to rely upon UC's IRB. If documentation is available from the non-UC site requesting that UC serve as the IRB of Record, it should be included in the submission. Standard review of the research will be done in accordance with UC HRPP policies and procedures.

In addition to all other required attachments, an IAA form must be attached with study-specific information included on it, with UC shown to be the institution providing IRB review (Institution A). A template IAA form with UC's information given as Institution A is posted on the IRB's website for the PI's convenience. UC's Institutional Official (IO) will sign the IAA form after UC IRB approval has been obtained. The signed document will be provided to the PI so it can be forwarded to the external IRB. The PI is responsible for providing the finalized IAA form with signatures by both institutions' signatory officials to the UC IRB for inclusion in the IRB's documentation. The IO will determine if the IAA requires a Contract Approval Cover Sheet (A-910) and submit for the Office of General Counsel review.

When UC is the IRB of Record, the UC researcher is responsible for

1. providing information to the UC IRB about all non-UC sites where the research will be conducted,

2. providing any documentation needed to the external IRB(s),
3. including information and documentation from the non-UC site(s) in the UC IRB continuing review, and
4. notifying the external IRB(s) when the research is closed.

Either UC or the non-UC institution may end the reliance at any time by notification in writing. When the study is closed at UC, the reliance will be considered ended.

UC IRB AS THE RELYING IRB (Institution B for a single study)

The UC researcher must submit a research proposal to the UC IRB as described in UC HRPP policies and procedures, indicating that it involves reliance on an external IRB. The submission must include discussion of the need for UC to rely upon the external IRB. If documentation is available from the non-UC site requesting that UC rely upon the external IRB, it should be included in the submission.

The protocol, informed consent document (ICD), recruitment materials, data collection forms and other documents reviewed and approved by the external IRB must be attached to the submission to UC's IRB, along with the external IRB's approval letter. The attached documents, already approved by the external IRB, do not need to be re-written to conform to UC IRB templates. The documents approved by the other IRB will be reviewed to assure protection of UC research participants. Either the expedited or full review process may be used, as appropriate for the submission. As part of the approval, the UC IRB will document whether or not reliance on the other IRB is appropriate.

In addition to all other required attachments, an IAA form with study specific information included on it, with the external IRB shown to be the institution providing IRB review (Institution A), must be provided. A template IAA form with UC's information given as the relying IRB (Institution B) is posted on the IRB's website for the PI's convenience. UC's IO will sign the IAA form after UC IRB approval has been obtained. The signed document will be provided to the PI so it can be forwarded to the external IRB. The PI is responsible for providing the finalized IAA form with signatures by both institutions' signatory officials to the UC IRB for inclusion in the IRB's documentation. The IO will determine if the IAA requires a Contract Approval Cover Sheet (A-910) and submit for the Office of General Counsel review.

Either UC or the non-UC institution may end the reliance at any time by notification in writing. When the study is closed at UC, the reliance will be considered ended.

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MEMORANDUM OF UNDERSTANDING (for multiple studies)

A Memorandum of Understanding (MOU) between UC and the non-UC institution must be on file with the UC IRB before a research proposal may be submitted to the UC IRB for this kind of reliance. The MOU will define UC's role (either IRB of Record or relying IRB, and under what circumstances the role is determined) for studies covered by the MOU.

The document submission and review processes follow the explanations given above, except no IAA form is needed if an MOU is in place.

Central IRBs such as Western IRB (WIRB) or Schulman Associates IRB (SAIRB) have requirements about the documentation they need to receive before they can begin review as the IRB of Record. The UC researcher must submit those documents to the UC IRB, which then will forward them to the central IRB along with UC-specific documents as defined in the MOU.

Either UC or the non-UC institution may end the reliance at any time by notification in writing. Closure of a study does not automatically end the MOU.

Applicable Regulations and Document(s):
21 CFR 56.114
45 CFR 46.103
45 CFR 46.114
UC HRPP Policy III.06 *Reliance Agreements Between the University of Cincinnati Institutional Review Board and Other Institutional Review Boards*
UC HRPP Procedure 303 *Procedures Followed for Conducting Initial Full Board Protocol Review*
Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement (UC-A)
Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement (UC-B)

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
03/2005	M. Belskis	07/2007	J. Lindwall	Addition of the Processing Documentation section.

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		12/2013	C. Norman	Change title from "Review of Approved Research by Another Institution's IRB" to "Review of Research Involving A Reliance Agreement". Add information relating to central IRBs. Revise format and wording for clarification and to conform to other HRP procedures. Remove language that more appropriately belongs in other documents. Add to the list of Applicable Regulations and Documents.
		5/2014	K. Mills	Streamlining and clarifying procedure

Date June 2014 **Signature signed copy on file**