



## Human Research Protection Program Policy

**Policy Number: III.06**

**Reliance Agreements Between the UC  
IRB and Other IRBs**

**Adopted: 11/2005**

**Revised: 03/2014**

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### **RELIANCE AGREEMENTS BETWEEN THE UNIVERSITY OF CINCINNATI INSTITUTIONAL REVIEW BOARD AND OTHER INSTITUTIONAL REVIEW BOARDS**

#### **POLICY**

Research being done at multiple locations may be subject to oversight by multiple Institutional Review Boards (IRBs). To reduce duplication of effort, institutions may enter into a joint agreement to allow one IRB to rely upon the review of another qualified IRB. On a case by case basis, the UC IRB will evaluate requests from UC investigators to enter into a reliance agreement whereby

1. the UC IRB will be considered the lead IRB (the "IRB of Record") and the other IRB will rely upon UC's IRB for oversight of the research, or
2. the non-UC IRB will be considered the IRB of Record and UC's IRB will rely upon the other IRB for oversight of the research.

#### **UC IRB AS THE IRB OF RECORD for a single research study**

Usually, the UC IRB is expected to be the IRB of Record for all human subjects' research

1. conducted by or under the direction of any university employee or agent of the University in connection with his/her institutional responsibilities; or
2. conducted by or under the direction of any university employee or agent of the university using any university property or facility; or
3. involving the use of the university's non-public information to identify or contact human research subjects or prospective subjects.

Further details are provided in HRP Policy III.01 *Review by the Institutional Review Board of Human Subjects Research*.

When UC's IRB is the IRB of Record, the UC Principal Investigator (PI) must submit a standard research proposal to the UC IRB as described in HRP Procedure 303 *Procedures Followed for Conducting Initial Full Board Protocol Review* and obtain UC IRB approval before the study may begin. To initiate reliance the submission must include an IRB Authorization Agreement (IAA) form containing study-specific information, with UC shown to be the institution providing IRB review (Institution A). UC's Institutional Official (IO) or Counsel will sign the form after UC IRB approval has been obtained. The agreement will take effect after appropriate signatures from both institutions have been obtained. When the study is closed, the IAA will be considered ended.



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### **UC IRB AS THE RELYING IRB for a single research study**

UC's IRB may rely upon a non-UC IRB to provide oversight of a research study is being done at a non-UC location or is being done by a non-UC PI. If the study is federally funded, the non-UC IRB must have a valid Federalwide Assurance (FWA).

The UC researcher must submit a research proposal to the UC IRB, indicating that it involves reliance on a non-UC IRB. The submission must include an IAA form with study specific information included on it, with the other IRB shown to be the institution providing IRB review (Institution A). UC's IO will sign the form after the necessary documents have been obtained. The agreement will take effect after appropriate signatures from both institutions have been obtained. When the study is closed, the IAA will be considered ended.

### **MEMORANDUM OF UNDERSTANDING for multiple research studies**

UC's IRB may enter into an agreement with one or more non-UC IRBs that permits reliance for a period of time or a certain type of research or other specifications. A Memorandum of Understanding (MOU) will be created that identifies the criteria when UC will be the IRB of Record or when the other IRB(s) will be the IRB of Record. The agreement will take effect after signatures of each institutions' officials have been obtained. The MOU will remain in effect until the institution(s) specifically terminate it.

UC researchers requesting reliance through an MOU must submit documentation as indicated above for single-study submissions except that no IAA form is needed when an MOU is in place.

UC's IRB registration with the Office of Human Research Protections (OHRP) will be updated to include reliance on any non-UC IRB to indicate the entities upon which UC relies for IRB oversight. When the relationship has ended, UC's IRB registration will be updated to remove the non-UC IRB

### **MULTI-SITE RESEARCH STUDY where UC is the lead site or a UC investigator is the lead PI**

Multi-site research is defined as a study where other performance sites have their own local PI and research team that are not supervised directly by the lead institution's PI. When UC is the lead site or a UC investigator is the led PI in a multi-site research study, an IAA or MOU is not required with the other sites. Instead, the UC PI must provide information about the sites and approval letters from their IRBs as described in HRP Procedure 324 *Review of Multi-Site Research*.



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**Applicable Regulations and Documents:**

- 21 CFR 56.114
- 45 CFR 46.114
- HRP Policy III.01 *Review by the Institutional Review Board of Human Subjects Research*
- HRP Procedure 303 *Procedures Followed for Conducting Initial Full Board Protocol Review*
- HRP Procedure 321 *Review of Research Involving a Reliance Agreement*
- HRP Procedure 324 *Review of Multi-Site Research*
- 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:
11/2005	M. Belskis	11/2006	J. Gerlach	Title change from "Accepting Approval from Another Institution's IRB" to "The IRB of Record". Add reference to UC being the IRB of Record. Clarifications to "Definitions" and "Applicability" sections (due to AAHRPP requirements).
		12/2013	C. Norman	Title change from "The IRB of Record" to "Reliance Agreements Between the University of Cincinnati Institutional Review Board and Other Institutional Review Boards." Revise format and wording for clarification and to conform to other HRP policies. Remove language that more appropriately belongs in other documents. Add "Applicable Regulations and Documents" information and revision table to the end of the document.
		06/2014	A. Braggs-Brown	Revised to reflect organizational changes

Date June 2014      Signature signed copy on file