



## Human Research Protection Program Policy

### **COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD**

#### **POLICY**

The University of Cincinnati (UC) shall have the number of Institutional Review Boards (IRBs) required to review submitted research protocols in a timely manner. Members of the IRB shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted at the University.

#### **COMPOSITION OF THE IRB**

Composition of the UC IRB shall meet the requirements of federal regulations at 45 CFR 46.107 and 21 CFR 56.107. It shall also meet the requirements in the Veterans Affairs (VA) Handbook when reviewing research using the Veterans Affairs Medical Center (VAMC) facility, employees, resources or patients. The IRB shall consist of at least five members, appointed by the Institutional Official (IO). IRB members representing the VAMC must be dually appointed by the VAMC Director and the UC IO.

- IRB members shall be appointed for up to three years with appointment terminating or renewing on July 1 of the year immediately preceding 3 years duration. A member may be reappointed for additional three-year terms.
- IRB members shall be selected to assure appropriate review of research, including
  - members with training in the scientific disciplines of the research that are typically reviewed by the IRB,
  - at least one member who is a non-scientist (a person without significant prior scientific training or background),
  - members who are licensed physicians (when articles regulated by the Food and Drug Administration (FDA) are involved),
  - at least two members affiliated with the VAMC, (VAMC representatives shall be full members of the IRB with authority to review all research that comes before the IRB); either the VAMC director or UC IO may suspend or terminate the membership of VAMC representatives on the IRB who are not fulfilling their member responsibilities or obligations.
  - members representing the ethnic, gender, and cultural diversity of the community,
  - members who can advocate for vulnerable subjects, including
    - at least one member with behavioral science expertise, with appropriate background and experience relating to individuals with mental disability or impaired decision-making capacity, when research involving such participants is reviewed, and

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- at least one member who is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, when research involving prisoners, as defined in 45 CFR 46.303(c), is reviewed. A prisoner representative must review all research involving prisoners.
  - members affiliated with UC and at least one member who is not affiliated with UC.
    - An individual is considered to be “affiliated” if he or she is a
      - current or former employee or family member of any current or former employee,
      - retiree, trainee, consultant, or board member of any affiliated practice corporation, UCHealth, Cincinnati VAMC, Shriners Hospital, Cincinnati Children’s Hospital Medical Center, or any institution for which UC has served as the IRB of record; or
      - if the individual’s relationship with the institution is anything other than that of an IRB member.
    - Alumni are not considered to be “affiliated”.
- When research is reviewed at a convened meeting, the IRB Chair shall assure
  - if the research will be conducted at the VAMC, at least one member affiliated with that VAMC is present.
  - if the research will be conducted at the CVAMC and will involve participants with mental disabilities or impaired decision making capacity, one expert behavioral member from the VAMC is present.
  - if the research will involve prisoners, a prisoner representative is present.
- Officials of UC whose responsibilities include developing or allocating research resources or overseeing the research program may consult with the IRB but may not serve as members.
- Individuals who are responsible for business development (i.e. commercialization of the technology) are prohibited from carrying out the day-to-day operations of the review process.
- For VAMC research, VAMC Research and Development administration officials including, but not limited to, the Associate Chief of Staff for Research and Development and the Administrative Officer for Research and Development, may not serve as voting members of the IRB.
- For VAMC Research, a VAMC Research Compliance Officer (RCO) may act as a consultant to the IRB, but may not serve as a member (voting or nonvoting) of the IRB. RCOs may attend IRB meetings when requested by the IRB or as specified by Human Research Protection Program (HRPP) policies and procedures.
- One individual may fulfill more than one of the requirements listed above, i.e., a member who is a non-scientist and also unaffiliated fills both requirements for membership.
- No IRB member may participate in initial or continuing review of any research in which the member has a conflict of interest as defined in Procedure 102 *"Managing Conflicts of Interest of IRB Members and Consultants"*, except to provide information requested by the IRB.



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The IRB Chair, with the assistance of HRPP staff, will periodically review the composition of the IRB to ensure that requirements are met. The IRB Chair and HRPP Director shall assess the performance of individual IRB members prior to reappointment and more frequently if circumstances warrant. Input will be sought from other IRB members and from HRPP staff. In the event that any changes to IRB membership are needed, the IRB Chair shall notify the IO and provide recommendations for modification to the membership.

### **IRB MEMBER ROSTER**

IRB members shall be identified as belonging to one of the following categories:

- M.D., scientist
- Non-M.D., scientist
- Non-M.D., non-scientist

A current roster of all IRB members shall be maintained in the HRPP office. The Office of Human Research Protections (OHRP) shall be notified of any changes, as required by OHRP policy.

A current list of IRB members shall be made available on the IRB's website.

Each member of the IRB shall receive a stipend of up to \$1,000 annually that may be spent on any item or service that contributes to that member's professional development.

IRB members who are UC faculty shall have their IRB service recognized for purposes of reappointment and tenure.

### **THE IRB CHAIR**

The IRB Chair shall be appointed for a three-year term by the IO. A Chair may be reappointed for additional three-year terms.

The IRB Chair shall be evaluated on an annual basis by the Institutional Official. The Institutional Official will seek input from IRB members and members of the Human Research Protection Program in a formal manner. Evaluation will include consideration of effort, quality of work, and reappointment as appropriate.

If the IRB Chair must be absent, or must recuse him/herself from review of a research study, or for any reason is unable to fulfill the duties of the Chair, the Vice-Chair or an experienced IRB member may fulfill the Chair's duties.



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### **THE IRB VICE-CHAIR**

One or more Vice-Chair(s) for the IRB may be appointed by the IO. The term of service is at the discretion of the IO. The Vice-Chair(s) may be reappointed for additional terms. The IRB Chair shall assess the performance of each Vice-Chair annually. The Chair will seek input from IRB members and members of the Human Research Protection Program in a formal manner. Evaluation will include consideration of effort, quality of work, and reappointment as appropriate.

### **IRB MEMBER ROSTER**

Each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. The minutes of an IRB meeting should document the attendance of all primary and alternate IRB members who attended any part of the IRB meeting. If both a primary IRB member and his or her alternate(s) attend the same IRB meeting, then the primary member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting will indicate clearly that the alternate IRB member has replaced the designated primary IRB member and the reason.

### **LIABILITY COVERAGE FOR IRB MEMBERS**

UC, through its Office of Risk Management and Insurance, maintains a comprehensive program of self-insurance and commercially purchased insurance, covering property, casualty and liability exposures to the university and its employees, agents and volunteers, while acting on the University's behalf.

#### **Applicable Regulations and Documents:**

21 CFR 56.107

45 CFR 46.107

45 CFR 46.303

VA Handbook 1200.05

Policy I.03 *Demonstrating Knowledge of HRP by IRB Members*

Policy III.01 *Authority of the Institutional Review Board*



**Policy Number: I.01**

**Composition of the Institutional Review Board**

**Adopted: 11/2005**

**Revised: 03/2015**

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Procedure 101 *IRB Members*

Procedure 102 *Managing Conflicts of Interest of IRB Members and Consultants*

HHS FAQ 12/2/2010

<b>Adoption Date:</b>	<b>Created by:</b>	<b>Date of Revision:</b>	<b>Revised By:</b>	<b>Summary of Revision:</b>
11/2005	IRB Director	07/2007	J. Lindwall	Revision has been made to include the definition of Shared Membership
		05/2008	J. Gerlach	Revision has been made to the review of behavioral research. Addition of IRB Vice-Chair appointment and responsibilities. Addition of language defining the funding of IRB Chairs to attend HSRP programs.
		07/2008	J. Gerlach	Reformatted Membership section. Additional definition of unaffiliated member. Additional responsibilities for the prisoner representative added
		07/2009	J. Gerlach	Corrected redundant information regarding action of Institutional Official and determining reappointment of IRB Chair. Added additional IRB member roster attributes.
		1/20/2012	C. Norman	Revise wording and formatting for clarification. Change VP for Research to Institutional Official. Omit IRB Director. Define the three categories of members (MD/scientist, non-MD/scientist, non-MD/non-scientist). Define stipend for full members and co-members. Clarify annual evaluations.
		06/2012	C. Norman	Add reference to VA Handbook, COI, and identifying new IRB members. Add footer. Remove language that more appropriately belongs in other documents.
Feb 2014		02/2014	J. Strasser	Standardize appointment length, remove co- and alternate members
		9/2014	A.Braggs-Brown	Revised to include AAHRPP recommendations
3/2015		3/2015	J. Strasser	Revisions for clarification

**Date Adopted** March 2015      **Signature** signed copy on file