IRB MEMBERS

DESCRIPTION

All University of Cincinnati (UC) Institutional Review Board (IRB) members must have sufficient qualifications, background and training to effectively protect human research participants.

RESPONSIBILITY

The IRB Chair is responsible for assuring compliance with this procedure. Duties related to assuring compliance may be delegated to designees.

PROCESS

BASIC QUALIFICATIONS

All IRB members must have basic qualifications in order to function effectively on the Board, including the following. In addition, Board members must conform to requirements found in Policy I.01 "Membership of the Institutional Review Board".

- Commitment to protecting human research participants from unethical research
- Understanding of the ethical and regulatory basis for the IRB
- Ability to think critically
- Good computer skills
- Ability to devote sufficient time to IRB-related activities

THE IRB CHAIR

Any individual appointed as Chair of the IRB shall have served as an IRB member prior to the appointment as Chair and shall demonstrate knowledge of human subject protections. Service as an IRB member may have been with an IRB that is not affiliated with the University of Cincinnati.

THE IRB VICE-CHAIR

An IRB Vice-Chair shall be a respected, active member of the IRB who is knowledgeable of regulations relevant to the protection of human participants in research.
NEW IRB MEMBER ORIENTATION AND TRAINING

All new IRB members must undergo orientation and training, including the following elements. A formal letter appointing the new member to the Board will be generated by the Institutional Official.

- General orientation regarding federal regulations pertaining to human research protections
  - 45 CFR 46
  - 21 CFR 50, 56, 312, 812
  - Appropriate websites and guidance documents
- General orientation regarding UC's Human Research Protection Program (HRPP)
  - HRPP Policies and Procedures
  - Organizational structure and personnel
- Specific training on computer programs, processes and documentation used by UC's IRB
- Observation of two convened IRB meetings before being eligible to vote.
- Demonstration of knowledge of human research subject protections by completing required training as described in Policy I.03 “Demonstrating Knowledge of Human Research Protection by IRB Members”.

CONTINUING EDUCATION

All IRB members must maintain current CITI certification and/or Cincinnati Veterans Administration Medical Center (CVAMC) training as described in Policy I.03 “Demonstrating Knowledge of Human Research Protection by IRB Members”. Additional training and continuing education may be required by the IRB Chair or designee. Continuing education is provided several times each year.

MEMBER EVALUATION

The IRB Chair and HRPP Director shall perform annual review of each member of the IRB. They will seek input from IRB Vice-Chairs and HRPP staff.

IRB member review shall include consideration of each of the following factors:
- The representative capacity of the member, including scientist/non-scientist, affiliated/unaffiliated, and expertise,
- The member’s conflict of interest disclosures,
- The member’s knowledge of regulations, policies and procedures relating to human subject protections,
- The member’s participation in convened meetings and full-board reviews,
- The member’s participation in expedited reviews, and
- Other factors pertinent to IRB membership, as appropriate.
The Chair shall communicate the results of annual review to the IRB member. The HRPP Director will ensure that any findings needing follow-up is resolved in a timely manner.

If annual review reveals the need for additional IRB member(s) with specific expertise, the IRB Chair and Institutional Official shall identify and recruit such new members.

The IRB Chair shall be evaluated on an annual basis by the Institutional Official. The Institutional Official will seek input from IRB members serving under the Chair, HRPP staff, and others as appropriate. When appropriate, evaluation will include conditions for reappointment.

IRB member files shall also be reviewed annually. They shall contain documentation of the following:

- Appointment by the Institutional Official, and CVAMC Director if applicable,
- Curriculum vitae, received within the past two years,
- Training, as required in HRP Policy I.03 “Demonstrating Knowledge of Human Research Protection by IRB Members;” and
- Any other documentation pertinent to the member’s representative capacity.

Applicable Regulations and Documents:

Policy I.01 "Composition of the Institutional Review Board"
Policy I.03 “Demonstrating Knowledge of Human Research Protection by IRB Members”
IRB Member File Checklist

<table>
<thead>
<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/2005</td>
<td>M. Belskis</td>
<td>11/2005</td>
<td>J. Gerlach</td>
<td>Format changes only</td>
</tr>
<tr>
<td></td>
<td></td>
<td>08/2012</td>
<td>C. Norman</td>
<td>Major revision to clarify and to remove language that more appropriately belongs in other documents. Define CVAMC.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>06/2014</td>
<td>A. Braggs-Brown</td>
<td>Revised to reflect organizational changes</td>
</tr>
</tbody>
</table>

Date Adopted June 2014

Signature signed copy on file