Institutional Review Board (IRB) members, including chairs, will be trained through an initial orientation process and continuing education to ensure that all IRB members are appropriately educated about the regulatory requirements and ethical considerations for the protection of human subjects involved in research.

**Orientation**

New IRB members are required to complete an orientation process prior to reviewing any human research studies.

New member orientation should include meetings with the Human Research Protection Program (HRPP) director, IRB chair, and IRB administrator(s) or staff. The focus of the meetings will include:

- History of regulations and purpose of IRBs
- Human subject protection at MSU
- Other regulations that pertain to human subject research
- Key issues in the protection of human subjects
- Day-to-day operations of the IRB
- MSU IRB online system

Copies of appropriate documents will be provided to the IRB members. These include:

- Belmont Report
- 45 CFR 46
- 21 CFR 50, 21 CFR 56
- Michigan laws governing the protection of human research subjects
- MSU HRPP Manual 4-5, 5-3, and 5-5
- Pertinent reviewer documents and checklists
- Other documents as appropriate.

IRB members are also provided with access to an online reference binder available through the MSU online system. Links to materials include:

- Introductory materials (e.g., mission statement, responsibilities of IRB members)
- Federal Wide Assurance and Terms of the Assurance
- Ethical codes (e.g., Nuremberg Code, Declaration of Helsinki, Belmont Report)
- Federal regulations and state laws (e.g., 45 CFR 46; 21 CFR 50, 56, 312, 812)
- MSU policies and procedures (e.g., MSU HRP Manual, Faculty Handbook)
- IRB application forms and instructions (e.g., initial application, reviewer forms)
- Other documents as appropriate (e.g., OHRP guidance documents)

Required initial IRB training consists of completion of the MSU IRB online tutorial available at the [HRPP website](#). Initial IRB training is valid for two years. IRB members will be asked to complete the MSU IRB tutorial prior to the initial orientation session. IRB members will also be encouraged to complete the Office for Human Research Protections (OHRP) training modules.

As part of the training process, new IRB members perform a minimum of six “shadow reviews” of new initial applications. “Shadow review” means that the IRB member is able to observe (via the MSU IRB online system) the initial application review process between the researchers and the IRB members assigned to review the application. The new IRB member is able to access and review all materials and comments that the assigned reviewers views. The new IRB member is not a reviewer on the research study, but may submit comments or questions if there is an issue they believe has not been addressed. IRB members also will attend a minimum of six convened IRB meeting as a voting member prior to being determined an experienced reviewer. See HRPP Manual 5-3 “IRB Membership” for requirements.

The orientation procedure for the IRB chair will vary by level of IRB experience and familiarity with the MSU IRB review process.

**Ongoing education**
The HRPP will provide and support continuing educational opportunities including:

- Opportunities for IRB members to attend training at the local, state, or national levels
- Updates on new federal and state laws and university guidelines and policies, as needed
- Refresher presentations and tutorials

To renew IRB training, IRB members are required to complete any six [Collaborative Institutional Training Initiative (CITI) modules](#) in the protection of human research subject. On the date of IRB training expiration, if six CITI modules have been completed, IRB training will be renewed for two additional years. Alternate, equivalent IRB training may be substituted with written approval from the IRB manager. Continuing education encompasses many additional activities, such as education at convened IRB meetings, retreats, subscriptions, and other resources. The HRPP, in coordination with the Office of Regulatory Affairs (ORA) education program coordinator as appropriate, works on the development and implementation of additional continuing education activities as needed. IRB members, including chairs, are encouraged to take part in continuing education opportunities annually.

**Convened IRB Meetings**
At convened IRB meetings, IRB staff disseminate updates, guidance, and other materials containing ethical and regulatory guidance for the review of protocols, including in specialized areas (i.e. tissue banking) or selected vulnerable subject populations (i.e. prisoners). IRB staff also may make presentations to the members at the scheduled IRB meetings or invite guest speakers to present. The IRB chair may conduct presentations as needed. The presentations will typically last 10-15 minutes. Presentations may focus on topics specific to items on the agenda. IRB members are encouraged to contact the HRPP director with topic suggestions. These presentations may be posted on the HRPP website to be accessible to any interested individual. Records of the training will be documented in the IRB minutes. The IRB administrator will post to the ANGEL site (online learning management system) materials distributed at the IRB meeting (e.g. the presentation) so that non-attendees of the IRB meeting may access the materials.

**Human Research Protection Program Retreat**
Beginning in 2006, the HRPP plans and conducts an HRPP retreat at a minimum of every three years for members of all MSU IRBs and IRB staff. Updates and education on human research protection are provided throughout the retreat, in addition to other pertinent discussions.

**Subscriptions**
The HRPP maintains subscriptions to journals and news services related to human research protection, as appropriate. IRB members are provided with weekly e-mail updates through Illuminata, a news service that provides links to updates on regulatory guidance, news, and journal articles. IRB members are provided with copies of the journal of *IRB Ethics and Human Research Ethics*. The Human Research Protection Program also maintains office subscriptions, such as to the *Journal of Empirical Research on Human Research* and the *Journal of Medical Ethics*.

**Resource Library**
The Office of Regulatory Affairs (ORA) maintains a resource library which includes books on human research protection. IRB members and staff may access and check out such books.

**Other Activities**
IRB members are also encouraged to participate in the IRB conferences and the workshops described in HRPP Manual 11-1-A “Investigators and Research Staff.” They also receive electronic communications, such as IRB newsletters, with updates.

**Fulfillment of Requirements**
Education requirements are monitored by the IRB chair and IRB administrator. IRB members who do not complete the required IRB training within the allotted time frames will not be involved in reviewing research studies or voting at the convened meetings until the requirement is satisfied.
If the IRB chair does not fulfill his/her initial and/or continuing education requirements, the Institutional Official may require removal.