Part 13 – Education and Training

This section describes educational and training opportunities offered to IRBMED members, office staff, and researchers and study team members comprising the University research community.

I. EDUCATION IN GENERAL

Refer to HRPP OM Part 13.I

A. Required Training

Refer to HRPP OM Part 13.I.A

B. Educational Initiatives for the Research Community

The IRBMED provides researchers, board members, and IRBMED office staff with opportunities for the continuing education comprised of:

- Routine workshops on regulations, institutional policy and procedures, and the application process throughout the year and upon the request of a department or unit (see the IRBMED Education page)
  - New workshops as needs are identified
- Special educational events, including, but not limited to:
  - IRBMED Seminar Series or other live conferences featuring multiple speakers on regulatory, ethical, and practical information of concern to researchers
  - Presentations by researchers, regulators, and regulatory experts from within and outside of the university
- Hosted webinars offered by professional organizations
- Web-based instructional modules developed at U-M by content experts
  - U-MIC (University of Michigan IRB Collaborative) modules on regulatory and procedural topics. Each newly developed module is presented to the convened boards and the IRBMED office staff.
- Routine publication of electronic newsletters for the research community
- Consultations with study teams either upon the request of the study team or upon IRBMED (staff or boards) identification of the need for a consultation on one or more issues
  - Specified educational sessions as part of a corrective and preventative action plan following a noncompliance assessment
- Guidance posted on the IRBMED website
  - Developing new guidance as needs are identified
- Information and Technology Services (ITS) provides help guides and other resources on using eResearch.
- A web-based archive of materials from prior presentations

II. TRACKING AND COMMUNICATING NEW DEVELOPMENTS

Refer to HRPP OM Part 13.II

IRBMED monitors FDA and other regulatory communications, including MEDWATCH reports. Based on these reports, as well as new information available through other sources, such as medical and ethical journals, FDA warning letters, or OHRP determination letters, the IRBMED may require changes to ongoing and proposed research. These changes may be communicated to researchers in various ways depending on the nature of the information. Examples include, but are not limited to:

- Postings on the IRBMED website
- Global e-mail to all researchers
- Directed e-mail or phone calls to particular researchers, units, or departments
- Announcements in UM communication venues such as, but not limited to, the UMHS Daily Bulletin, Biomedical News, or the University Record

When the IRBMED changes or adds posted guidance or informed consent or assent templates, an announcement will appear on the IRBMED homepage, along with any deadlines for compliance. Announcements regarding the changes may also be communicated via the means listed above.