

Procedure Category:	Clinical Management
Procedure CLM-01-13:	Training of Clinical Research Monitoring Personnel

Procedure Overview

To define the standard procedures and documentation for training of clinical research monitoring personnel.

Responsible Individuals

Qualified MICHHR personnel (including, but not limited to, Project Manager and Clinical Research Monitor); Contracted Research Associates; Director, MICHHR.

NOTE: Training of Contract Research Associate personnel is primarily the responsibility of the Contract Research Organization (CRO). Documentation of training and qualifications of Contract Research Associates will be collected by and maintained at MICHHR.

Policies

- Adequate training is required by the principles of the International Conference on Harmonization (ICH), Guideline for Good Clinical Practice: "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
- Orientation and training must be available to all new Project Management and Monitoring (PMM) personnel.
- PMM personnel are responsible for completing initial and well as ongoing training as required per their role in MICHHR.
- Adequate and complete training records must be maintained for all PMM personnel (including Contract Research Associates) throughout their employment with MICHHR.

Procedure

The following tasks are performed during orientation of PMM personnel:

- Completion of the University of Michigan and the Medical School New Employee Orientation Programs are required as part of the University of Michigan and Medical School Administration New Employee Orientation Policy. Documentation of completion of these orientation programs are retained and on file at the University of Michigan Human Resource Department.
- On the new employee's first/second/third day, provide orientation to the office area and its computer environment, which may include, but is not limited to, the following:
 - Set-up of desk top unit through consultation with Medical School Information Systems
 - Instruction on the completion of MICHHR staff request for time off forms

Version Number: 002	Implementation Date: October 28, 2002
Page 1 of 4	Revision Date: June 30, 2004
	Review Date: June 30, 2006
Approval Signature, Date:	

Procedure Category:	Clinical Management
Procedure CLM-01-13:	Training of Clinical Research Monitoring Personnel

- Review of MICHHR Office Policies and Procedures
- Assignment of SOP binder and instruction on access of electronic SOPs
- Review and discussion of SOPs
- Completion of the NIH Human Participant Protections Education for Research Teams computer based training program
- All new PMM personnel must complete a training program and on-job-training (OJT) with experienced staff, prior to independently performing site monitoring activities.
- Topics are delivered as a 2-3 day lecture series and SOP readings which include, but are not limited to:
 - Drug Development Process
 - Good Clinical Practice
 - The Clinical Research Team
 - Site Selection Process
 - Site Qualification Process
 - IRBs and the Protocol Approval Process
 - Informed Consent
 - Investigator / Coordinator Meetings
 - Initiation Visits
 - Study Documents / Source Documents
 - Case Report Forms
 - Routine Monitoring Visits
 - Investigational Material Accountability
 - Close-out Visits
 - Reporting of Adverse Events
 - Investigational Study Files
- Documentation of training through the lecture series includes a listing of topics delivered and signature of all personnel present. Signed copies of the training documents are retained in the respective personnel files.
- Participate in OJT on an ongoing basis, retaining copies of co-signed visit reports, follow-up letters, and other documentation.
- OJT consist of the following:
 - OJT co-visit 1: The new employee will accompany the monitoring preceptor to a site and will observe the conduct of the visit and review study documents.
 - OJT co-visit 2: The new employee will accompany the monitoring preceptor to a site and will observe the conduct of the study, review study documents, and write the monitor visit report and follow-up letter

Version Number: 002	Implementation Date: October 28, 2002
Page 2 of 4	Review Date: June 30, 2004
	Revision Date: June 30, 2006
Approval Signature, Date:	

Procedure Category:	Clinical Management
Procedure CLM-01-13:	Training of Clinical Research Monitoring Personnel

- to the site. Both the report and the letter will be reviewed for accuracy and completeness and will be co-signed by the monitoring preceptor.
- OJT co-visit 3: The new employee will conduct the monitoring visit (with the monitoring preceptor present) and complete the monitoring visit report and follow-up letter to the site. Both the report and the letter will be reviewed for accuracy and completeness and will be co-signed by the monitoring preceptor.
 - If three co-visits are adequate, the manager, monitoring preceptor, and new monitor complete and sign the OJT Training Verification Form and forward to the MICHHR Administrative Assistant for placement in personnel records.
 - If three co-visits are not adequate, continue OJT, and review progress after each additional site co-visit.
 - *NOTE:* OJT may be shortened or lengthened based upon the manager's evaluation of the new clinical research monitor's progress.
 - Provide adequate supplemental training on study specific topics (e.g., protocol, case report forms, monitoring guidelines, Investigator's Brochure, Project Manual of Operations, etc.).
 - File and retain training records for new clinical research monitors appropriately.

Documentation

The following serve as documentation:

- Signed copy of lecture series training agenda
- Monitor reports
- Site visit follow-up letters
- OJT Training Verification Form

Deviation Approval

The Director, MICHHR or designee, must approve deviation from this procedure. The Director, MICHHR or designee, must store documentation of the deviation approval.

Procedure Author

Manager, Project Management and Monitoring Unit, Michigan Institute for Clinical and Health Research

Version Number: 002	Implementation Date: October 28, 2002
Page 3 of 4	Review Date: June 30, 2004
	Revision Date: June 30, 2006
Approval Signature, Date:	