Educational Formats for Research Training at MetroHealth

Target audience: Investigators, coordinators and other study staff

Initial Training of Study Coordinators and other Study Staff 2 Day Training:

**Day 1:**
EPIC Training Manual
EPIC Chart Review and Inbasket Manual

Budgeting
- Contracts
- Grants
- Salary Recovery

Time and Effort Certification

**Day 2:**
IRB Ethics
Federal Regulations
SOP’s
Informed consent
HIPAA
CREC
Reportable Events
Noncompliance
Audits

Conflict of Interests

CRU
eIRB System tutorial (live demonstration)

Good Clinical Practice

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Routine Education:

Target audience: Investigators, coordinators and other study staff

Monthly Meetings of research staff:

Format:

- Guest speakers
- Webinaires (i.e ACRP, HCCA)
- Live Demonstrations

Email Distribution of:

- Research Regulator (CASE Office of Research Compliance)
- Journal of Clinical Research Best Practices (Monthly)
- Relevant Regulatory updates and Research Articles
- ACRP sponsored Educational Events
- SOCRA sponsored Educational Events

DVD Library in IRB Office:

DVD’s on various regulatory topics are distributed to Investigators, study coordinators and other research staff these are pre approved by CASE for CREC Credit.

Websites used for Education:

- CITI
- OHRP
- VA
- NIH
- CASE
- MHS eIRB Home Page

User Manuals available online or in print
Education Targeted at IRB Members and Staff:

IRB Member Training:

Written Publications given to each new Member:

Institutional Review Board Member Handbook, Robert Amdur
Protecting Study Volunteers in Research, Cynthia Dunn, and Gary Chadwick
Orientation sessions with IRB Manager and staff (6-8 hours)

Review of MHS IRB SOPs

User Manual

IRB Member Guidance Review Cards (Laminated)

IRB Staff Training and Education Materials:

Written Publications given to each new IRB Staff:

Institutional Review Board Member Handbook, Robert Amdur
Protecting Study Volunteers in Research, Cynthia Dunn, and Gary Chadwick
Institutional Review Board Management and Function, Mary Bankert, and Robert Amdur

Code of Federal Regulations:

- FDA Information sheets
- FDA Bioresearch Monitoring Compliance Program
- DHHS guidance on HIPAA Privacy in Research
- Title 21 Parts 11, 50, 54, 56, 803, 807, 812, 814, 820
- 45CFR46
- HIPAA Privacy Rule, Research: Title 45, Part 164
- ICH Guideline on Good Clinical Practice
• Health Insurance Portability and Accountability Act 1996 Title II, Subtitle F (Administrative Simplification), 110 Stat. 1936
• Code of Federal Regulations Title 45: Public Welfare Parts 160, 162, 164
• DHHS (OCR) Guidance Standards to Protect Privacy of Personal Health Information with FAQs
• FDA Guidance – Premarketing Risk Assessment
• European Directives on GCP
• Introduction to the Drug Approval Process
• Clinical Research Dictionary

All New IRB Staff attend PRIM&R IRB 101 and 102 Courses within 3 months of hire

Review of MHS IRB SOPs

User Manual

Ongoing Education Provided to IRB Members and Staff Via:

PRIM&R Conferences and training events

OHRP Conferences

CASE Annual IRB Member Conference

Webinaires (i.e. PRIM&R)

Journal Articles (i.e. Hastings Center, JAMA)

Newspaper Articles

Regulatory Updates (i.e. new guidance from regulatory agencies)

Best Practice conferences for Click Users

IAC Meetings

Email Distribution of information from:

• Research Regulator (CASE Office of Research Compliance)
• Relevant Regulatory updates (i.e. OHRP, FDA, NIH)
• Research Articles
• OHRP sponsored Educational Events
• PRIM&R sponsored Educational Events
• Relevant information from IRB Forum
• Bioethics blog

Online Resources for IRB and Compliance professionals:
CITI
IRB Forum
FDA News
OHRP
HCCA
Medscape Week in Review