

Marianne M. Elliott

Office of Research Integrity and
Ethics

Bureau of Medicine and Surgery

U. S Navy

Research Compliance Audit aka Monitoring Research Integrity

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Marianne M. Elliott, M.S., C. I. P.
Director, Clinical Investigation & Responsible Conduct of Research Programs
Office of Research Integrity and Ethics, U. S. Navy

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The opinions expressed in this presentation are solely those of the author and do not reflect the official position or views of the United States Navy, the Department of Defense or the U. S. Government.

Objectives: Monitoring Research Integrity

1. Describe monitoring and the basis for monitoring research integrity in HRPP
2. Describe dimensions of monitoring in HRPP
3. Provide suggestions for practical approach

What is monitoring?

- What do you say you do?
written policies & procedures
- What do you do?
verify actual practice
- How well do you do it?
evaluate, assess & improve

Basis for Monitoring Research Integrity

- Ethical Principles
- Regulations
 - Common Rule – Federal Policy
 - FDA
- Continuous Quality Improvement through Self Assessment
- Accreditation standards
- Institutional policy & procedure

Basis for Monitoring Research Integrity

Ethical Principles from *The Belmont Report*

Respect for Persons

Beneficence

Justice

Basis for Monitoring Research Integrity

Common Rule

- *.109(e) – IRB shall conduct continuing review... authority to observe or have third party observe the consent process and the research
- *.111(a)(6) – When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects

Basis for Monitoring Research Integrity

Continuous Quality Improvement through Self-Assessment

- FDA model
- VA model
- HHS- OHRP model
- Navy model
- Business model

Dimensions of Monitoring Research Integrity

- Investigator – Protocol
- IRB as part of HRPP
- IRB operations/office
- Institutional HRPP - integration

Monitoring Research Integrity – Investigator-Protocol

Research protocol includes:

- post approval monitoring plan
 procedure for unanticipated problems &
 adverse events
- consent process & documentation
- eligibility, inclusion/exclusion criteria
- data verification – accuracy, safety

Monitoring Research Integrity – Investigator-Protocol

Define & describe post approval monitoring plan

- Investigator as sole monitor
- Research team as monitor
- Medical monitor
- Data Monitoring Committee (DMC) or DSMB
- Independent Committee – protocol unique

Monitoring Research Integrity – IRB as part of HRPP

IRB policy for reviewing research protocols:

- Address ethical principles
- Meet or exceed regulatory requirements
- Approve protocol with post approval monitoring plan
- Determine frequency of continuing review
- Document review & decisions
- Observe consent process and research

Monitoring Research Integrity – IRB as part of HRPP

Monitoring the IRB

- Observe IRB ‘in action’ - meeting
- Review documentation of decisions/actions
 - IRB meeting minutes, review guides
- Verify decisions/actions planned
 - appropriate? implemented?
- Evaluate decisions/actions – standards met?

Monitoring Research Integrity – IRB office

IRB Office & staff

- Role & responsibilities
- Staff qualifications & numbers
- Pre-review – ethical principles, regulatory requirements
- Investigator education – 1 by 1
- Document decisions/actions
- Process flow & efficiency

Monitoring Research Integrity – IRB office

IRB Office & staff

- Observe IRB office ‘in action’
- Review documentation of pre-review decisions/actions
 - protocol records, review guides
- Verify decisions/actions planned
 - appropriate? implemented?
- Evaluate decisions/actions – standards met?
- Track actual work flow

Monitoring Research Integrity – Institution's HRPP

Institution

- Create culture of research integrity
- HRPP structure & authority
- Organizational roles & responsibilities
- Communication amongst components
- Education program – all levels

Monitoring Research Integrity – Institution’s HRP

Institution

- Observe institution ‘in action’
 - administration & key leader
 - public relations, community outreach
- Process & documentation of decisions/actions
 - complaints, allegations,
- Verify decisions/actions planned
 - appropriate? implemented?
- Evaluate decisions/actions – standards met?

So, what is monitoring research integrity?

- What do you say you do?
- What do you do?
- How well do you do it?

Coming full circle while connecting the dots....