

Marianne M. Elliott

Office of Research Integrity
and Ethics

Bureau of Medicine and Surgery
U. S Navy

Investigator Education: Training for Accountability in Human Research Protection Programs

Concurrent Session 3.03

Thursday, April 22, 2004

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

Disclaimer:

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: Training for Accountability

1. Explore the 'landscape' of education:
'responsible conduct of research'
2. Describe 'sowing and growing'
strategies
3. Suggestions for 'feeding and weeding'

Landscape

Rough terrain - jungles, mountains & valleys

- NIH Policy effective October 2000
- ORI Policy - still pending
- Institutional policies - variability

Landscape

Where are the 'roots' of education & accountability?

- Family 'Tree' values - individuals
- Community 'forest' - neighborhoods
- Education - grade & high school, college
- On-the-Job training - adult learning

Sowing & Growing

Creating a culture of integrity & accountability:

- values - established early in life
- attitudes - can be difficult to change
- behavior - observable, can be altered

Sowing & Growing

Create a culture:

- awareness of ethical principles
- understanding regulatory requirements
- applying guidance
- clear expectations of standards-norms

Sowing & Growing

Start early and integrate:

- Kindergarten - 'garden of children'
respect, sharing, working together
- Grade school and high school
basic science, language arts
integrity, honesty, team work

Sowing & Growing

- College
sciences, research methods, humanities
integration & application
- Graduate & Professional
integration & application
teaching, mentoring, roles & responsibilities

Feeding & Weeding

On-the-Job training - late start,
intervene now

- initial orientation to expectations
acceptable values & behaviors (norms)
specific to roles & responsibilities
- on-going awareness & confirmation
meeting expectations

Feeding & Weeding

OJT: Adult learning principles

- tailored to individual needs
- applicable & relevant to 'work' (role)
- set clear expectations
- appropriate methodologies
- integrated

Feeding & Weeding

Many methods & approaches:

- Traditional 'classroom' - face-to-face seminars, lectures, workshops
- e-learning - flat or interactive, distance

Feeding & Weeding

Achieving accountability through:

- on-going evaluation of education programs
- on-going monitoring of direct application

Feeding & Weeding

Evaluate education programs

- clear objectives & expectations
- content & presentation
- individual & aggregate feedback
- revise & update

Feeding & Weeding

Evaluate direct application:

- post approval monitoring of research
 - feedback from research team, supervisors
 - feedback from subjects
 - IRB assessment - continuing review, observation
 - Institutional assessment - other HRPP components
 - documentation
 - transparency

Feeding & Weeding

Evaluate direct application:

- continuous quality improvement -HRPP
- review & verify publications & presentations

Feeding & Weeding

Disclose actual performance:

- marketing & public relations
- community - sharing results, good & 'not so good'
- presentations - local, national, global

Conclusion

Education for accountability in HRPP

- 'Change' the landscape, create the culture
- Sow early & intervene now
- Clear expectations - values, behaviors
- Monitor direct application
- Share & communicate