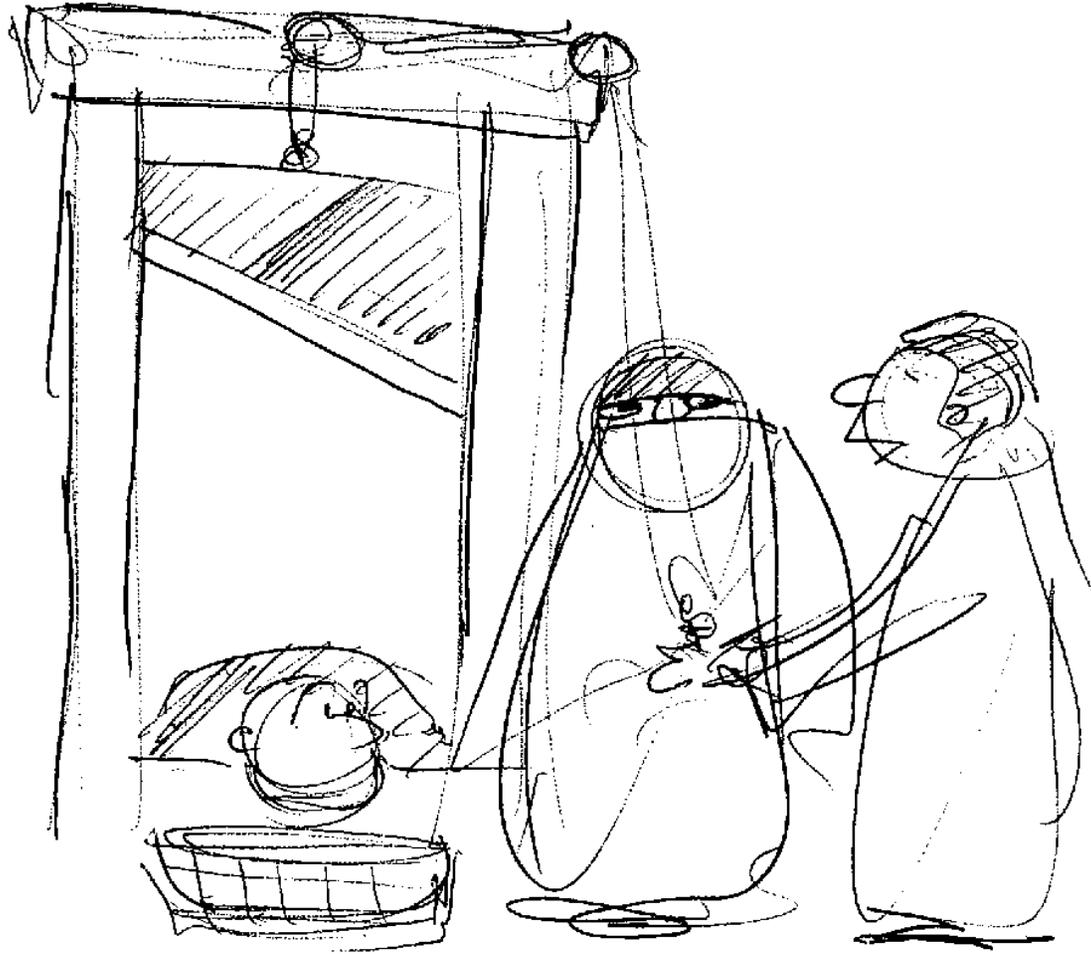


Research Program Accreditation: A New Addition to Human Subjects Protection

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Hold it! Do you
have informed consent?

Main Points

- Institute of Medicine Report
- Accreditation Program Review
- AARHPP Accreditation
- NCQA Accreditation

Institute of Medicine (IOM) Reports

- DHHS asked the IOM to conduct a two-year study, with a six-month fast track component, to address:
 - Accreditation standards for Human Research Participant Protection programs (HRPPPs) (6 month fast track)
 - The overall structure/functioning of human subject protection activities, but not restricted to IRBs (2002)
 - Criteria for evaluating the performance of HRPPPs (2002)

IOM 6 Month Report (April 2001)

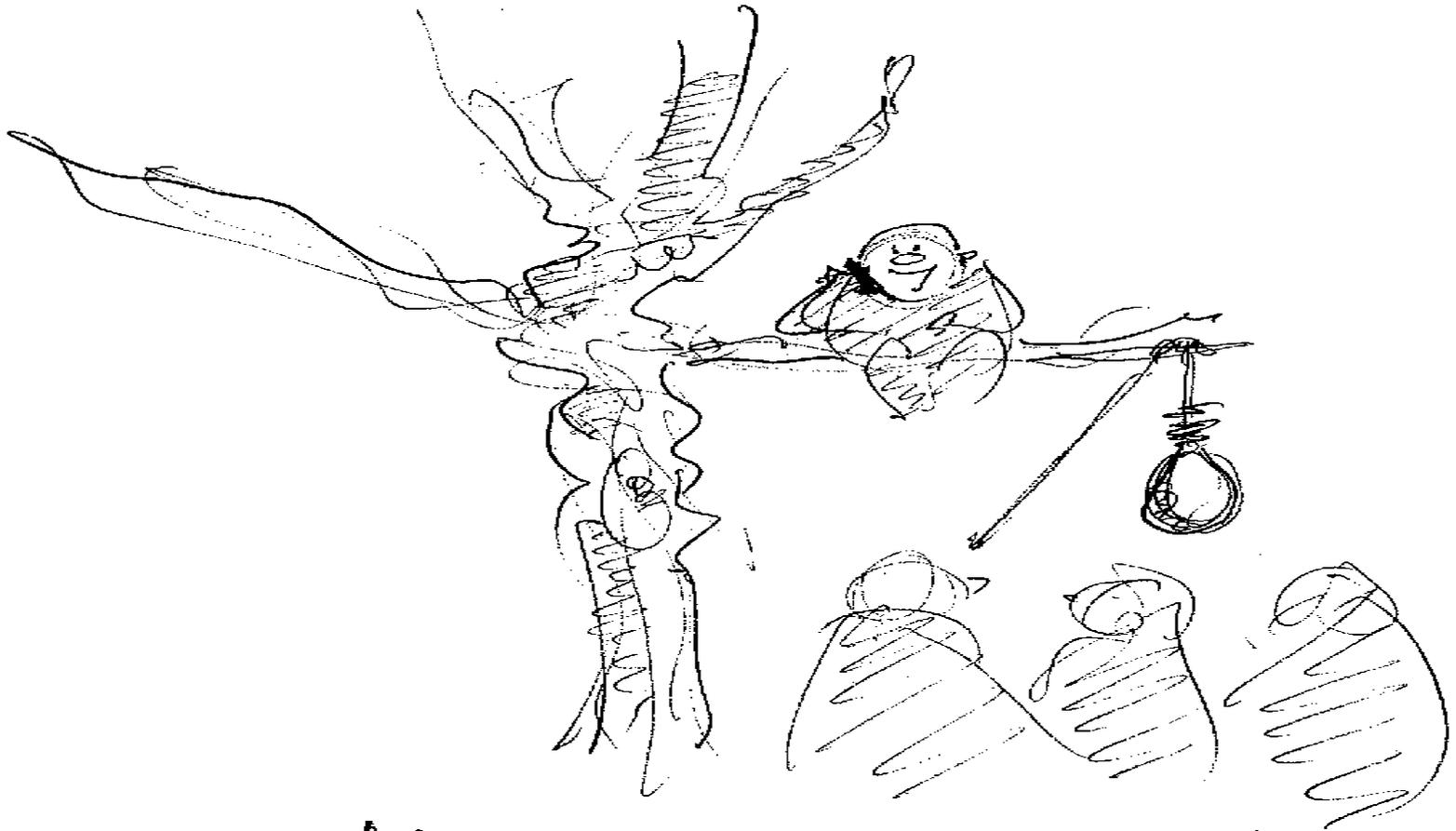
- Accreditation organizations should be independent, non-governmental organizations;
- Directly involve research participants;
- Move beyond traditional models and be appropriate for methods other than clinical research

IOM Press Release

- “By offering a recognized seal of approval, accreditation could establish a measure of excellence sought by research organizations, raising the bar for all and laying a path for continuous improvement.”

NCQA - VA Standards

- “NCQA's standards were deemed, on the whole, to be more immediately applicable for pilot-testing than those drafted by PRIM&R. NCQA's standards not only draw upon existing federal regulations, said the committee, but also rely on rigorous quality improvement programs at research sites and have the potential to elevate the enterprise beyond a system focused on administrative compliance.”



You said I could call it
I had problems

Accreditation

- A voluntary process in which an organization is evaluated against a set of external standards and for which at least summary results are made public
- Has roots in professionalism and in regulation-and is often a substitute for more formal regulation

Why Accreditation is Better than Regulation

- Better balance between researchers and those wanting accountability
- Standards and measures built more on evidence than politics
- Better able to respond to changes in the field than regulations

Accreditation Programs Should:

- Provide external validation and stimulus for quality improvement
- Be independent-but responsive
- Apply continuous quality improvement to accreditation process
- Publicly report accreditation results
- Rely on expert surveyors
- Provide for appeal of decisions

Accreditation Programs Should:

- Maintain transparency in translating standards into assessments
- Base standards on widely accepted ethical principles or scientific data
- Base standards in federal regulations, but evolve
- Emphasize self-assessment and continuous quality improvement

Views of Accreditation

- Drives improvement
- Galvanizes resources
- Potentially offers oversight relief
- One more hoop to jump



A Vision for the Future of HRPP

- Culture of respect
- Systems approach to assuring that protections are sufficient and effectively implemented
- Continuous measurement, evaluation and improvement of HRPP
- Public accountability for HRPP effectiveness



Hi, we're here to help you.

Accreditation Programs

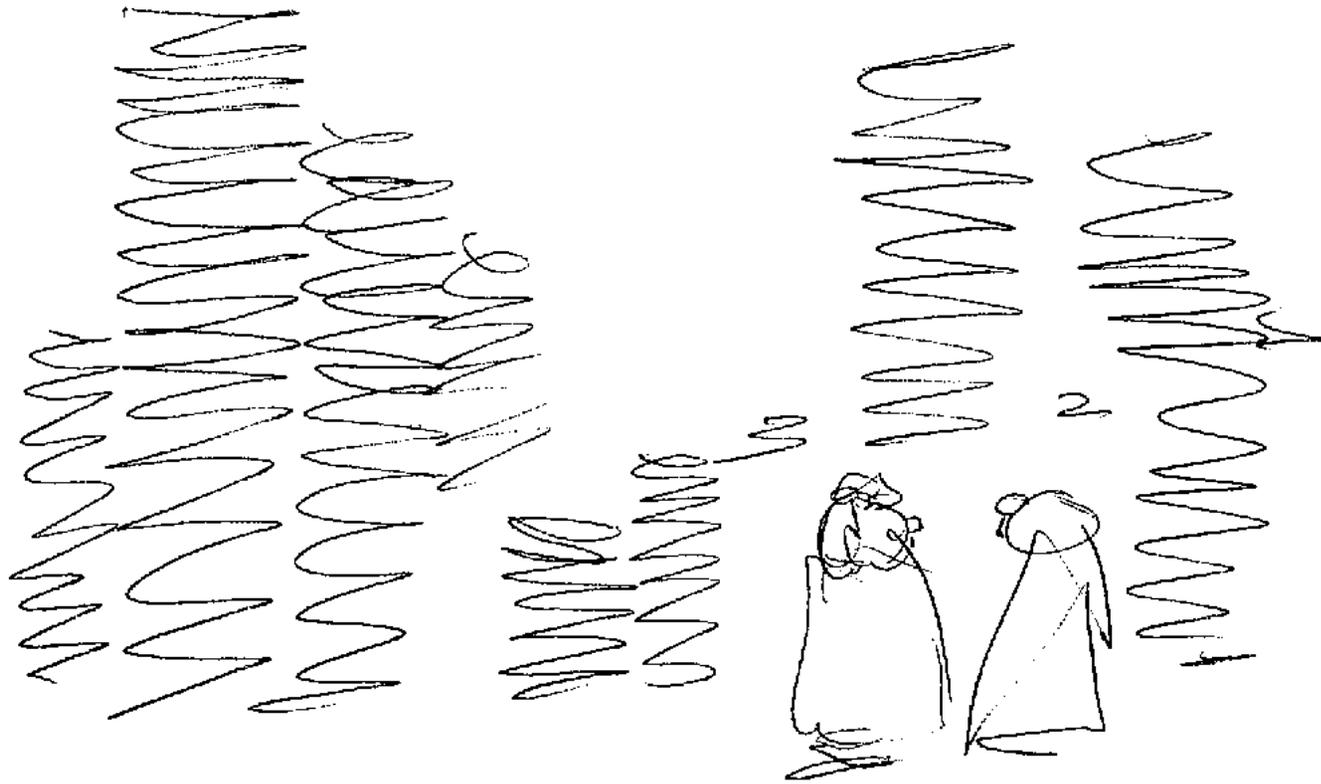
- Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- National Committee for Quality Assurance (NCQA)

AAHRPP

- National, nonprofit accrediting organization incorporated in April 2001
- 10 Member organizations
- Supported by PRIM&R

AAHRPP

- Five Domains
 - Organization
 - Research Review Unit
 - Investigator
 - Sponsor
 - Participant
- 19 Standards



Will you need any
other records?

Mission: To improve the quality of health care delivered to people everywhere

Vision: To become the most widely trusted source of information driving health care quality improvement

NCQA Assessment Programs

- HMOs
- Managed Behavioral Health Care Organizations
- PPOs
- Disease Management Firms
- Human Research Protection Programs

Why NCQA Accreditation of HRPP?

- Independence
- Reliance on expert panels for content-and advisory groups for program development
- 11 Years of Accreditation Experience
- HRP Experience with VA
- Strong Endorsement by Institute of Medicine for NCQA standards and approach to HRPP accreditation

NCQA Requirements for Sound Accreditation Program

- Operational accreditation standards, guidelines, scoring:
 - Initially based on existing regulations, etc.
 - Will be periodically updated based on experience, new requirements and to strengthen beyond regulatory requirements

NCQA Requirements for Sound Accreditation

- Certified surveyors to perform site visits
- Separation of site surveys from accreditation decisions
- Appeal mechanism
- Quality improvement systems
- Absence of conflicts of interest

NCQA VA Accreditation Program

- 6 Domains
 - Institutional Responsibilities
 - IRB Structure and Operations
 - Consideration of Risks and Benefits
 - Recruitment and Subject Selection
 - Privacy and Confidentiality
 - Informed Consent
- 130 Standards

NCQA VA Accreditation Program

- 4 Pilot Sites
- 20+ VAMCs reviewed
- Standards Version 1.2 coming

Surveyors are Key

- Authorities in the field
- Represent NCQA
- Serve as jury of peers to VAMC
- Work in a fishbowl



Let me introduce our senior
surveyor. She'll give our
closing remarks

VA-HRPP Outcomes

- Accredited
- Accredited with Conditions
 - Ongoing monitoring
 - Opportunity to upgrade
- Not accredited

Monitoring and Follow Up

- Annual report
- Remedial action plan
- Progress reports

NCQA Common Findings

- Documentation
- Expedited review
- Continuing review
- Continuous quality improvement

Application to Other Settings

- OHRP recent findings
 - Documentation
 - Expedited review
 - Continuing review

NCQA Accreditation

- Now - VAMC Contract
- Future - Nationwide Accreditation of HRPP

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