Accreditation:
Establishing an Infrastructure to Allow for Flexibility and Efficiency

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Association for the Accreditation of Human Research Protection Programs, Inc.®

Accreditation of Human Research Protection Programs- Historical Context

- Government shutdowns of Institutional Review Boards in the late 1990's
- Evidence of compliance lapses and ethical violations
- Huge costs to universities and hospitals while all research was shut down
- Newspaper coverage of research violations damaged the public trust and support of research

The Research Community Responds

- University and other research stakeholders supported voluntary accreditation
- Preferred “self-policing” to increased regulatory burden
- Formed a working group to consider accreditation
  - The process developed at the grass roots level from including researchers, IRB members, research administrators, and importantly unaffiliated (community) members

Founding Members: Association for the Accreditation of Human Research Protection Programs (AAHRPP)

- Association of American Medical Colleges
- Association of American Universities
- Association of Public and Land-grant Universities
- Consortium of Social Science Associations
- Federation of American Societies for Experimental Biology
- National Health Council
- Public Responsibility in Medicine and Research

Driving Philosophy

- Peer Review Process
  - Collegial, conducted by others involved in research administration, as well as IRB members and investigators
- Educational
- Voluntary
- Rigorous standards based on regulations
- Human Research Protection Program (HRPP) concept
  - Institute of Medicine report in 2000: “A Shared Responsibility”

How Does Accreditation Work and How Can it Promote Efficiency?

- Accreditation is a 2-step process
  - Written policies and procedures are peer reviewed
  - Site visit team ensures policies and procedures are followed and understood by the research community
  - Organization indicates the regulations they will follow
    - e.g. ICH-GCP(E6), DoD, FDA, EPA
- AAHRPP advocates flexibility among accredited organizations
  - Promoting equivalent protections (flexibility) after organization demonstrates a robust program
  - Unchecking “the box” allows non-federally funded research to be “flexed”

AAHRPP Standards

- 90% of AAHRPP Standards operationalize regulations
- Other Standards promote quality agreed upon by stakeholders
  - Evaluation of IRB members and chairs
  - Required quality improvement activities and quality assurance activities (compliance)
  - Sponsor's commitment (through clinical trial agreements) to sharing information with IRBs
  - IRB membership
    - Minimum attendance requirement of unaffiliated member
    - One member with the perspective of research participants

Accreditation Bodies Reflect the Research Community and Evolving Standards

- Membership on Council on Accreditation rotates
- Peer Review: current leaders in the human research protection field from accredited organizations
  - The standards (or interpretation of standards) may be revised as needed
  - Share best practices through policy sharing, webinars, conferences and newsletter
  - Collect bench-marking data from annual reports and make available to public (AAHRPP metrics)

How Can an Accrediting Body Promote Quality and Efficiency in Clinical Research?

- More Collaboration in Research and IRB Review
- Single IRB review for multi-site trials
- Encourage education and consensus on topical issues: e.g. patient centered research, informed consent for biospecimen use
- Evidence shows fewer findings on FDA inspections of investigators from AAHRPP accredited organizations
- Maintaining accreditation is a continuous quality improvement process
  - Use data collected by AAHRPP for bench-marking (AAHRPP compiles metrics annually from 225 accredited organizations)

Regulatory Harmonization

- AAHRPP has advocated for harmonization
- President and CEO served on SACHRP sub-committee on harmonization
- 21st Century Cures legislation moves the goal closer
- VA handbook has been revised; effective march 2015 to closely track the Common Rule

In Conclusion . . .

- Accreditation standards can evolve more readily than regulations
- Can become a type of “safe harbor” or bench marking for compliance
- Can promote global standards
- Can encourage flexibility within a robust human protection environment
- Can promote collaboration through mutual trust and therefore less duplication of effort

Thank you for your time!

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