GETTING READY FOR ACCREDITATION:

A Comparison of the NCQA & AAHRPP Standards

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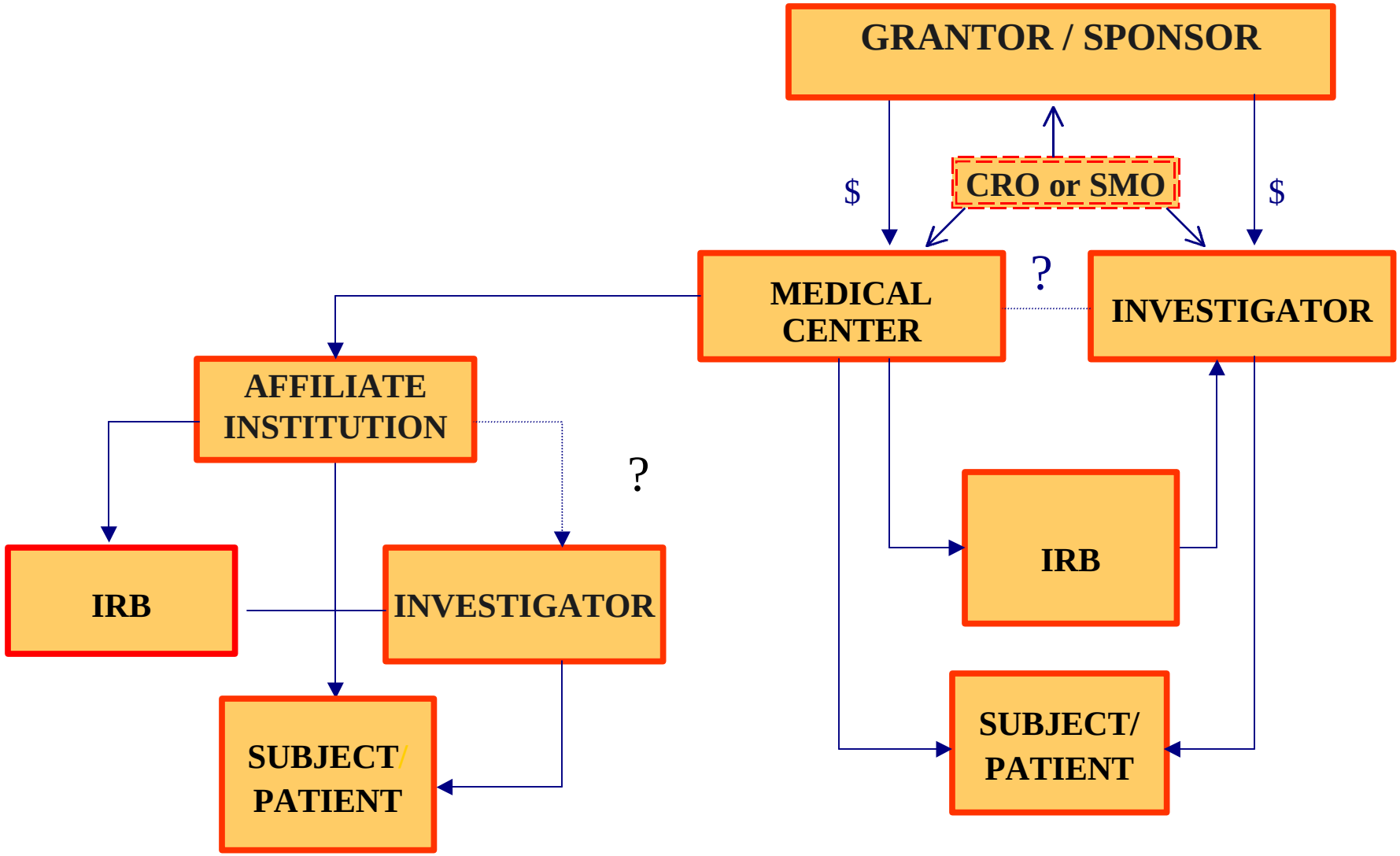
Agenda

- Background
- Backdrop to Accreditation Initiative
- Factors Favoring Accreditation
- Comparing How Standards Are Organized
- A Closer Look at Some Key Differences in the Standards
- Implications of Accreditation
- Questions & Answers

The Research Scheme



Allocation of Compliance Responsibilities

Institutional Conflicts of Interest
Billing & Coding for Services (False Claims)
Financial Reporting (False Claims)
Grant Management
Patient Safety
Insurance
Unspent Funds
Relationship with Investigators
— Stark
— Fraud and Abuse
— Private Inurement
Scientific Misconduct
—As a medical staff issue
—As an employment issue

Composition and Deliberation
Conflicts of Interest
- **IRB Members**
- **Investigator**

Review of Protocol
Informed Consent and Other Protections
Ongoing Monitoring
Scientific Misconduct
Financial Incentives for Recruitment
Pre-Recruitment Activity Content
Confidentiality & Privacy
HIPAA and State Laws

Informed Consent
Patient Safety
Adverse Events
Clinical and Scientific Reporting

Backdrop to the Accreditation initiative

- Several highly publicized patient deaths have occurred since 1999
- Federal authorities were reshuffled in response
  - OHRP created, moved from NIH to DHHS Secretary
- Increased federal enforcement beginning in 2000
- Increase in law suits, including suits naming IRB members

Backdrop to the Accreditation initiative

- Use of contract research organizations (CROs) and site management organizations (SMOs) adds more actors to research scheme
- Increased use of non-academic medical center trial sites
- Globalization of clinical trials
- Contraction of health care reimbursement leads providers to look for other revenue sources

Factors Favoring Accreditation

- Overlapping laws increase the difficulty of compliance
- Enforcement resources at the state and federal level are limited and uncoordinated
- Poster child approach to enforcement (e.g., Johns Hopkins) has begun
- Qui Tam (Whistleblower) Statute applies to federally funded grants

Factors Favoring Accreditation

- Government has experience combining the "poster child" and qui tam enforcement in health care as an efficient use of enforcement resources
- Government has experience in using accreditation in managed care and health care facility certification
- Accreditation, like OIG's "compliance guidance," will set a voluntary standard that eventually becomes industry norm
- Shifts costs to research institutions

Institute of Medicine Report

- Following patient death, DHHS commissioned IOM to conduct a 2-phase study in 1999
- 1st phase report: "*Preserving the Public Trust; Accreditation and Human Research" (August 2001)*
- IOM advocates a move from reliance on IRBs to broader Human Research Protection Programs (HRPP)

Institute of Medicine Report

- IOM identifies principal functions of HRPPs as:
  - Ensure research design is sound and that a study's promise for augmenting knowledge justifies the involvement of human subjects
  - Assess risk and benefits of a study independently of the investigators who carry out the research
  - Ensure that participation in research in voluntary and informed
  - Ensure that participants are recruited equitably and that risks and benefits are fairly distributed

Institute of Medicine Report

- IOM advocates accreditation of HRPPs
  - by a national independent organization
  - using standards flexible enough to apply to a variety of settings
  - rigorous enough to ensure protection
  - clearly written
  - straightforward to execute

Institute of Medicine Report

- Accreditation standards must also be:
  - consistently applicable and measurable
  - address organization's level of functional performance in specific areas
  - reflect widely accepted ethical principles that form the norms for research behavior
- IOM endorses NCQA over AAHRPP standards

National Bioethics Advisory Commission

- Recommends legislation to:
  - Create a single federal office to coordinate oversight of human research
  - Develop a unified comprehensive federal policy in a single set of regulations
  - Require certification of investigators, IRB members, IRB staff
  - Require accreditation of sponsors, institutions and independent IRBs

Accreditation Bodies

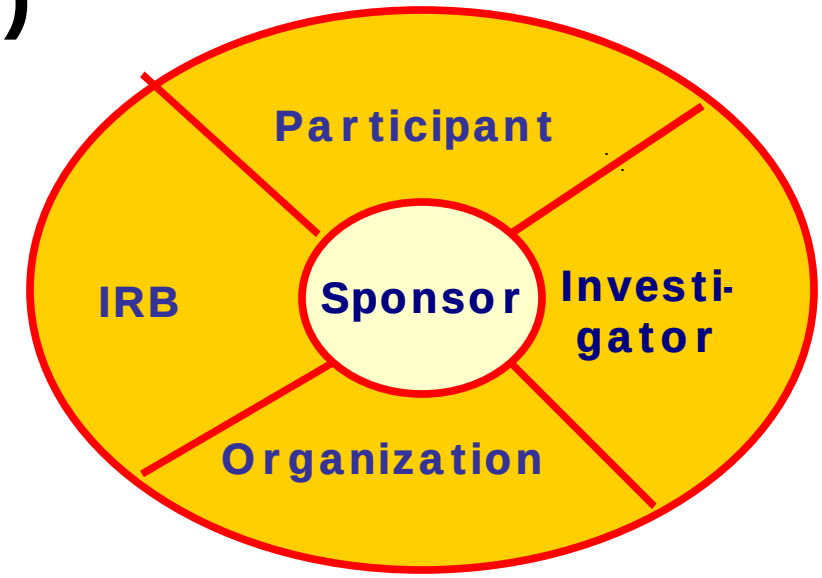
- National Committee for Quality Assurance
  - non-profit organization
  - experienced in accreditation (HMOs, managed care organizations)
  - www.ncqa.org
- Association for the Accreditation of Human Research Protection Programs
  - founding members are associations of academic institutions
  - www.aahrpp.org

Organization of The Standards

- NCQA standards are organized as follows:
  - Institutional Responsibilities
  - IRB Structure and Operations
  - Consideration of Risks and Benefits
  - Recruitment and Subject Selection
  - Privacy and Confidentiality
  - Informed Consent
- Generally follows the organization of applicable regulations

Organization of The Standards

- AAHRPP standards are organized by "domains," which reflect the major actors involved in research (see slide 3)



NCQA v. AAHRPP

- NCQA incorporates methods similar to health care compliance
- Both emphasize written policies, but
- NCQA includes specific standards for education, training, and documentation
- Specificity of NCQA standards more likely to change behavior than AAHRPP's general statements
- Major failing of NCQA is that it does not address key roles of sponsors

Closer Look: Resources

AAHRP I-2: ***The Organization assures the availability of resources sufficient to ensure the rights and welfare of human research participants taking into consideration the research activities in which they are asked to participate.***

- **I.2.B:** ***The Organization assures that resources available to the HRPP are sufficient for conducting the activities that are under its jurisdiction***

Closer Look: Resources

- **NCQA INR2:** ***The institution provides sufficient resources for the HRPP, R&D Committee and its IRB(s).***
  - **INR2A:** ***The institution engages in systematic budgeting for the HRPP including the R&D Committee and the IRB at least annually.***
- **At this level, the two standards are comparable.**

Closer Look: Resources

- **However, NCQA provides more detail.**
- **INR2A [continued]*:***
  - ***Budgeting includes consideration of (1) the analysis of the volume of research to be reviewed and (2) feedback from IRB members and staff.***
    - ***100% score - review of 2 factors***
    - ***50% score - review of 1 factors***
    - ***0% score - less than 1 factor***
  - ***Budget records, institutional budget policy, IRB forms.***

Closer Look: Resources

- **INR2B:** ***During the budgeting process, resources reviewed include but are not limited to:***
  - ***(1) Personnel, (2) materials and supplies, (3) space,***
    (4) capital equipment, (5) training and education
  - **100% score- review of all 5 factors**
  - **75% score- review of 3 factors**
  - **50% score- review of 2 factors**
  - **0% score- less than 2 factors**
  - **Budget records, institutional budget policy, budget analysis forms, reports**

Closer Look: Conflicts of Interest

AAHRPP addresses conflicts of interest in each domain.

- **AAHRPP I.3.B [Organization Domain]**

  The Organization has policies and procedures to identify and manage conflicts of interest of investigators and IRB members

Closer Look: Conflicts of Interest

AAHRPP addresses conflicts of interest in each domain.

- **AAHRPP 1.3.C [Organization Domain]**

  The Organization has policies and procedures to identify, manage and minimize institutional conflicts of interest that may affect its relationships with the IRBs that review research, with investigators and sponsors

Closer Look: Conflicts of Interest

- **AAHRPP II.1.D [IRB Domain]**

  The IRB has a system for assuring that protocols are reviewed by individuals with appropriate expertise and that reviewers' potential conflicts of interest are identified and managed.

- **AAHRPPIII.1.A [Investigator Domain]**

  The Organization has a mechanism for identifying, managing and minimizing Investigator conflicts of interest that may affect the Investigator's relationship with the participant and/or the outcome of the research, and is able to demonstrate the effectiveness of Investigator compliance.

Closer Look: Conflicts of Interest

- **AAHRP IV.4.A [Sponsor Domain]**

  The Organization has an agreement with the Sponsor that the Sponsor will require investigators to disclose to the Organization and the Sponsor, all compensation, consulting agreements and financial interests that may be affected by the outcome of the sponsored research protocol.

- **AAHRPP IV.4.B [Sponsor Domain]**

  The Organization has an agreement with the Sponsor that the Sponsor makes available information regarding its relationships with and/or support of any research component of the Organization separate from its support of a sponsored research protocol.

Closer Look: Conflicts of Interest

- **NCQA INR4** ***The institution has policies and procedures to identify and manage institutional, IRB member and investigator conflicts of interest with research conducted at the institution*****.**

- **Note, NCQA addresses only 3 of AAHRPP's domains**

Closer Look: Conflicts of Interest

- **INR4A:** ***The institution has policies and procedures for the identification and management of conflict of interests for IRB members***
  - **Applies to each IRB used**
  - **100% or no compliance**
- **Appears to cover outside IRBs**

Closer Look: Conflicts of Interest

- **INR4B:** ***The institution has policies and procedures for the identification and management of conflict of interests for the (1) institution, including the R&D Committee, and (2) investigators.***
  - **Evaluates element <u>once</u> for the institution.**
  - **100% score - P&P addresses both**
  - **50% score - P&P addresses one**
- **This standard appears somewhat lax, but may be a result of VA specific factors**

Closer Look: Conflicts of Interest

- AAHRPP standards address all players
- NCQA does not address role of sponsor
- NCQA does not specifically require disclosure of investigator financial interests; AAHRPP accomplishes this by making the Sponsor agree to require investigators to disclose
- Neither gives much guidance as to how to resolve or manage conflicts of interest, leaving it to the institution

Closer Look: Role of Sponsors

- NCQA does not address role of sponsors.
- AAHRPP standards require written agreements with sponsors that address specific issues.
- This would create contractual obligations with sponsors to be involved in compliance and give the organization an opportunity to sue for breach.
- Consider using AAHRPP standards for sponsors when reviewing contracts and grants and negotiating responsibilities of sponsors up front.

Closer Look: Role of Sponsors

- **AAHRPP IV.1 [General policy statement]**

  The Organization demonstrates its ability to involve external sponsors in its program to protect the rights and welfare of research participants.

- **AAHRPP IV.2 [General policy statement]**

  The Organization has a mechanism for ensuring that Sponsors assume responsibility for ensuring that studies are organized, managed and documented in compliance with the protocol and applicable regulatory requirements and, where applicable, implement and maintain quality assurance and control systems.

Closer Look: Role of Sponsors

- **IV.2.A. [Requires written agreements between sponsors and investigators]**

  Agreements between the Sponsor and the investigator/institution or any other parties involved in implementing the research protocol are in writing.

- **IV.2.B. [Requires sponsors to assure qualifications of research team]**

  The Organization and Sponsor have an agreement that in selecting investigators affiliated with the Organization, the Sponsor will assure that the research team is appropriately trained and qualified to conduct the research

Closer Look: Role of Sponsors

- **IV.2.C. [Requires the Sponsor to be responsible for informed consent forms.]**

  The Organization has an agreement with the Sponsor that informed consent and individual authorization forms meet the Organization's requirements and comply with state and local, as well as applicable federal laws.

- **IV.2.D. [Requires the Sponsor to be responsible for case report forms.]**

  The Organization has an agreement with the Sponsor that case report forms meet organizational standards for maintaining confidentiality of participants as well as accuracy and integrity of data.

Closer Look: Role of Sponsors

- **IV.3 [Requires Sponsors to provide relevant information]:**

  The Organization has procedures for assuring that Sponsors cooperate in a timely fashion in communicating information that may affect the on-going oversight of a protocol by the HRPP.

Closer Look: Role of Sponsors

- **IV.3.A. [Requires the Sponsor report adverse events to all investigators and institutions]**

  The Organization has an agreement with the Sponsor that the Sponsor promptly reports any serious or unexpected adverse events to all investigators, institutions and regulatory authorities that are involved with a protocol and provides regular reports of adverse reactions in accordance with FDA regulations.

Closer Look: Role of Sponsors

- **IV.3. B. [Requires the Sponsor to report any events affecting an approved protocol]**

  The Organization has an agreement with the Sponsor that the Sponsor reports to investigators, IRBs and institutions involved with a protocol any developments that may affect the HRPP and its responsibility for ongoing monitoring of an approved research project, any proposed changes to the protocol, including participant recruitment methods, and any information needed for the IRB's continuing review.

Closer Look: Role of Sponsors

- **IV.3.C. [Requires the Sponsor to provide all other information needed for Organization to comply with law]**

  The Organization has an agreement with the Sponsor that the Sponsor provides information needed to document the Organization's compliance with applicable law, regulations, and federal agreements.

Closer Look: Role of Sponsors

- **IV.5 [Academic freedom and Scientific Integrity]**

  The Organization has procedures for ensuring that Sponsors respect the integrity of research and the academic freedom of investigators.

  - **IV.5.A.** ***Where a research grant has been awarded to an affiliated investigator, the Organization has a mechanism to avoid undue influence by the Sponsor on the design, conduct or reporting of the research, or selection of research participants.***
  - **IV.5.B.** ***Sponsored research agreements preserve the investigators' and the Organization's authority to conduct human research ethically and to protect participants.***

Closer Look: Role of Sponsors

- **IV.5.C.** ***Sponsored research agreements respect and adhere to the Organization's policies concerning investigators' rights and accountability for independent inquiry and publication.***
- **IV.5.D.** ***The Organization has procedures for dealing fairly with the rights of investigators, sponsors, participants, and research institutions in matters relating to discoveries with potential commercial value.***

Closer Look: Outside IRBs and CROs

- **AAHRPP I.2.A**

  The Organization provides for the number of IRBs appropriate to the volume and types of human research to be reviewed. An Organization may use the IRB(s) of another Organization to meet the needs of its research program.

- **This standard for use of other IRBs does not address proprietary IRBs and reflects current regulations**

Closer Look: Outside IRBs and CROs

- **NCQA INR3.A [Requires written agreements with outside IRBs]**

  If the institution uses the IRB(s) of a VA regional system, affiliated university or another VA facility, there is a legal document, e.g. Memorandum of Understanding (MOU), contract or letter of agreement (Formal IRB Agreement). This document includes, at a minimum:

  - **Specific requirements for the membership and operation of the IRB to review VA research in compliance with VA regulations.**

Closer Look: Outside IRBs and CROs

- The respective responsibilities of the institution and the designated IRB for human subject protection.
- The scope of activities delegated to the IRB.
- The method, frequency and nature of reporting to the R&D Committee.
- The process by which the institution evaluates the IRB's performance.
- The remedies, including revocation of the Formal IRB Agreement, available to the institution if the designated IRB does not fulfill its obligations.

Closer Look: Outside IRBs and CROs

- This standard does not address proprietary IRBs and restates current regulations; but it provides for contract remedies and should facilitate compliance.
- Scoring
  - 100% – Formal IRB Agreement includes 6 factors
  - 75% – Formal IRB Agreement includes 5 factors
  - 50% - Formal IRB Agreement includes 4 factors
  - 0% Score - No Formal IRB Agreement or it includes less than 4 factors
  - N/A – The institution has its own IRB

Benefits of Accreditation

- Uniformity of standards across institutions
- External independent validation of an institution's performance in protecting human research subjects
- Eventually a "seal of approval" or "standard of excellence"

Challenges of Accreditation

- Expensive
- Favors large institutions
- Community hospitals may have to rely on outside IRBs
- Requires changes in behavior and practices of investigators as well as institutional staff
- Administrative burden

Limitations to HRPP Accreditation

- Does not address other research compliance issues, such as:
  - Financial accounting
  - Billing and coding
  - Use of unspent funds as a tax issue
  - Financial relationships with investigators that implicate Stark or Anti-Kickback
- Overlap with health care compliance

OPEN QUESTIONS

- **Will proprietary IRBs, CROs, SMOs or non-biomedical research institutions be required to be accredited?**
- **How will investigators be reviewed beyond the review of protocols by the IRB?**

OPEN QUESTIONS

- **Are there sufficient mechanisms to hold institutions and sponsors accountable for funding, supporting and rewarding HRPP?**
- **Can quality improvement and self-assessment mechanisms of accreditation ensure subject safety?**

IMPLEMENTATION

- Government has not decided whether accreditation should be mandated
- Might be effective way for government to shift costs of in the name of self-regulation to institutions and make effective use of its enforcement resources – the health care model
- Like fighting fraud, it's good PR
- Implementation is not likely to occur before NCQA and AAHRPP test programs wrap up
- Rulemaking process

What To Do Now

- Providers/Institutions with significant research $$ should:
  - Use proposed guidelines for baseline assessment of research compliance risks
- Providers/Institutions with limited research $$ should
  - Strengthen IRB compliance within budgetary constraints, pay attention to related issues

Observations

- Public demands accountability
- Public now more informed - internet, etc.
- Bad apples create significant media attention
- Conflict between expectations of the public and those of pharma
  - R&D to market
  - New drugs without risk; research without risk

Questions and Answers

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