

The Experience of Receiving IRB Accreditation

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Learning Objectives

- Why accreditation?
- Process of planning and preparation
- Benefits of accreditation

Recent US History and Events Leading to Interest in Accreditation of Human Research Protection Programs

- October 1996 - President Clinton established National Bioethics Advisory Commission
- June 1998 – Office of the Inspector General (OIG) reports the IRB system is in jeopardy
- March 1999 - The headlines reflect the story- Suspensions
- April 2000 - OIG strikes again, concerned no action taken

June 2000 - New Initiatives from the Office of the Secretary, US Department of Health and Human Services

- Proposed sanctions for research violations (requires congressional approval)
- Education/training in human subject protections required for key personnel receiving federal grants
- Informed Consent Audits/Third party monitoring by IRB
- Improved Trial Monitoring - Phase I, II and III (DSMB) and management of Adverse Events
- Conflict of interest policies/procedures

Examples of Proactive Compliance Approaches Initiated in US Since 2000

- Training Opportunities for Investigators, Ethics Committees and Staff
- Accreditation of Human Research Protection Programs
- Federal Grants Awarded for Enhancing Human Subject Protections to top NIH funded organizations in US

Why accreditation?

- External review with verification by an independent body of experts
- Improves protection programs
- Assists in achieving compliance
- Builds public trust

Accreditation Model in US

- *Association for the Accreditation of Human Research Protection Programs*
- Based in Washington, DC
- Developed with support of several national organizations such as AAMC, AAU, FASEB, PRIM&R
- Modeled after AAALAC, the US animal care accreditation program

Domains for Accreditation Standards

- Organization
- Research Review Unit, Including IRBs
- Investigators
- Sponsored Research
- Participants

Process

- Self assessment/generate program description
- On-site evaluation
- AAHRPPs Council on Accreditation makes determination for accreditation status based on review presented by expert site visitors

Issues to Consider During the Self-Assessment

- Institution-wide perspective
- Focus on systems (policies and procedures, not individual protocols or investigators)
- Internal tracking or auditing procedures used for continuous quality improvement
- Strengths, weaknesses, improvements, streamlines
- Ask for assistance

Process of Planning and Preparation of IRB/Ethics Committee Accreditation

- Requires institutional support/resources for applying for accreditation
- Orchestrate planning meetings and timelines
- Include the organizational stakeholders

How long does it take to prepare for accreditation?

- It depends..... on size and volume of research activity, novelty and complexity of research activity (e.g., gene therapy, Phase I trials, Multi-site activity)
- Audits by other regulatory or independent groups may help you prepare for accreditation (e.g., FDA, OHRP, external consultants)

Preparing your SOPs and Policies

- Use consistent methods in drafting SOPs
- Be sure the policy statement is carried out in the SOP method – continuity is critical
- All relevant regulations (local, national and international) need to be considered when preparing SOPs

Importance of Sound Organizational Infrastructure

- Its easy to modify well organized SOPs and policies, based on auditors recommendations
- Updating essential – there is always room for improvement
- Your staff and the research team benefit from common understanding of the organizational/institutional policy, ethical principles and relevant regulations

Benefits of Accreditation - Insights from organizations who have received AAHRPP accreditation

- *Self assessment helps an organization understand areas for improvement and recognize existing strengths.*
- *It was a huge undertaking – well worth it.*

Insights (continued)

- *It forced us to document and update all procedures.*
- *It proved to us (the IRB and those who needed to see it) that we know what we are doing and we do it pretty well.*

