**AAHRPP and
the Flexibility Coalition:
Working Together for a Common Cause**

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What is the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)?

Global non-profit organization founded in 2001

- **Offers accreditation to organizations that conduct, review, or manage research involving human participants**

- **Seeks to identify quality programs; promote innovative practices; and, ensure regulatory compliance**

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 Supports the Flexibility Coalition!

What's Going On & Emerging Issues…

- AAHRPP Standards and the Regulations
- NPRM/Final Rule
- Encouraging Innovations
- Reaccreditation Tips
- Key Factors in a Successful Program

AAHRPP and the Regs: Filling the Void

- Where the regulations and federal guidance exists, AAHRPP will NOT expect you to go beyond the regulations

- AAHRPP fills the void when:
  - The regulations are silent
  - the regulations are "skeletal" and no Federal guidance

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

Getting into Shipshape: AAHRPP Accreditation Standards

AAHRPP process is outcomes-based → many possible avenues to achieve shared goal:

Protection of the health and welfare of research volunteers, whose participation makes the whole enterprise possible

AAHRPP and the NPRM

- We are working on our comments, like the rest of you!

- We will support changes that address issues of importance to the Flex Coalition

Final Rule?

- If and when a Final Rule comes out, AAHRPP will seek input from the Flexibility Coalition, our AAHRPP Council, and accredited organizations on creative ways to update our standards to reflect the Final Rule.

Final Rule: AAHRPP Implementation and Compliance

- **We will give ample time for revisions and updates**

- **We will continue to develop mechanisms for you to keep AAHRPP appraised of your changes**

- **Send us your ideas on how to ensure timeline compliance with the new regs and developing your SOPs**

- **Compliance Enforcement: Generous leeway from AAHRPP in using "enforcement discretion"**

AAHRPP: Encouraging Innovation and Creativity

- Tell us about your innovations: creative ways to meet AAHRPP standards (plan for website postings with permission)

- Don't reinvent the wheel: SHARE!

Reaccreditation: Tips and Tricks

Be careful about what you check on the Step 1 application.
If you don't do it, don't check it!

Tips on Preparing for Reaccreditation

- **Keep your application current**
- **Have a backup**
- **Start your reassessment in plenty of time to meet the deadline for renewal**
- **Communicate constantly and effectively**
- **Save time for formatting**

More Tips…

- **Focus on SOPs that have changed since your last cycle**
  - **In general: rebuttable presumption that already approved SOPs are OK**

- **Look at the feedback you received**
  - **Status Reports**
  - **DSVR**
  - **Close-out Visit**

More tips…

- **Site Visit**
  - **Ensure all staff are trained (especially new staff); focus on new/updated/changed SOPs or SOPs based on regulatory changes**

Remember:

Create/Fix/Change
Educate
Monitor/Measure/Evaluate

Key Factors in Having a Successful HRPP

IRB Performance:
- **Following the Regulations/Laws/Standards**
- **Communication**
- **Collaboration**
- **Continuous Quality Improvement**

AAHRPP 2.0:
A Commitment to Improvement

What's ahead:

- **Feedback/Satisfaction Survey**
- **Form Update**
- **Continued Training of our Site Visitors**
- **"Reaccreditation with Distinction" (not just for initial accreditation)**
- **Overhaul of Reaccreditation Process for "Legacy" Organizations**

What AAHRPP Accreditation
Can Do for Your Organization. . .

- **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**

Stay Flexible!

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