AAHRPP

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

Ask... AAHRPP®

January 14, 2025

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Conducting the Self-Assessment

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  - AAHRPP
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  - Director of Accreditation and Global Outreach
  - AAHRPP

Suzanne Bushfield, PhD, MSW

Suzanne Young Bushfield, PhD, MSW has been an Accreditation Consultant for AAHRPP since 2017. She had retired from AAHRPP after serving as AAHRPP's Chief Operations Officer and Accreditation Director from 2010-2013 but returned to continue her work in support of human research protections.

Suzanne began her 40-year career as a social worker in health care, working in oncology, hospice, and behavioral health; after completing her Ph.D. she served as a social work faculty member and researcher in the fields of clinical practice and ethics at Arizona State University, New Mexico State University, Lewis Clark State College, where she chaired the IRB, and the University of North Dakota.

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What is “Ask AAHRPP”?

- Bimonthly (six times per year) forum with:
  - Practical approach to achieving and maintaining accreditation
  - Brief presentations on topics relevant to organizations applying for initial accreditation or reaccreditation
  - An emphasis on Q&A on topics presented as well as questions submitted when participants register
  - Organized around the steps in the accreditation process
- Open and free to everyone
- Recordings available

“Ask AAHRPP” Webinar Series (six times per year)

- Tuesday, January 14, 2025, 3:00 pm ET: **Conducting the Self-Assessment**
- Tuesday, April 8, 2025, 3:00 pm ET: **Evaluation of Written Materials**
- Tuesday, June 10, 2025, 3:00 pm ET: **Evaluation of Practice - What to Expect During the Site Visit**
- Tuesday, August 12, 2025, 3:00 pm ET: **Responding to the Draft Site Visit Report**
- Tuesday, October 14, 2025, 3:00 pm ET: **Council on Accreditation Review**
- Tuesday, December 19, 2025, 3:00pm ET: **Responding to Council Review and Maintaining Accreditation**

Learning Objectives

- After this session, you will be able to:
  - Describe the AAHRPP accreditation process
  - Formulate an approach to the self-assessment step
  - Understand the format and content of the Evaluation Instrument
  - Identify materials that will become part of the initial application for AAHRPP accreditation
  - Know who to contact at AAHRPP with questions

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What is AAHRPP?

- Global Nonprofit NGO – 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
- AAHRPP accredited organizations on five continents and across every human research sector

AAHRPP-Accredited Organizations

As of December 2024, over 600 entities

Truly global – AAHRPP-accredited organizations in: Australia, Belgium, Brazil, Canada, China, India, Japan, Jordan, Korea, Mexico, Saudi Arabia, Singapore, Taiwan, Thailand, United States

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Accreditation Standards

Based on U.S. and International Frameworks for Conducting Human Research

- ICH-GCP (E6) and other country-specific GCP
- US FDA or other country drug agencies
- Department of Health and Human Services
  - For research funded by US DHHS agencies (NIH)
- Laws of other countries

HRPPs

- Go beyond the ethical review of human participants research
- Include all of the activities that contribute to research participant safety and research integrity
- Are a communication system that works together to protect research participants

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HRPP Components Mapped to AAHRPP Standards and Elements

Conflict of interest: Standard I-6, Element III.1.B
Community engagement: Standard I.4
FDA regulations program: Standard I-7
Grants, contracts, billing, budgets: Standard I-8, Element III.1.D
Institutional safety committees: Standard I-2
IRB: Standard I-3, Standard I-9, Domain II
IT/data security reviews: Elements I.1.D, I.1.H, II.3.D, II.3.E
Legal Counsel: Element I.1.G, Standard I-3, Standard II-3,
Research quality and compliance programs: Standard I-5
Research pharmacy: Standard I-7
Research privacy: Elements II.3.D, II.3.E
Scientific review: Elements I.1.F, III.1.C
Study teams: Standard I-3, Domain III
Training and education: Elements I.1.E, III.2.A

What is accreditation of an HRPP?

- Accreditation of an Organization:
  - is voluntary
  - is flexible
  - is based on outcome-based standards
  - evaluates structures, processes, and outcomes
  - is not an audit of ethics decisions
  - is not an audit of individual studies
  - focuses on quality

AAHRPP Standards and Philosophy

- An educational, collegial, and transparent process
- Peer Review (not an audit)
- Goal to assist organizations in accreditation
  - Agreed upon standards
  - Fill in gaps
  - Collaborate
  - Be efficient and effective
- Share responsibility throughout the organization

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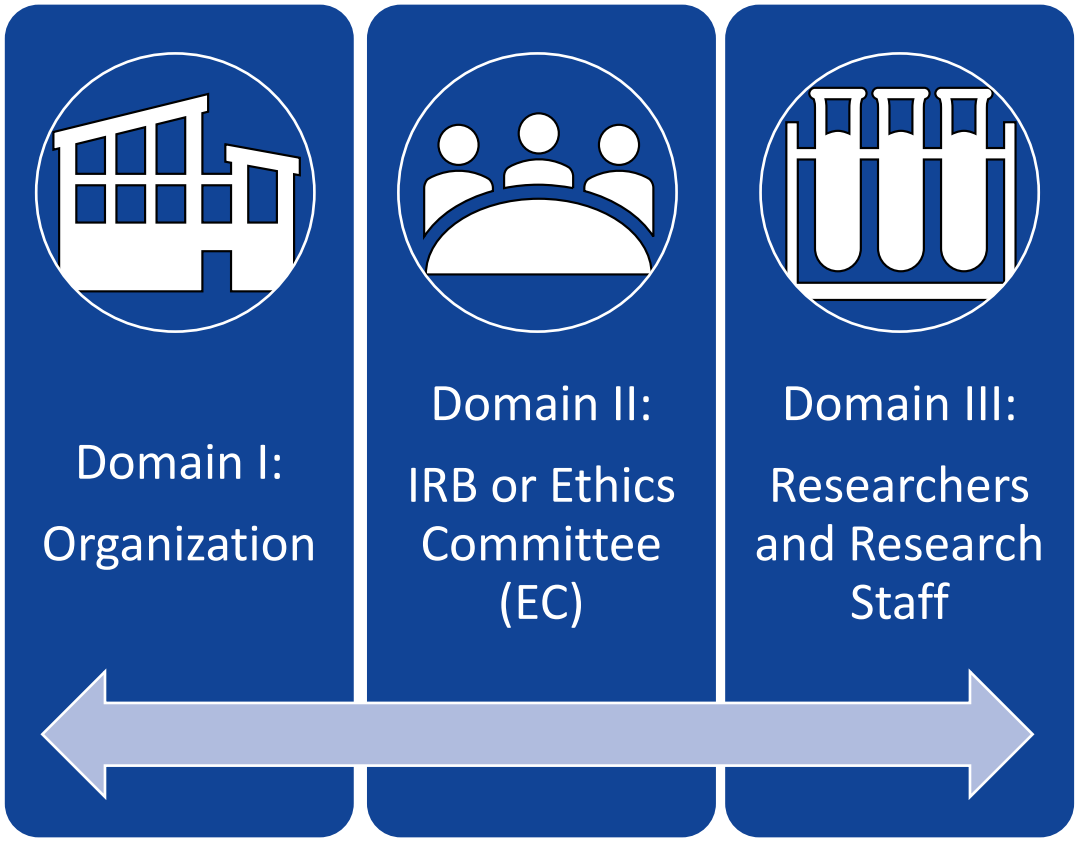
What Does Accreditation Cover?

Accreditation of the entire Human Research Protection Program (HRPP) – not just IRBs or ECs



Protecting research participants is a shared responsibility

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Brief Overview of What AAHRPP Focuses on for Each Domain

Domain I – Organization

- Structure and purview of the HRPP
- Role of organizational official
- Ethical standards and practices applied
- Research ethics education and training
- Applicable laws the organization follows
- Scientific Review
- Emergency preparedness
- Resources available to support the HRPP
- Transnational research
- Responding to research participant concerns
- Community Engagement
- How compliance with policies and procedures and applicable laws, regulations, codes, and guidance is measured and improved
- How the organization measures and improves, when necessary, the quality, effectiveness, and efficiency of its HRPP
- Disclosure and management of institutional and researcher conflicts of interest
- Oversight of the use of investigational or unlicensed test articles
- Human participant protections in sponsor agreements
- Use of external IRBs/ECs

Domain II – IRB or Ethics Committee

- Covers the review function
- Composition of the IRB
- Policies consistent with regulatory review criteria
- Additional protections for vulnerable participants
- Handling unanticipated problems
- Appropriate documentation

Domain III – Researcher and Research Staff

- Expectations for researchers and research staff
  - Know the ethical standards relevant to their discipline and to the protection of the rights and welfare of research participants
  - Know reporting requirements
  - Responsive to questions or concerns of participants
  - Appropriately oversee the research
  - Adherence to the protocol and organizational policies

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The Accreditation Process

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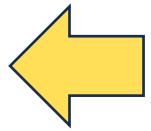
The Accreditation Process

PART 1: CONDUCT A SELF-ASSESSMENT



PART 2: BUILD AND DEVELOP AN APPLICATION

PART 3: EVALUATION OF WRITTEN MATERIALS

PART 4: EVALUATION OF PRACTICE

PART 5: COUNCIL ON ACCREDITATION REVIEW

PART 6: RESPONSE TO COUNCIL REVIEW

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Self-Assessment

PART 1: CONDUCT A SELF-ASSESSMENT

- The self-assessment is a critical, introspective examination of a Human Research Protection Program (HRPP) in which the program is evaluated according to each element of the AAHRPP Accreditation Standards.
- The organization reviews its HRPP and evaluates its compliance with the AAHRPP Accreditation Standards and Elements.

Components of the Self-Assessment

- Convene a task force or working group
- Understand the Evaluation Instrument
- Evaluate and revise written materials

Convene a Task Force or Working Group

- Assemble the core team
- Delegate responsibilities and tasks
- Meet regularly

Advantages of a task force or working group

- Facilitates discussion across different organizational units
- Helps develop a systematic, integrated HRPP
- Raises awareness of the HRPP throughout the organization and highlights efforts to improve through accreditation
- Will be able to continue to make progress even if there are staff changes

How to identify team members?

- Download AAHRPP's Template for Key Personnel
- https://www.aahrpp.org/resources/for-accreditation/additional-resource/application-for-accreditation-or-reaccreditation-section-h-template-for-key-personnel

Tips

- Download and review the *Evaluation Instrument for Accreditation*
- Gather all written policies and procedures and organize them by topic
- Tackle the Evaluation Instrument Element by Element
  - Some Elements do not require documentation and will be assessed during the site visit
- Identify and fill in any gaps
- Construct an Element-by-Element index of your supporting documents
  - Start building a repository of relevant documents associated with each Element
- Reach out to AAHRPP with questions

Evaluation Instrument for Accreditation

To achieve accreditation, an organization must meet all relevant accreditation Standards and Elements

https://www.aahrpp.org/resources/for-accreditation/instruments/evaluation-instrument-for-accreditation/introduction

ELEMENT I.4.A.

Each Standard or Element includes:

ELEMENT I.4.A.: The organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Organizations should provide information to current, former, and prospective research participants about whom to contact for concerns, questions, or complaints about the research; obtain information; or offer input. Organizations should also have a mechanism to solicit concerns, questions, or input from prospective participants. The organization should have policies and procedures that describe the steps followed by the organization to respond to contacts from participants or others.

Regulatory and guidance references

- **DHHS**: 45 CFR 46.116(a)(6)-(7)
- **FDA**: 21 CFR 50.25(a)(6)-(7), FDA Information Sheets: A Guide to Informed Consent
- **VA**: VHA Directive 1200.05(3) section 17

Commentary: Provides an explanation of how to interpret the Element or Standard

Required written materials

(1) Essential requirements:

(a) Contact information for an individual or office that is unaffiliated with a specific research study is available to current, former, and prospective research participants to:

(i) Discuss problems, concerns, and questions.

(ii) Obtain information.

(iii) Offer input.

(b) Policies and procedures describe the steps followed when the organization responds contacts from participants or others.

Common types of materials that may be used to meet the element

- Web site
- Pamphlet or brochure
- Consent template

Outcomes

- The organization provides information to current, former, and prospective participants or others about whom to contact in the organization to discuss problems, concerns, and questions; obtain information; and offer input.
- The organization responds to contacts from participants or others.

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Regulatory and guidance references:

Lists regulatory and guidance citations from US federal agencies that oversee research with human participants
Lists requirements under the International Council on Harmonisation – Good Clinical Practice (E6) Guideline

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Required written materials:

Define essential requirements that must be included in written materials
Meet many requirements under the laws of the US and other countries
For some Elements, additional requirements are listed for specific US federal government agencies
AAHRPP Addenda describe additional requirements for organizations outside the US

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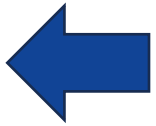

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(ii) Obtain information.

(iii) Offer input.

(b) Policies and procedures describe the steps followed when the organization responds contacts from participants or others.

Outcomes: The practices an organization should have in place

Common types of materials that may be used to meet the element

- Web site
- Pamphlet or brochure
- Consent template

Outcomes

- The organization provides information to current, former, and prospective participants or others about whom to contact in the organization to discuss problems, concerns, and questions; obtain information; and offer input.
- The organization responds to contacts from participants or others.

Evaluation Instrument for Accreditation

- Some Elements also include a list of common types of materials that may be used to meet an Element
  - This items on this optional list are provided only as examples and guidelines
  - Organizations that do not have these materials should not create them just to meet an Element
- Organizations may use many different types of written materials to meet AAHRPP requirements, such as:
  - Policies
  - Standard Operating Procedures
  - Websites
  - Manuals

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Example of How to Get Started

Step 1

Create a list all written materials (policies, manuals, worksheets, webpages)

- This will become Section D of your application

Create a separate “working” folder for AAHRPP

- Consider grouping related materials and adding numbers to the beginning of the document titles – this will make it easy to assemble your application later

Step 2

- After you complete the list of all written materials, start to group them by subject areas defined in AAHRPP Standards and Elements
- Example materials for ELEMENT I.1.E.: *The organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.*
  - Relevant policies and procedures
  - Education plans
  - Lists of types of educational programs supported or conducted
  - Examples of educational materials (e.g., researcher manual)

Step 3: **Assign responsibilities for reviews**

- Coordinate with your working group to assign responsibilities and assign due dates
  - Often this is done by subject area, such as those involved with:
    - Scientific review process (Element I.1.F)
    - Research participant education and outreach (Element I.4.B)
    - Compliance activities (Standard I-5)

Step 4: Analyze your written materials and practices

- Key questions to ask to identify potential gaps or changes:
  - Are they current?
  - Are they internally consistent?
  - Do they address the Standard or specific Element?
- If updates or new documents and/or processes are deemed to be necessary:
  - What would fill this gap?
  - Who should take the lead in updating or creating the new material(s) and/or process(es)?
  - What reviews or approvals might be necessary for any new or updated processes or documents?

Step 5 Organize the Work

- Have a project manager or document specialist keep a list of required revisions and maintain version control of documents
- Example tracking approach:

Element	REGS	SOP(s)	GAPS	RESPONSIBLE PARTIES	SOP Due Date	Forms to create	Other Resources	Completed
Element I.1.A.								
Element I.1.B.								

Self-Assessment Suggestions

- Complete the review of materials before making changes
  - Organize materials by Element
  - Make notes of gaps where materials do not address all essential requirements for an Element
  - Avoid making changes until you have completed your entire review – you might find that another document already addresses an AAHRPP requirement

AAHRPP Educational Activities

Webinars:

Ask AAHRPP

Ask AAHRPP International

HRPP Innovations

Conferences:

2025 AAHRPP Around the World – Abu Dhabi UAE

2025 Annual Conference - Denver

News:

Advance Newsletter

AAHRPP Website

“Ask AAHRPP” Webinar Series (six times per year)

- Tuesday, January 14, 2025, 3:00 pm ET: **Conducting the Self-Assessment**
- Tuesday, April 8, 2025, 3:00 pm ET: **Evaluation of Written Materials**
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“Ask AAHRPP” International (two times per year)

LIVE webinar during your workday!

Middle East:

June 24, 2025: 3:00 pm AST/4:00 pm GST (8am ET)

December 17, 2025: 3:00 pm AST/4:00 pm GST (7am ET)

Asia:

June 26, 2025: 9:30am CST/10:30 am KST/JST (9:30pm ET – 6/25)

December 19, 2025: 10:30 am CST; 11:30 am KST/JST (9:30am ET – 12/18)

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"HRPP Innovations" Webinar (three times per year)

Topics of interest, featuring presenters from AAHRPP-accredited organizations

- Monday, March 11, 2025; 1:00 pm – 2:30 pm ET
- Tuesday, July 8, 2025; 1:00 pm – 2:30 pm ET
- Tuesday, November 18, 2025; 1:00 pm – 2:30 pm ET

Pre-Conference Workshops (May 20, 2025):

Accreditation Workshop

Comprehensive course in how to achieve accreditation or reaccreditation featuring experts from accredited organizations.

CAN Workshop

Exclusively for AAHRPP-accredited organizations – a great networking and best-practice sharing opportunity.

AAHRPP News

AAHRPP Website

(available 24/7)

Advance Newsletter

(two times per year)

- Spring – March/April
- Falll – September/October

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Thank You!

- Please complete the survey
- Slides and a link to the recording of today's session will be provided with 14 days.

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Contact AAHRPP

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