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

Ask... AAHRPP®

January 13, 2026

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Conducting the Self-Evaluation

Robert Hood, PhD
Director of Accreditation and Global Outreach
AAHRPP

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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

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2026 Ask AAHRPP

- **Save the date for 2026 "Ask AAHRPP" webinars:**
- **January 13:** Conducting a Self-Assessment
- **April 14**: Peer review of written materials
- **June 9**: Peer review of your HRPP in practice – what to expect for site visit
- **August 11**: Responding to the Draft Site Visit Report
- **October 13**: Understanding the Council on Accreditation Review
- **December 8**: Responding to Council Review and maintaining accreditation

Visit Webinars (aahrpp.org) for more information and registration links

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Learning Objectives

- After this session, you will be able to:
  - Describe the AAHRPP accreditation process
  - Start conducting the self-assessment of your HRPP
  - 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

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AAHRPP-Accredited Organizations

As of December 2025, 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 Arab Emirates, 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

CELEBRATING 25 YEARS OF HRPP ACCREDITATION
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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

HRPP Components Mapped to AAHRPP Standards and Elements

Conflict of interest: Standard I-6, Element III.1.B
Community engagement: Standard I.4
Investigational products: 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

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AAHRPP Standards and Philosophy

A voluntary, educational, collegial, and transparent process

Flexible peer review (not an audit)

Goal to assist organizations in accreditation

- Agreed upon standards
- Fill in gaps
- Collaborate
- Be efficient and effective
- Focus on quality, efficiency, and effectiveness

Share responsibility throughout the organization

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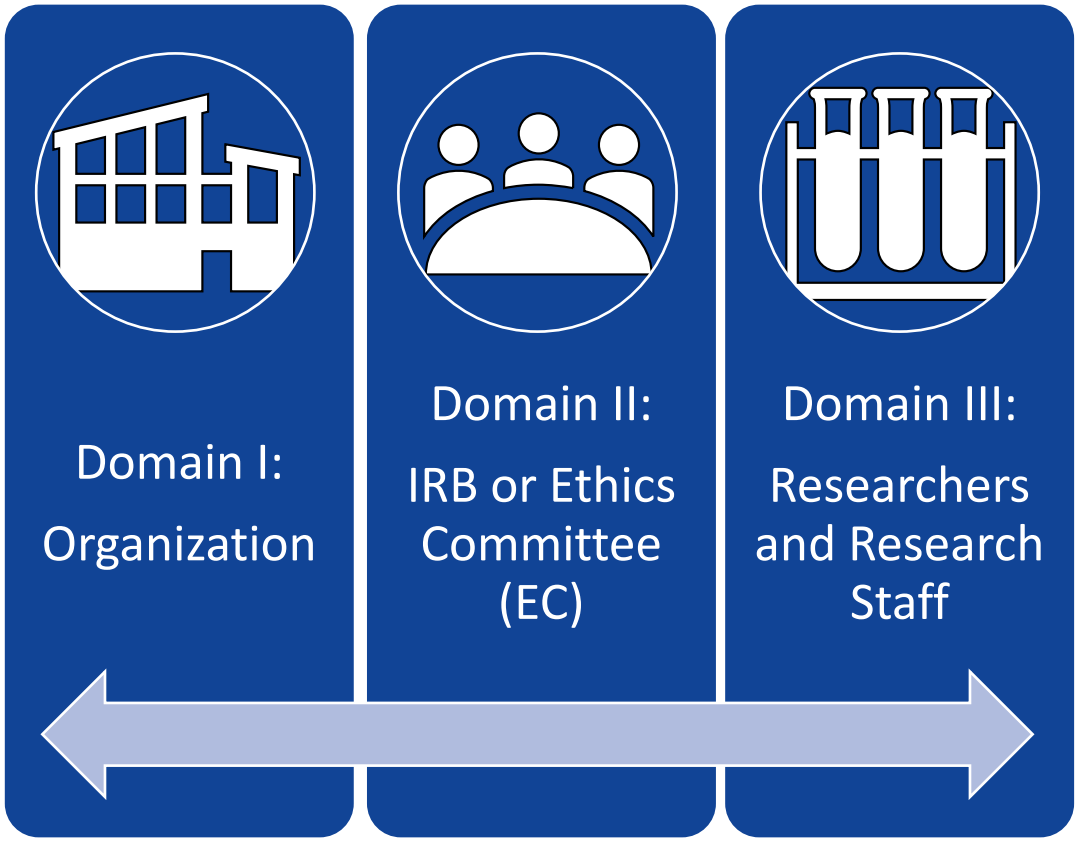
What Does Accreditation Cover?

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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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 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 investigational products (drugs, devices)
- Human participant protections in sponsor agreements
- Use of external IRBs/ECs

Domain II – IRB or Ethics Committee

- Covers the ethics review function
- Composition of the IRB/EC
- Policies consistent with regulatory review criteria
- Additional protections for vulnerable participants
- Handling noncompliance and 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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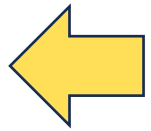
The Accreditation Process



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

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.

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1. Convene a Working Group

RESOURCES: For Accreditation - Additional Resources

APPLICATION FOR ACCREDITATION OR REACCREDITATION: SECTION H TEMPLATE FOR KEY PERSONNEL, INCLUDING RESEARCH TEAMS

Latest Update: January 9, 2026

RESOURCES: For Accreditation - Evaluation Instrument

EVALUATION INSTRUMENT FOR ACCREDITATION

DOWNLOAD AS PDF

Latest Update: September 8, 2025

Assemble	Assemble the core team
Identify	Identify gaps and revise materials
Delegate	Delegate responsibilities and tasks
Meet	Meet regularly

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Advantages of assembling a core team

RESOURCES: For Accreditation - Additional Resources

APPLICATION FOR ACCREDITATION OR REACCREDITATION: SECTION H TEMPLATE FOR KEY PERSONNEL, INCLUDING RESEARCH TEAMS

Latest Update: January 9, 2026

- 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

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How to identify team members

RESOURCES: For Accreditation - Additional Resources

APPLICATION FOR ACCREDITATION OR REACCREDITATION: SECTION H TEMPLATE FOR KEY PERSONNEL, INCLUDING RESEARCH TEAMS

Latest Update: January 9, 2026

https://www.aahrpp.org/resources/for-accreditation/additional-resource/application-for-accreditation-or-reaccreditation-section-h-template-for-key-personnel

2. Identify supporting materials

Tracking progress
Standard or Element
ELEMENT III.1.A.: Researchers and research staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.
ELEMENT III.1.B.: Researchers and research staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the organization, manage, minimize, or eliminate financial conflicts of interest.

See: Sample tracking spreadsheet

- Responsible office or person / role
- Policies and procedures
- IRB/EC applications
- Minutes templates
- Reviewer comment forms
- Researcher manuals
- Conflict of interest disclosure forms
- Reliance agreement templates

Track progress

- Keep a list of required revisions and maintain version control of documents

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

3. Use the Evaluation Instrument for Accreditation to evaluate your HRPP

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.
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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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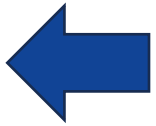

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Outcomes: The practices an organization should have in place

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.

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?

Analyze written materials and practices

Complete the review of materials before making changes

- Organize materials by Standard or 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

Track changes to written materials

- Create a “policy on policies”
- Describe location of written materials
- Specify who is responsible for ensuring they are current
- Specify time frame for periodic review of materials

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Educational Activities

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AAHRPP Educational Activities

Webinars:

Ask AAHRPP
Ask AAHRPP International
HRPP Innovations

Conference:

2026 Annual Conference - Detroit

News:

Advance Newsletter
AAHRPP Website

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Visit Webinars (aahrpp.org) for more information and registration links

“HRPP Innovations” Webinars

Topics of interest, featuring presenters from AAHRPP-accredited organizations

- **Why HRPPs Matter**
- Presenters: Debra Dykhuis, University of Minnesota; Rachel Karlnoski, University of South Florida Health and Tampa General Hospital; Scott Lipkin, Baptist Health South Florida
- Tuesday, February 17, 2026; 1:00 pm – 2:30 pm ET

https://www.aahrpp.org/education-news-and-events/webinars

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2026 AAHRPP
ANNUAL CONFERENCE:
GREAT LAKES,
GREAT MINDS
MEET IN MICHIGAN
SAVE THE DATE!
MAY 19-21, 2026
DETROIT MARRIOTT
AT THE RENAISSANCE CENTER
400 RENAISSANCE DR W
DETROIT, MICHIGAN
MARK YOUR CALENDARS FOR ONE OF THE RESEARCH
COMMUNITY'S MUST-ATTEND ANNUAL EVENTS.
MORE DETAILS TO FOLLOW.

AAHRPP News

AAHRPP Website

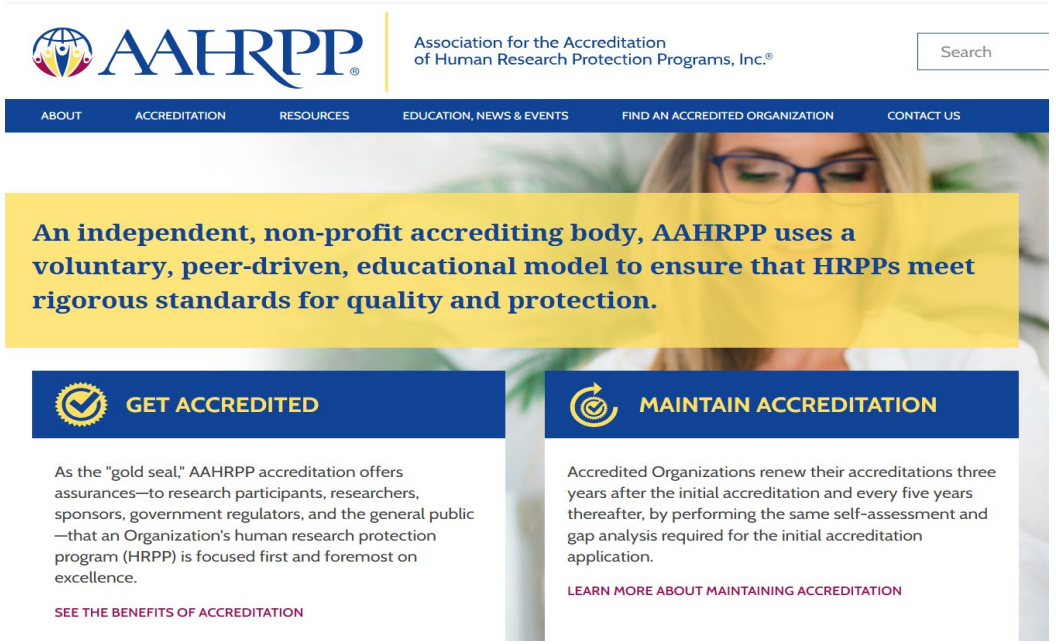
(available 24/7)

Advance Newsletter

(two times per year)

Spring – March/April

Fall – September/October



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Contact AAHRPP

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Please complete the survey

Slides, tools, and a link to the recording of today's session will be provided in an email soon.

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Thank You!