AAHRPP

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

January 10, 2023

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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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2023 Schedule

- January 10, 2023: Conduct a Self-Assessment
- March 14, 2023: Build and Develop an Application
- June 13, 2023: Evaluation of Written Materials
- August 8, 2023: Evaluation of Practice
- October 10, 2023: Council on Accreditation Review
- December 12, 2023: Respond to Council Review and maintain accreditation

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FYIs

- Please provide feedback by completing the survey
- A link to the talk will be sent to those who registered for the talk when it is posted
- If you have any questions during the sessions, please use the chat function or Q&A function to submit them

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Conduct a Self-Assessment

- The Self-Assessment is the first step in AAHRPP accreditation of your organization's entire HRPP
  - Convene a task force or working group
  - Using the Evaluation Instrument
  - Evaluate and revise written materials
- Timeline:
  - Time for Self-Assessment:
    - Initial accreditation 6-12 months
    - Reaccreditation process <6 months or earlier
  - Submission of Application to Council review – about 12 months
    - See video "Getting Started" on AAHRPP's website

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Focus of Accreditation

- Organization
- IRB or EC
- Researchers and Research staff

} **Human Research Protection Program**

All equally important

Systematic, comprehensive HRPP

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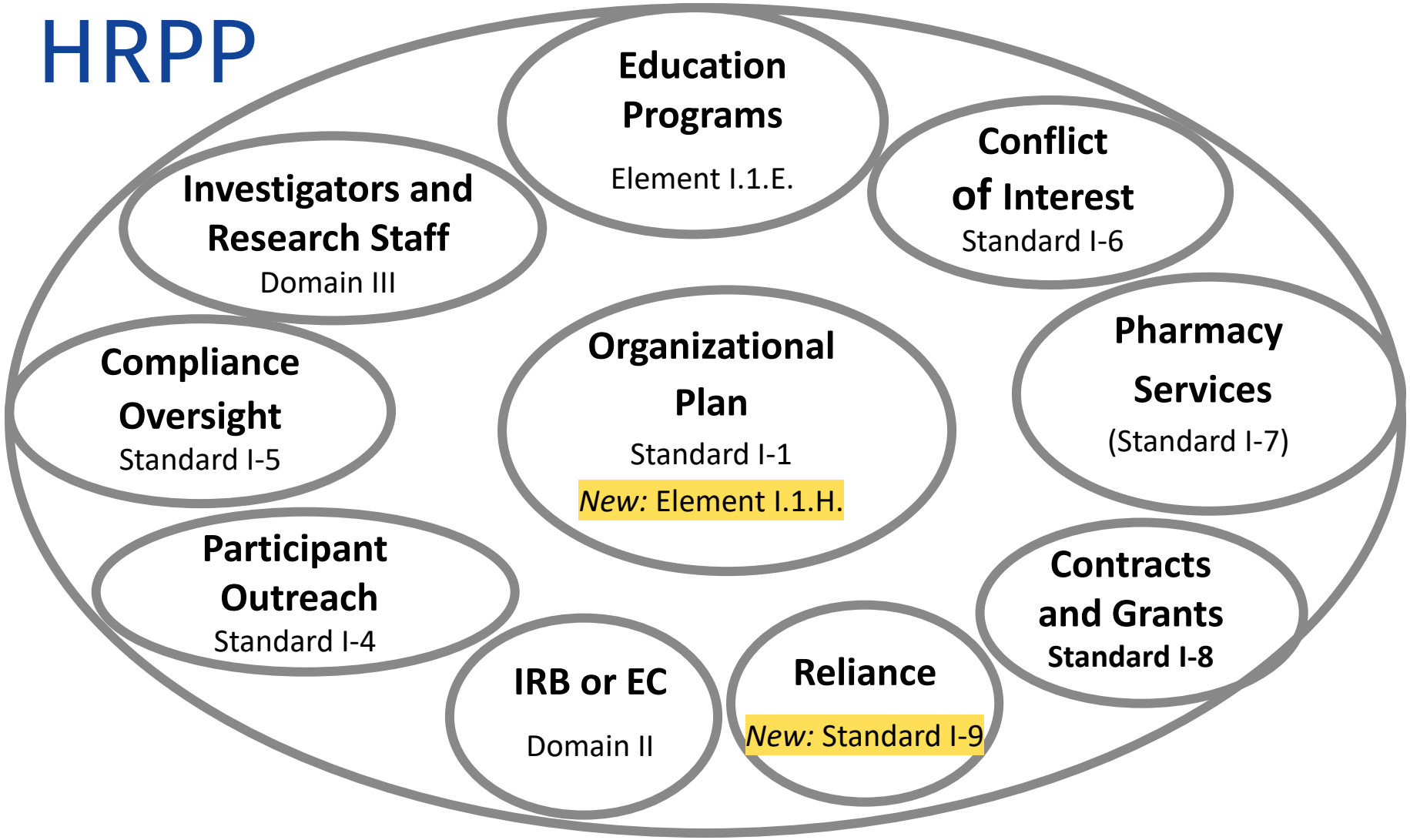
HRPP



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Part I: Convene a Task Force

- 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
- Identify a Core Team, meet regularly
- Charge from leadership – coordinate responsibly

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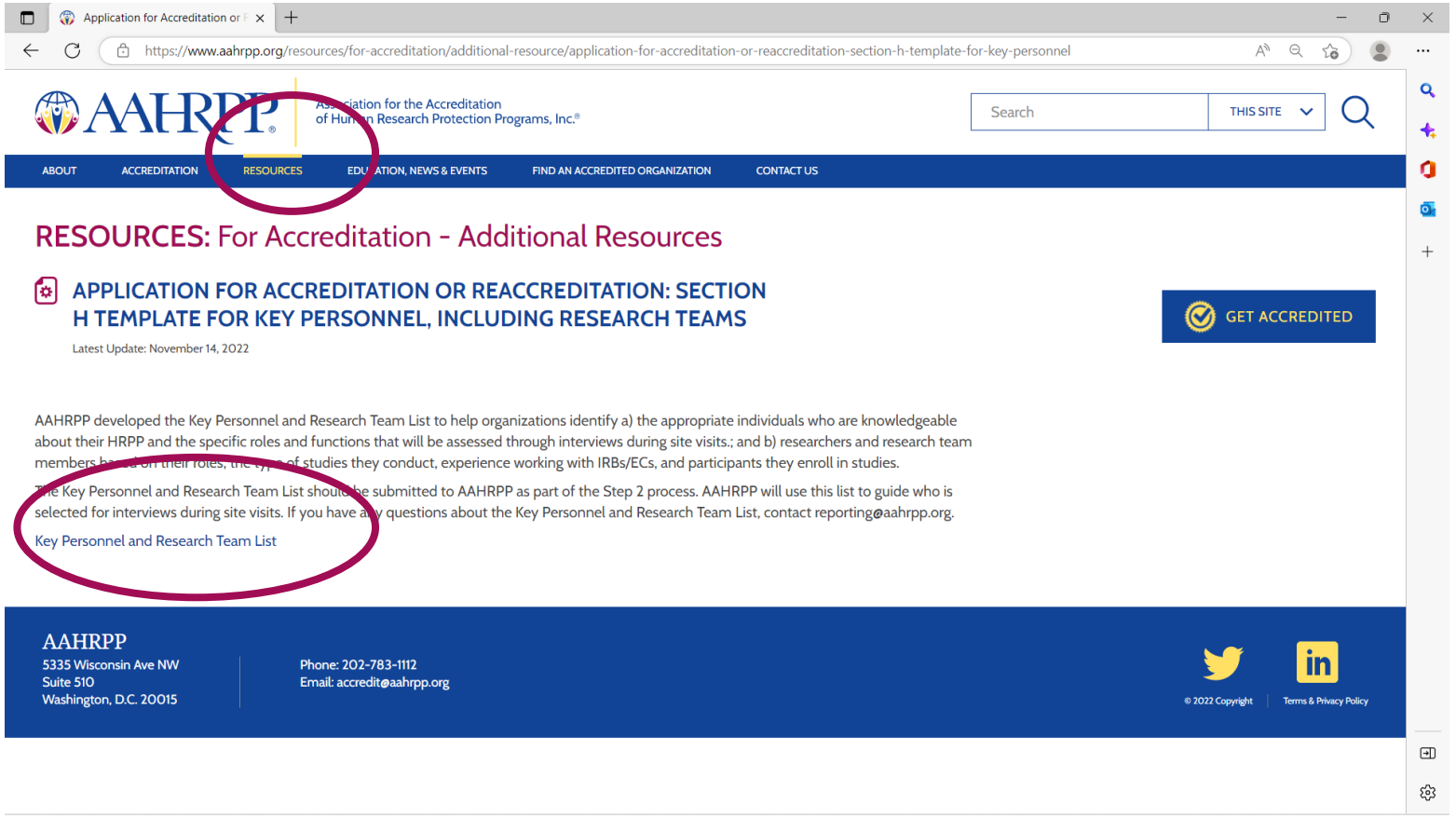
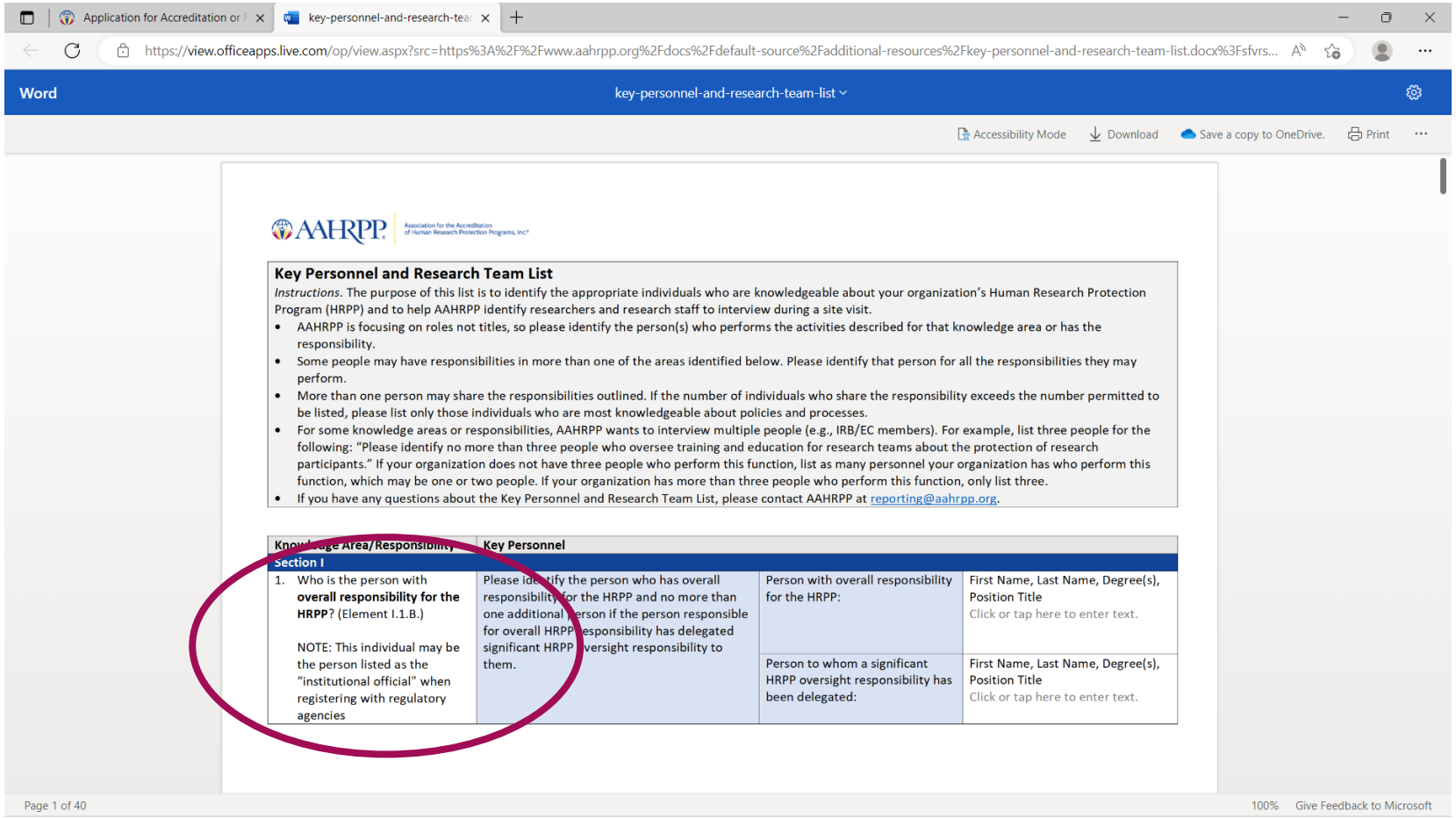
Who should be on taskforce?



Key Personnel and Research Team List



Application for Accreditation or F | key-personnel-and-research-tea

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Word — key-personnel-and-research-team-list

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Key Personnel and Research Team List

Instructions. The purpose of this list is to identify the appropriate individuals who are knowledgeable about your organization's Human Research Protection Program (HRPP) and to help AAHRPP identify researchers and research staff to interview during a site visit.

- AAHRPP is focusing on roles not titles, so please identify the person(s) who performs the activities described for that knowledge area or has the responsibility.
- Some people may have responsibilities in more than one of the areas identified below. Please identify that person for all the responsibilities they may perform.
- More than one person may share the responsibilities outlined. If the number of individuals who share the responsibility exceeds the number permitted to be listed, please list only those individuals who are most knowledgeable about policies and processes.
- For some knowledge areas or responsibilities, AAHRPP wants to interview multiple people (e.g., IRB/EC members). For example, list three people for the following: "Please identify no more than three people who oversee training and education for research teams about the protection of research participants." If your organization does not have three people who perform this function, list as many personnel your organization has who perform this function, which may be one or two people. If your organization has more than three people who perform this function, only list three.
- If you have any questions about the Key Personnel and Research Team List, please contact AAHRPP at reporting@aahrpp.org.

Knowledge Area/Responsibility	Key Personnel		
Section I			
1. Who is the person with **overall responsibility for the HRPP**? (Element I.1.B.) NOTE: This individual may be the person listed as the "institutional official" when registering with regulatory agencies	Please identify the person who has overall responsibility for the HRPP and no more than one additional person if the person responsible for overall HRPP responsibility has delegated significant HRPP oversight responsibility to them.	Person with overall responsibility for the HRPP:	First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.
		Person to whom a significant HRPP oversight responsibility has been delegated:	First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.

Page 1 of 40 — 100% — Give Feedback to Microsoft

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Part II: Using the Evaluation Instrument

An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection.

GET ACCREDITED

As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an Organization's human research protection program (HRPP) is focused first and foremost on excellence.

SEE THE BENEFITS OF ACCREDITATION

MAINTAIN ACCREDITATION

Accredited Organizations renew their accreditations three years after the initial accreditation and every five years thereafter, by performing the same self-assessment and gap analysis required for the initial accreditation application.

LEARN MORE ABOUT MAINTAINING ACCREDITATION

WHAT'S NEW

HIGHLIGHTED RESOURCES

AAHRPP Accreditation Procedures

Evaluation Instrument for Accreditation

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THE FIVE SECTIONS OF ELEMENTS AND STANDARDS

THE FIVE SECTIONS OF ELEMENTS AND STANDARDS:

Elements and Standards contain the following Sections:

1) Commentary

This section provides an explanation of how to interpret the Element.

2) Regulatory and Guidance References

Listed here are regulatory and guidance citations from the U.S. federal agencies that oversee research with human participants. These citations were updated on September 22, 2016. Also, listed here are the guidance citations from the International Committee on Harmonisation - Good Clinical Practice (E6) guideline.

Organizations that must follow a certain set of regulations (e.g., DHHS or FDA) must meet the regulatory requirements. Organizations that are not bound to follow a particular set of regulations are not required to meet them, but they should describe and provide equivalent protections, when applicable.

3) Required Written Materials

This section contains the requirements for written materials an organization must have to meet the Element.

AAHRPP uses the generic term “policies and procedures” to refer to all types of written materials. Policies and procedures include any written materials that the organization uses to define and communicate its practices, such as standard operating procedures, policy statements, procedure descriptions, checklists, guidelines, educational materials, job descriptions, memoranda, forms, templates, strategic plans, Web sites, charters, by-laws, mission statements, or other forms, that are used to administer the Human Research Protection Program. Policies and procedures are not limited to IRB or EC policies and procedures; other organizational procedures are likely to be relevant, such as some policies related to human resources, budgeting, pharmacy, contracting, student orientation, corporate compliance, or corporate ethics.

A policy is generally defined as a strategy, goal, or objective. It defines an expectation regarding a behavior or course of action. A procedure is a method by which a policy can be accomplished. Procedures should describe the operational steps that are followed to meet regulatory requirements. A restatement of the regulations or guidance is generally insufficient to provide the necessary specificity. Procedures should include:

(1) An explanation of how key regulatory terms are interpreted,
(2) The actions that are taken,
(3) The title of the person, office, or entity responsible for taking the action, and 4) The timing of actions.

No single format is required for policies and procedures, and no specific wording is required to be used in policies and procedures. Organizations have used a range of models for writing policies and procedures. Procedures should provide enough detail to be understandable to individuals within the organization who use them. Procedures should reflect actual practice within the organization.

AAHRPP has provided a description of the content for many policies and procedures. U.S. regulatory requirements, such as the criteria for approval of research, elements of disclosure for the consent process, or types of disclosure for financial interests, are not listed. The organization must use the federal regulations to obtain these requirements.

4) Common Types of Materials That May Be Used to Meet the Element

These are examples of the types of materials organizations have provided to meet the Element. Sometimes, materials are listed under this section when there is requirement for written materials to meet the Element. AAHRPP has included this section under the Element to assist organizations in meeting the Element. Organizations that do not have the materials should not create them to meet the Element. The listing is intended only a facilitative tool.

In this section, “procedures” are not listed as an example of a written material that may be used to the meet the Element. In some cases, the combination of an application form and reviewer evaluation tool will be sufficient to meet the Element, and a written procedure in addition to the application form and reviewer evaluation tool is not needed. This must be judged uniquely for each Element and for each organization.

5) Outcomes

These are the practices that an organization should have in place.

PROCEED TO: GLOSSARY OF TERMS

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ELEMENT I.1.E.

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.

The protection of research participants is the responsibility of many individuals in an HRPP, including IRB or EC members, chairs, and staff; researchers and research staff; and the organizational official. To protect research participants these individuals need to understand and be able to apply several areas of knowledge, including ethical principles, professional standards, organizational policies and procedures, and laws, regulations, codes, and guidance.

The depth of knowledge and skill required depends on each individual's specific task and role. For example, IRB or EC chairs or reviewers designated to use the expedited procedure for review should have more knowledge and skill than a new IRB or EC member. Researchers need different skills depending on the nature of their research or the expertise of their support staff.

An organization should have a process to ensure that individuals involved with human research protection have appropriate knowledge and skills. Such a process can include formal training and evaluation of previous training and experience. The size and breadth of the education program should be customized to meet the needs of the organization.

An organization should periodically evaluate the knowledge and skills of individuals involved in the HRPP.

Regulatory and guidance references

- **DoD**: Instruction 3216.02 5 paragraph 1.f.; 3216.02 6 paragraph 5.a-d. SECNAVINST 3900.39D paragraph. 6a(2), Minimum Education Requirements for DoD Personnel Involved in Human Research Protection Guidance (August 16, 2012)

Required written materials

(1) Essential requirements:
(a) The organization maintains a list of educational activities designed to contribute to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
(i) Policies and procedures specify:
(A) Initial education requirements, including timeframes, for researchers and research staff; IRB or EC staff, IRB or EC chairs, and members; and others.
(B) How education requirements are monitored.
(C) Continuing education requirements and time frames.
(D) What actions the IRB or EC or the organization takes if education requirements are not fulfilled.

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

- Lists of educational activities
- Education plans
- Education records

Outcomes

- The organization has an education program to ensure that individuals involved in the HRPP have appropriate knowledge and skills.

RESOURCES: For Accreditation - Evaluation Instrument

EVALUATION INSTRUMENT FOR ACCREDITATION

DOWNLOAD AS PDF

Latest Update: May 15, 2022

GET ACCREDITED

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INTRODUCTION

USE OF THE EVALUATION INSTRUMENT FOR ACCREDITATION

The Evaluation Instrument for Accreditation is intended for use by organizations seeking accreditation and by site visitors who evaluate organizations. To achieve accreditation, an organization must meet all the accreditation Standards and Elements. If an organization meets the Elements for a particular Standard, it meets the Standard. This Evaluation Instrument provides the information necessary to meet each Element.

AAHRPP has defined Domains of responsibility: *Organization*, *Institutional Review Board (IRB) or Ethics Committee (EC)*, and *Researchers and Research Staff*. Within each Domain are Standards, and for each Standard there are Elements that provide more specificity for the Standard. Each Element contains four parts: Commentary, Regulatory and Guidance References, Required Written Materials, and Outcomes.

For some Elements, Common Types of Materials That May Be Used to Meet the Element are included. Listed under this heading are examples of written materials that organizations have used to meet the Element. They are not required, and organizations may use other types of written materials to meet the Element. If an Element refers to written policies and procedures it generally means that a written procedure (e.g., standard operating procedure) is required to meet the Element. In some cases, an application form or reviewer checklist can serve the same purpose as a written procedure. AAHRPP has attempted to identify those Elements.

By designating certain types of written materials that may be used to meet an Element, AAHRPP does not desire to reduce the flexibility of the accreditation or limit creativity. The listing of Common Types of Materials That May Be Used to Meet an Element is intended to be helpful by providing guidance on the types of materials that can meet an Element.

This Evaluation Instrument is designed to be used by organizations in the United States as well as organizations in other countries that are obligated to follow U.S. federal regulations and those that are not so obligated. The Evaluation Instrument separately designates regulations and guidance from various U.S. federal agencies as well as the International Committee on Harmonisation – Good Clinical Practice Guideline (ICH-GCP) (E6). This includes regulations and guidance from the Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA), as well as other departments or agencies that have additional requirements, such as the Department of Defense (DoD), the Department of Education (ED), the Department of Energy (DOE), the Department of Justice (DOJ), the Department of Veteran Affairs (VA), and the Environmental Protection Agency (EPA).

For each Element, there are essential requirements that all organizations must follow. These essential requirements meet many U.S. and international government requirements for protection of human research participants. For some Elements, additional requirements are listed for specific U.S. federal agencies and the ICH-GCP (E6) Guideline.

Each Element (or Standard without Elements) begins on a separate page. This gives the appearance that the Evaluation Instrument is longer than it actually is. Separating each Element provides discrete documents to print and consider.

RESOURCES: For Accreditation - Tip Sheets

SINGLE IRB OR EC REVIEW

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Latest Update: November 8, 2018

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OVERVIEW
RECOMMENDED CONTENT

Related Accreditation Elements: I-9:

Overview

Organizations should define the roles and responsibilities of each collaborating organization when working with other organizations for oversight of research. Although Standard I-9, to which this relates, touches upon overarching HRPP responsibilities, this Tip Sheet focuses on responsibilities when collaborating on IRB or EC review. Policies and procedures, IRB or EC applications, IRB or EC member and staff worksheets, written agreements between organizations, and HRPP workflows should be reviewed carefully to ensure that they comprehensively include the breadth of responsibilities and activities required in these roles. This Tip Sheet provides suggestions on how to implement Standard I-9, including what information could be included in policies and procedures; agreements between organizations; and checklists, templates, and other materials. This Tip Sheet follows the same structure as Standard I-9 in terms of responsibilities of the organization relying upon an external IRB or EC, responsibilities of the reviewing IRB or EC, and responsibilities that may be shared.

Recommended Content

General Considerations

Organizations should define responsibilities, roles, and workflows related to Standard I-9. Suggested information for policies and procedures may include a description of:

- Required written agreement(s) (such as a memorandum of understanding, attestation, or reliance agreement) that document the roles of the reviewing IRB or EC and the relying organization(s). Policies and procedures should identify which agreement terms are required, those that are negotiable, and the process for adding participating sites or additional research to existing agreements.
- The process to ensure the organization maintains a record of all research conducted by the organization regardless of whether the research is under a local review or review by an external IRB or EC.
- The process for ensuring organizational compliance with the requirements of other parts of the HRPP. For example, if the relying organization typically requires approval by other internal review committees prior to IRB or EC approval (e.g., Institutional Biosafety, Radiation Safety), describe the process for ensuring these required approvals are secured and for communicating the approvals to the reviewing IRB or EC.
- How researchers are provided information on the process to use a reviewing IRB or EC and to rely on another IRB or EC.
- The process for how the organization and researchers will identify and maintain compliance with each IRB's or EC's policies and procedures under which their research is conducted. Organizations may consider publishing information on websites, developing tip sheets, adding information to researcher manuals, and sending mass emails to raise awareness or other approaches that fit the needs of the organization.

Examples of Additional Materials that may be created to assist organizations in meeting requirements in Standard I-9.

- The organization may develop decision trees, matrices, or other tools based on types of research, funding sources, or other pertinent criteria to guide decision-makers and researchers in the reliance determination.
- Template reliance agreements and checklists of items to negotiate may be developed to identify required terms and points for negotiation.
- Guidance documents and website information that are readily available to sponsors and researchers may be used to inform the research community when the organization will rely on an external IRB or EC or serve as a reviewing IRB or EC, and to provide a contact for questions.
- The organization may develop checklists, databases, or other tools to aid researchers in tracking their responsibilities when relying upon other IRBs or ECs, and to help manage compliance with a variety of IRB or EC policies and procedures.

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Part III: Tracking changes to written materials

Element	REGS / updates?	SOP(s)*	GAPS	RESPONSIBLE PARTIES	SOP Due Date	*Policies/Forms to revise/ create	Completed
Element I.1.A.							
Element I.1.B.							

*Policies, Applications, IRB or EC worksheets and checklists, minutes templates, letter templates, Websites, Manuals

If you anticipate major changes – e.g., new electronic system - contact AAHRPP ASAP

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Tracking changes

Element	SOP(s)	GAPS	RESPONSIBLE PARTIES	SOP Due Date	Other Resources	Completed
Element I.1.A.	100-01-HRPP-01	Describe who is responsible in the absence of the organizational official and how to brief new organizational officials	HRPP director			
Element I.7.A.	Policy 102, 300-04-IRB-members	Clarify that a pharmacy liaison will attend all IRB meetings	Pharmacy, IRB office			

Tracking changes between cycles

Policy	Revised version	Prior version	Owner/person responsible	Change	Education
100-01-HRPP-01	8/01/2023	5-Aug-21	HRPP Administrator	Clarified who serves as backup when organizational official when VP for Research is not available	planned
300-01-Form-DoD	9/15/2022	4/2/2021	IRB Administrator	Added IRB required determinations when following DoD requirements	complete
500-06-COI-Disclosures	9/15/2022	1/1/2020	COI administrator	Added COI disclosures due to changes in state law	complete

Written materials

- Living documents – education, monitoring, tracking revisions
- Review and update policies periodically (e.g., when the annual report is due?) – reduces time needed to prepare reaccreditation application

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Best practices for changes between cycles

- Engage with stakeholders and communicate changes
- Record changes to written materials
- Describe education to assess understanding
- Monitor changes to see if they are implemented

Examples of questions that can arise during the Self-Assessment

- HSR Quality Assurance Group - to whom should they report?
- How to revise "revamp" an existing procedure?
- Specific criteria to consider for assessing an organization's research education program?
- Research outside the US: what laws and regulations need to be followed? Do we need to follow US regulations?
- How do we develop a schedule? How do we get started?
- Reviewing new research outside my country?

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Thank You!

- A link to the talk will be sent to those who registered for the talk when it is posted

- Look for future dates on the AAHRPP website:
  - March 14, 2023: Build and Develop an Application
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Contact AAHRPP

Robert Hood, Ph.D.
Director of Accreditation and Global Development

rhood@aahrpp.org

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2023 AAHRPP Annual Conference

Challenge and Change in Charm City

May 16-18, 2023 | Hyatt Regency Baltimore