

# Updates on AAHRPP Annual Reports and Other Reporting Requirements

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## Presenters

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## Moderator

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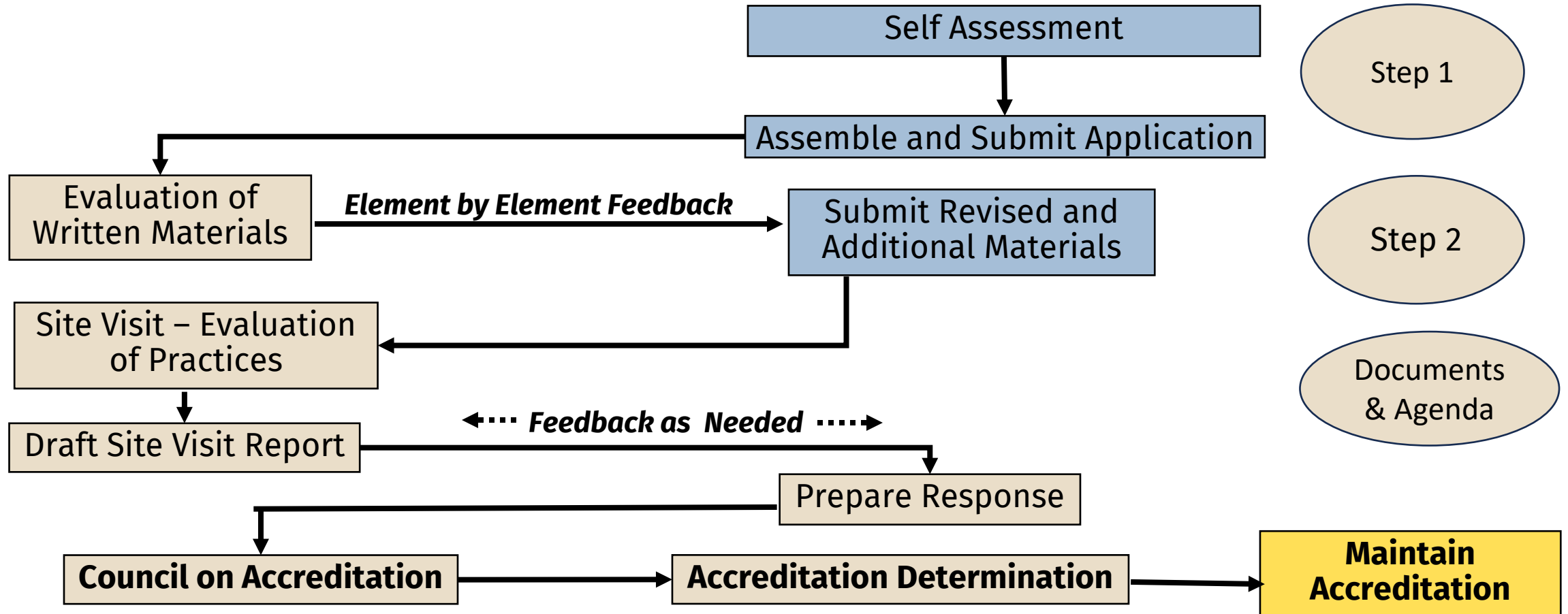


## FYIs

- Please provide feedback by completing the survey
- A link to the webinar will be sent to those who registered for the session when it is posted, and slides will be made available.
- If you have any questions during the session, please use the Q&A icon to submit them



# Accreditation Process



<https://aahrpp.org/accreditation/get-accredited/overview>

# Learning Objectives

- Understand AAHRPP's three reporting requirements:
  - Annual Reports – submit **yearly\***
  - Notification of substantive program changes – submit **within 30 days**
  - Notification of other reportable events – submit as soon as possible but **within 48 hours**

# Annual Reports

- For accredited organizations, Annual Reports are generally due on the 15th of the anniversary month of your organization's accreditation.
- However, Annual Reports are **not** due:
  - the year your organization submits an Application for Reaccreditation
  - the year your organization's Application for Reaccreditation is scheduled for review by the Council on Accreditation

# Example Organization Timeline

Initial Accreditation Awarded	Reaccreditation Application Due	Council Review for Reaccreditation	Reaccreditation Application Due	Council Review for Reaccreditation
June 2015	June 2017	June 2018	June 2022	June 2023
Annual Report Due: June 2016		Annual Reports Due: June 2019, June 2020, June 2021		

# Rest assured!

AAHRPP will provide the due dates for your organization's next Annual Report and Step 1 Application when communicating that your organization has been granted accreditation or reaccreditation.

Example:

Annual Report Due Date	
June 15, 2019	
Reaccreditation Application Due Date	Council Review
June 15, 2022	June 2023



# Annual Report Reminders

- AAHRPP will send a reminder with instructions for submitting your Annual Report approximately 60 days before it is due.
  - Also link to SurveyMonkey form (next slide)
- If the Application Contact changes between reports, notify us by submitting a PDF of the first two pages (Section I) of the [Section A Form](#) to [reporting@aahrpp.org](mailto:reporting@aahrpp.org)


# SurveyMonkey Form Logistics


- At the time you receive the Annual Report reminder, will also receive a link from a SurveyMonkey email address
  - Contact [reporting@aahrpp.org](mailto:reporting@aahrpp.org) if link is missing
  - If accessed this way, the survey should autosave while you work on it

## AAHRPP 2025 Annual Report



reporting@aahrpp.org via SurveyMonkey <member@surveymonkeyuser.com>

To  Melinda Renuart

 If there are problems with how this message is displayed, click here to view it in a web browser.

Click here to download pictures. To help protect your privacy, Outlook prevented automatic download of some pictures in this message.

## AAHRPP 2025 ANNUAL REPORT

Greetings from AAHRPP!

The anniversary of your organization's AAHRPP accreditation date is approaching.

# Resources for Annual Report



## ANNUAL REPORT GUIDANCE

Latest Update: January 17, 2025

The Annual Report is completed via an online survey that is sent to your Organization's Application Contact via email. On this page are documents to help you prepare for completing that report.

### Summary of Changes to the 2025 Annual Report

This document identifies the changes made to the 2025 Annual Report Form and the guidance below.

### Guidance on Completing the 2025 Annual Report

This document provides question-by-question guidance for the current Annual Report.

### Annotated 2025 Annual Report

<https://www.aahrpp.org/resources/for-accreditation/additional-resource/annual-report-guidanceGuidance>

# Annotated Annual Report

Question numbers may be different than in SurveyMonkey

<https://www.aahrpp.org/resources/for-accreditation/additional-resource/annual-report-guidance>

## External IRBs/ECs

Please tell us about your organization's use of external IRBs/ECs:

**For all organizations that use External IRBs/ECs**

\* 33. What is the number of open studies (excluding exempt human participants research) reviewed by an external IRB(s)/EC(s)

\* 34. Does your organization rely on a **non-accredited IRB(s)/EC(s)** for the review of some or all of its human participants research?

- Yes, my organization relies on a non-accredited IRB(s)/EC(s) for the review of ALL of its human participants research.
- Yes, my organization relies on a non-accredited IRB(s)/EC(s) for the review of SOME of its human participants research.
- No, my organization does not rely on any non-accredited IRB(s)/EC(s) for the review of its human participants research.

# Independent IRBs

- Biggest branching question in Annual Report survey: ***Is your organization an independent IRB/EC?***

Does your organization conduct research?

If yes, your organization is not an independent IRB.

- Independent IRBs are sometimes referred to as “commercial IRBs”
- Questions? Find your organization’s “type” (e.g., hospital, academic institution, government organization) on AAHRPP’s website: [Find an Accredited Organization](#)

# Why Annual Reports?

1. Update AAHRPP on the nature and size of your organization's HRPP and human research portfolio
2. Notify AAHRPP of any changes related to or that might affect your organization's HRPP\* (next slides!)
3. Contribute to AAHRPP's [Metrics on HRPP Performance](#)

The metrics questions are generally **not** meant to assess your organization's performance.

To see the questions AAHRPP uses for metrics and how they are presented, see: <https://aahrpp.org/resources/for-accreditation/metrics-on-hrpp-performance>

\* Some changes should be reported within 48 hours or 30 calendar days (coming up!) The Annual Report serves as a backup or as a summary of the previously reported changes.

# Changes Reported Include:

- Organizational Changes
  - Change in entity type or corporate structure.
  - Change in name of the Organization.
  - Change in ownership or control of the Organization.
  - Any mergers or acquisitions.
  - Change in leadership or governance of the Organization (e.g., President or Chief Executive Officer).
  - Change in the organizational official.
  - Change in the leadership of the Human Research Protection Program (i.e. the individual responsible for the day-to-day operation).
  - Change in the application contact.

# Changes Reported (cont):

- Changes in Resources
  - Significant change (10% or more) in the balance of resources and active research protocols.
  - Significant reduction (10% or more) in resources in the past 12 months and the consequences on the Human Research Protection Program, such as reduction in FTE or dissolution of an IRB, committee or other function.



# Changes Reported (cont):

- Changes in Program Scope
- Changes in method of providing services, such as use of external IRBs/ECs or contracting for services from another organization
- Catastrophic event that results in an interruption or discontinuance in part of or entire HRPP

# Annual Report FAQ: Timelines

- **January 1– December 31:** If submitting the Annual Report in June 2025, an organization would use for these questions the timeframe January 1, 2024 – December 31, 2024. This timeframe is used for most metrics questions.
- **Counting the number of convened or expedited protocols:** Please provide the number of open studies at the time you submit your Annual Report.
- **In the most recent 12 months:** For the Required Reporting Form at the end of the Annual Report, please use the most recent 12 months since the date that you submit your Annual Report.

# Resources for Annual Report



## ANNUAL REPORT GUIDANCE

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# Changes To 2025 Annual Report

\* 11. Does your organization have a US Federalwide Assurance (FWA)?

- Yes
- No

For organizations with a Federalwide Assurance (FWA):

\* 12. Do you apply:

- The same policies and procedures regardless of funding
- Different but equivalent policies and procedures for some or all research not covered by regulations

# Change to 2025 Annual Report Guidance

## Expedited Review Timeline

\* 50. For the most recent year (the period from January 1 through December 31), what was the MEDIAN number of calendar days from submission to approval via EXPEDITED REVIEW for initial review of human participants research?

For questions asking about the timeframe “from submission”, we have clarified guidance to confirm includes pre-review.

# Questions and Comments

- For questions about the Annual Report, contact [reporting@aaahrpp.org](mailto:reporting@aaahrpp.org).
- Can also share comments or suggestions in “Miscellaneous Comments” box at the end of the Annual Report.

Miscellaneous Comments

81. Please use this space for additional comments or clarifications.

# After Submitting your Annual Report

- Automatic confirmation with PDF of responses
- AAHRPP staff will email you that the review is complete, or to request additional information.

# Reportable Events

- Some events should be reported within 48 hours or within 30 days, instead of waiting until your next Annual Report or application.
- AAHRPP staff will review information regarding the event that is provided and will determine whether any action is indicated, or if additional information is needed. In some circumstances, the Council on Accreditation will be advised of the situation and requested to determine whether further action is needed, such as further reporting or a Limited Site Visit.
- Reporting certain events within 48 hours allows AAHRPP to provide assistance, particularly if your organization has to respond to a regulatory agency.



# Summary

## Negative Government Actions

**48 Hours**

- OHRP Determination Letters
- FDA Warning Letters
- FDA 483 Official Action Indicated
- FDA Restrictions on IRBs or Investigators,
- Compliance actions taken by non-US authorities

## Legal Issues Related to HRPP

**48 Hours**

- Litigation
- Arbitration
- Settlements

## Negative Press Coverage Related to HRPP

**48 Hours**

- Radio
- TV
- Newspaper
- Online Publications

## Major Organizational Change

**30 days**

- Name Change
- Change in Corporate Structure
- Change of Ownership or Leadership

## Unsure Whether to Report?

Please contact AAHRPP at [reporting@aahrpp.org](mailto:reporting@aahrpp.org)

# How to report:

Submit [Reportable Events Form](#) from AAHRPP's website, following its instructions.

## Instructions

Use this form to provide a summary of the issue(s) that require reporting. If applicable, include:

- Immediate actions taken to protect participants, if applicable
- Planned corrective actions with timeline, if applicable

If it is unclear whether a particular item is reportable to AAHRPP, please contact the AAHRPP office.

Email this form and PDF copies of supporting documents to:

- [reporting@aahrpp.org](mailto:reporting@aahrpp.org)
- [esummers@aahrpp.org](mailto:esummers@aahrpp.org)
- [mfeige@aahrpp.org](mailto:mfeige@aahrpp.org)
- [rhood@aahrpp.org](mailto:rhood@aahrpp.org)

Supply copies of supporting documents, including but not limited to:

- letters from a government oversight agency
- information about litigation, if public
- press coverage

# Contact AAHRPP

Questions About the AAHRPP Standards/Elements:

Robert Hood, Ph.D.

Director of Accreditation and Global Outreach

[rhood@aahrpp.org](mailto:rhood@aahrpp.org)

Questions About Reporting and Application Process:

Operations Division

[reporting@aahrpp.org](mailto:reporting@aahrpp.org)



# Questions and comments

