For All Organizations

Organizational Information

* 1. What is the legal name of your organization? (Please consult with your general counsel to ensure accuracy and do not use abbreviations)

* 2. What is your organization's preferred name (e.g., the name that should appear on AAHRPP's website and accreditation certificates)?

* 3. What is the address of your organization?

Street Address	
Street Address Line 2	
City	
State / Province / Territory	
Country / Region	
Zip/Postal Code	

Location of Research Activities, Types of Research, and Regulations Applied

* 4. Where does human participants research that your organization conducts, reviews, manages and/or sponsors occur (select all that apply)?

- [ ] Research activities occur in the state/province/region within the country where the organization is primarily based
- [ ] Research activities occur in other states/provinces/regions within the country where the organization is primarily based
- [ ] Research activities occur in countries other than the country where the organization is primarily based

* 5. What kind of research does your organization review, conduct, manage, and/or sponsor? (Select all that apply.)

	Yes	No
Biomedical / clinical	○	○
Social / behavioral / education	○	○

* 6. Does your organization review, conduct, manage, and/or sponsor studies involving any of the following?

	Yes	No
Investigational drugs, biologics, or dietary supplements	◯	◯
Investigational devices	◯	◯

* 7. Does your organization review, conduct, manage, and/or sponsor planned emergency research?

- ◯ Yes
- ◯ No

* 8. Does your organization review, conduct, manage, and/or sponsor studies involving any of the following vulnerable participant populations?

	Yes	No
Children	◯	◯
Pregnant women	◯	◯
Prisoners	◯	◯
Adults unable to provide informed consent	◯	◯

* 9. What type(s) of funding does your organization receive for the review, management, conduct, and/or sponsorship of human participants research?

	Yes	No
Sponsored by the US federal government	◯	◯
Industry sponsored	◯	◯
Sponsored by other external sources	◯	◯
Sponsored by internal sources (including unfunded research)	◯	◯

* 10. Which regulations does your organization reasonably expect could apply to your research portfolio, whether or not you have open studies that must comply with those regulations? The information helps AAHRPP identify the regulations under which it will evaluate your organization.

	Yes	No
US Department of Defense (DoD)	◯	◯
US Department of Education (ED)	◯	◯
US Department of Energy (DOE)	◯	◯
US Department of Health and Human Services (DHHS)	◯	◯
US Department of Justice (DoJ)	◯	◯
US Department of Veterans Affairs (VA)	◯	◯
US Environmental Protection Agency (EPA)	◯	◯
US Food and Drug Administration (FDA)	◯	◯
US National Science Foundation (NSF)	◯	◯

* 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

Organizational Information

* 13. Does your organization reasonably expect to adhere to the International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP)?

- ◯ My organization does not adhere to ICH-GCP E6.
- ◯ My organization adheres to ICH-GCP only as adopted by the US FDA or country-specific GCP (e.g., Japan GCP) for all applicable clinical trials.
- ◯ My organization only adheres to ICH-GCP E6 at a sponsor's request.
- ◯ My organization adheres to ICH-GCP E6 at a sponsor's request but otherwise adheres to ICH-GCP only as adopted by the US FDA or country-specific GCP (e.g., Japan GCP) for all applicable clinical trials.
- ◯ My organization adheres to ICH-GCP E6 for all applicable clinical trials.

* 14. Is your organization based primarily in the United States?

- ◯ Yes
- ◯ No

Organizations Outside the US

* 15. What country-specific laws, regulations, and guidance does your organization apply to research involving human participants?

Independent IRBs/ECs

* 16. Is your organization an independent IRB/EC?

NOTE:
An independent IRB/EC is an IRB or ethics committee that is *not* part of an organization that conducts research, and that is *not* owned or operated by the research organization for which it provides review services. These organizations are sometimes referred to as commercial IRBs.

IRBs/ECs embedded within the organization that may conduct research (such as academic organizations, hospitals, or health systems) are NOT considered independent IRBs/ECs.

You can check how AAHRPP classifies your organization's "Type" (e.g., hospital, academic institute, independent IRB, etc.) at https://www.aahrpp.org/find-an-accredited-organization

- ◯ Yes
- ◯ No

Organizations that are Independent IRBs/ECs

For Independent IRBs/ECs

* 17. How many IRBs or ECs does your organization maintain?

- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10
- ◯ More than 10 (please specify)

18. Please tell us about the staff for your internal IRBs/ECs:

Total number of **FTEs your organization has dedicated to your IRB(s)/EC(s)** in the most recent year (the period from January 1 through December 31) or last fiscal year.

* 19. Please tell us about your organization's IRB/EC review of studies:

Number of open studies **reviewed via expedited procedures** at initial review

Number of open studies **reviewed at a convened IRB/EC meeting** at initial review

Number of **exempt human participants research determinations** made within the most recent year (the period from January 1 through December 31).

Note: this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.

* 20. Please tell us about your IRB's/EC's review of reportable events within the most recent year (the period from January 1 through December 31):

Number of **determinations of serious noncompliance made by your IRB(s)/EC(s)**

Number of **determinations of continuing noncompliance made by your IRB(s)/EC(s)de**

Number of **determinations of unanticipated problems made by your IRB(s)/EC(s)**

* 21. In the most recent year (the period from January 1 through December 31), what was the number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections of research studies your organization reviews that resulted in a finding or a request for an official compliance action (e.g., issuance of a US FDA Form 483 or FDA Warning Letter)?**

If your organization does not track this information, please indicate this.

* 22. Please tell us about other compliance activities in the most recent year (the period from January 1 through December 31):

Number of **"for cause" audits your organization conducted of research studies** your organization reviews

Number of **"not for cause"/random/routine post-approval audits of research studies** your organization reviewed

Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections or reviews of IRB(s)/EC(s)**

Number of **"for cause" audits of IRB/EC records/processes** conducted internally

Number of **"not for cause"/random audits of IRB/EC records/processes** conducted internally

* 23. Please tell us about your organization's management of financial conflicts of interest related to human participants research in the most recent year (the period from January 1 through December 31):

Number of studies with a financial conflict of interest management plan for an initial review of a study or a change in research adding a new management plan reviewed by your organization's IRB(s)/EC(s)

Independent IRB/EC - Convened Board

* 24. Did your IRB(s)/EC(s) approve any studies at initial review at a CONVENED BOARD meeting in the most recent year (the period from January 1 through December 31)?

- ◯ Yes
- ◯ No

Independent IRB/EC - Convened Board Review Timelines

* 25. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from:

Submission to CONVENED BOARD REVIEW for initial review of human participants research

Submission to final approval via CONVENED BOARD REVIEW for initial review of human participants research

Independent IRB/EC - Expedited Review

* 26. Did your IRB(s)/EC(s) approve any studies at initial review outside a convened meeting (in the US called "**expedited review**") in the most recent year (the period from January 1 through December 31)?

- ◯ Yes
- ◯ No

Independent IRB/EC - Expedited Review Timelines

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

Independent IRB/EC - Exempt Human Participants Research

* 28. Did your IRB(s)/EC(s) determine any studies to be exempt human participants research in the most recent year (the period from January 1 through December 31)?

- ◯ Yes
- ◯ No

Independent IRB/EC - Timelines for Exemption Determinations

* 29. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from submission to an exemption determination?

Independent IRB/EC

30. Please tell us about any electronic (computer) systems your IRB(s)/EC(s) uses. Check all that apply.

My organization's IRB(s)/EC(s) uses an electronic system:

- ☐ ... that allows researchers to prepare and/or submit their applications for IRB/EC review.
- ☐ ... that allows IRB/EC members to review IRB/EC applications and supporting materials.
- ☐ ... that allows IRB/EC members and staff to communicate about IRB applications and other related materials.
- ☐ ... to document or record IRB/EC decisions and study-specific determinations within the system.
- ☐ Not Applicable. My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC submission and review process.

* 31. Does your IRB(s)/EC(s) compensate any IRB/EC members?

- ◯ Yes
- ◯ No

For all organizations that are NOT independent IRBs/ECs

Use of External IRBs/ECs

* 32. Does your organization use one or more external IRBs/ECs to review some or all of its human participants research?

- ◯ Yes
- ◯ No

For all organizations that use External IRBs/ECs

External IRBs/ECs

Please tell us about your organization's use of 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.

If answered "SOME" in above Q.34

Not AAHRPP-Accredited External Review

* 35. What is the approximate percentage of human participants research your organization relied on an external IRB(s)/EC(s) that is not AAHRPP-accredited for review during the most recent year (the period from January 1 through December 31)?

- ◯ < 1-5
- ◯ 6-25
- ◯ 26-50
- ◯ 51-75
- ◯ 76-100

If answered "ALL" in Q.34

Non-AAHRPP Accredited External Review - All Human Participants Research

36. Please provide the name(s) of the non-accredited IRB(s)/EC(s) upon which your organization relies for the review of ALL of its human participants research.

External Review Process

* 37. Please select the statement that best describes your organization's ethical review process:

- ◯ My organization relies on one or more external IRB(s)/EC(s) to review ALL of its human participants research, which could include determinations of whether research involving human participants is exempt research.
- ◯ My organization relies on one or more external IRB(s)/EC(s) to review ALL of its human participants research, but not for determinations of whether research involving human participants is exempt research.
- ◯ My organization relies on one or more external IRB(s)/EC(s) to review SOME of its human participants research, which could include determinations of whether research involving human participants is exempt research.
- ◯ My organization relies on one or more external IRB(s)/EC(s) to review SOME of its human participants research, but not for determinations of whether research involving human participants is exempt research.

For all organizations that have internal IRBs/ECs (but are NOT Independent IRBs/ECs)

Organizations with Internal IRBs/ECs

* 38. How many IRBs or ECs does your organization maintain?

- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10
- ◯ More than 10 (please specify)

* 39. Please tell us about the staff for your internal IRBs/ECs.

Total number of **FTEs your organization has dedicated your IRB(s)/EC(s)** in the most recent year (the period from January 1 through December 31)

* 40. Please tell us about other compliance activities related to **IRB/EC review** in the most recent year (the period from January 1 through December 31).

Number of **"for cause"** audits your organization conducted of IRB(s)/EC(s) at your organization

Number of **"not for cause"/random** audits your organization conducted of IRB(s)/EC(s) at your organization

Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections or reviews** of IRB(s)/EC(s) at your organization

41. Please tell us about any electronic (computer) systems your IRB(s)/EC(s) uses. Check all that apply.

My organization's IRB(s)/EC(s) uses an electronic system:

- ☐ ... that allows researchers to prepare and/or submit their applications for IRB/EC review.
- ☐ ... that allows IRB/EC members to review IRB/EC applications and supporting materials.
- ☐ ... that allows IRB/EC members and staff to communicate about IRB applications and other related materials.
- ☐ ... to document or record IRB/EC decisions and study-specific determinations within the system.
- ☐ Not Applicable. My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC submission and review process.

* 42. Does your organization serve as the reviewing IRB/EC for external organizations conducting research?

- ◯ Yes
- ◯ No

Reviewing IRB/EC

* 43. What is the number of open studies (not including exempt human participants research) for which your organization serves as a reviewing IRB/EC for external organizations conducting research?

* 44. Does your organization provide IRB review for a US Department of Veterans Affairs facility?

- ◯ Yes
- ◯ No

Veterans Affairs Academic Affiliate

* 45. Does your organization serve as the academic affiliate for a Veterans Affairs (VA) facility?

- ◯ Yes
- ◯ No

VA Academic Affiliate

* 46. My organization serves as an academic affiliate for the following VA facility(ies):

Expedited Review

* 47. Do the laws, regulations, codes, and guidance under which your organization conducts or reviews research involving human participants allow research that is not exempt to be reviewed by a non-committee process? Under the US Common Rule this non-committee review process is referred to as **expedited review**.

- ◯ Yes
- ◯ No

Expedited Review Process

* 48. What is the number of open studies reviewed by an internal IRB(s)/EC(s) under **expedited procedures** at initial review?

* 49. Did your IRB(s)/EC(s) approve any studies at initial review under expedited procedures **in the most recent year** (the period from January 1 through December 31)?

- ◯ Yes
- ◯ No

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?

Convened Board Review

* 51. What is the number of open studies reviewed by an internal IRB(s)/EC(s) at a convened meeting at initial review?

* 52. Did your IRB(s)/EC(s) approve any studies at initial review at a convened board meeting **in the most recent year** (the period from January 1 through December 31)?

- ◯ Yes
- ◯ No

Convened Board Review

* 53. For the most recent year (the period from January 1 through December 31), what was the MEDIAN number of calendar days from:

Submission to CONVENED BOARD REVIEW for initial review of human participants research

Submission to FINAL APPROVAL via convened board review for initial review of human participants research

For ALL organizations that are NOT Independent IRBs/ECs

Exempt Human Participants Research

* 54. Do the laws, regulations, codes, and guidance under which your organization conducts or reviews human participants research allow this research to be determined **exempt**?

- ◯ Yes
- ◯ No

Exempt Human Participants Research Determinations

* 55. Please select the statement that best describes your organization’s policies and procedures for exempt human participants research.

- ◯ My organization solely allows exempt human participants research determinations as outlined within US regulations.
- ◯ My organization allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.
- ◯ My organization does not follow the US Common Rule but allows exempt human participants research determinations as outlined within my country’s regulations or my organization’s policy.

* 56. What is the number of **exempt human participants research determinations made** within the most recent year (the period from January 1 through December 31) by an **external** review process (e.g., by an external IRB/EC)? Note this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.

* 57. Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?

- ◯ Yes
- ◯ No

* 58. Does your organization use an internal process to make exempt human participants research determinations?

- ◯ Yes
- ◯ No

Exemption Determinations by Internal Review Process

59. Were any exemption determinations made within the most recent year (the period from January 1 through December 31) by an **internal review process**? Note this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.

- ◯ Yes
- ◯ No

Exemption Determinations by Internal Review Process in most recent year

* 60. What is the number of **exempt human participants research determinations** made within the most recent year (the period from January 1 through December 31) **by an internal review process** (e.g., by an internal IRB/EC or other internal HRPP review process)? Note this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.

* 61. For **exemption determinations made through an internal review process** (which could include review by an IRB/EC) during the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from the submission to an exemption determination?

Review of Reportable Events for Organizations that are not Independent IRBs/ECs

* 62. Please tell us about your organization's review of the following events within the most recent year (the period from January 1 through December 31):

Number of **determinations of serious noncompliance**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB/ECs

Number of **determinations of continuing noncompliance**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB/ECs

Number of **determinations of unanticipated problems**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB/ECs

* 63. Please tell us about other compliance activities related to **research studies** in the most recent year (the period from January 1 through December 31)

Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections of research studies** your organization conducted, managed, reviewed, and/or sponsored **that resulted in a finding or a request for an official compliance action** (e.g., issuance of a US FDA Form 483 or FDA Warning Letter)

Number of **"for cause" audits** your organization conducted of research studies that your organization manages, conducts, reviews, and/or sponsors

Number of **"not for cause"/random/routine post-approval audits** your organization conducted of research studies your organization manages, conducts, reviews, and/or sponsors

Financial Conflicts of Interest

* 64. Please tell us about your organization's management of financial conflicts of interest related to human participants research in the most recent year (the period from January 1 through December 31):

What is the number of studies with a financial conflict of interest management plan for an initial review of a study or a change in research adding a new management plan reviewed by your organization's IRB(s)/EC(s) or external IRB(s)/EC(s)?

For Organizations that have internal IRBs/ECs or are Independent IRBs/ECs

Compensation of IRB/EC Chairs and Vice Chairs

* 65. Does your organization provide IRB/EC chairs/vice chairs with financial compensation?

- ◯ Not applicable - my organization does not have an internal IRB/EC and is not an independent IRB/EC
- ◯ Yes
- ◯ No

Type of IRB/EC Chair/Vice Chair Compensation

* 66. Please indicate any of the following types of FINANCIAL support your organization provides IRB/EC chairs or vice chairs (if your organization has vice chairs). (Check all that apply)

- ☐ Salary support (full or partial)
- ☐ Pay for specific activities (e.g., conducting IRB meetings, reviews)
- ☐ Stipend/honorarium
- ☐ Other, please describe
- ☐ Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees
- ☐ Reimbursement of the IRB/EC chair/vice chair's home department/clinic for time

Compensation for Affiliated IRB/EC Members Who are not Chairs or Vice Chairs

* 67. Please indicate any of the following types of FINANCIAL support your organization provides for **affiliated IRB/EC Members**. (Check all that apply)

- ☐ Salary support (full or partial)
- ☐ Pay for specific activities (e.g., attending IRB meetings, reviews)
- ☐ Stipend/honorarium
- ☐ Other, please describe
- ☐ My organization does not provide financial support for affiliated IRB/EC members.
- ☐ Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees
- ☐ Reimbursement of the IRB/EC IRB member's home department/clinic for time

Compensation for Unaffiliated IRB/EC Members Who are not Chairs or Vice Chairs

* 68. Please indicate any of the following types of FINANCIAL support your organization provides for **unaffiliated IRB/EC members**. (Check all that apply)

- [ ] Salary support (full or partial)
- [ ] Pay for specific activities (e.g., attending IRB meetings, reviews)
- [ ] Stipend/honorarium
- [ ] Other, please describe
- [ ] Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees
- [ ] My organization does not provide financial support for unaffiliated IRB/EC members.

For All Organizations

Required Reporting Form

Indicate if any of the following changes have occurred in your Organization in the last 12 months by checking the box.

* 69. Organizational Changes

- [ ] Change in name of the organization.
- [ ] Any mergers or acquisitions.
- [ ] Change in the organizational official.
- [ ] No organizational changes.
- [ ] Change in the leadership of the Human Research Protection Program (HRPP) (i.e., the individual responsible for the day-to-day operation)
- [ ] Change in the application contact.

* 70. Please provide a description of any organizational changes checked on the Required Reporting Form. If you have not had any organizational changes, please type "Not Applicable".

Required Reporting Form

Resource Changes

* 71. Has your organization experienced a change in resources, including but not limited to significant reduction (10% or more) in resources in the most recent 12 months?

- ( ) Yes
- ( ) No

Required Reporting Form

Resources Changes Description

* 72. Please describe the changes in resources in the past 12 months.

Required Reporting

Program Scope Changes

* 73. Indicate if any of the following Program Scope Changes pertaining to your HRPP have occurred in the last year by checking the box.

- [ ] Addition of new research programs (i.e., research not previously conducted or reviewed by the Organization, such as planned emergency research, research involving children, or gene transfer research).
- [ ] Addition, removal, or modification of functions, committees, or IRBs/ECs.
- [ ] Changes in organizations that are entities of your HRPP.
- [ ] No program scope changes.

* 74. Please provide a description and more information for any program scope changes checked above. If you have not had any program scope changes, please type "Not Applicable".

Required Reporting Form

Major Events

* 75. Indicate if any of the following MAJOR EVENTS pertaining to your HRPP have occurred in your organization in the last year by checking the box. NOTE: Major Events should be reported to AAHRPP within 48 hours after the organization becomes aware of them.

- [ ] Catastrophic event that results in an interruption or discontinuance in a component of or the entire HRPP.
- [ ] Any actions by a government oversight office, including but not limited to OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Researchers, and corresponding compliance actions taken under non-US authorities related to human research protections.
- [ ] Any litigation, arbitration, or settlements initiated related to human research protections.
- [ ] Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the organization's HRPP.
- [ ] No major reportable events.

76. Did you already report all of the events checked above to AAHRPP?

- ◯ Yes
- ◯ No
- ◯ None of the above major events occurred in my organization.

Required Reporting Form

Major Events Description

* 77. Please provide a summary of the major events that you have not previously reported.

Attestation

I hereby certify that all of the answers provided on my Annual Report have been reviewed by both the application contact and the organizational official and are correct.

* 78. Person completing this Annual Report

Prefix (Professor, Doctor, Mr., Ms., etc.)	
First Name	
Last Name	
Degrees and credentials	
Title	
Email Address	

* 79. Application Contact

Prefix (Professor, Doctor, Mr., Ms., etc.)	
First Name	
Last Name	
Degrees and credentials	
Title	
Department	
Primary Email	
Alternate Email	
Office Phone (including country code)	
Mailing Street Address	
Street Address Line 2	
City	
State/Province/Territory	
Zip/Postal Code	
Country/Region	
Other Contact (e.g., fax with country code; Skype, WeChat, or Line ID)	

* 80. Organizational Official

Prefix (Professor, Doctor, Mr., Ms., etc.)	
First Name	
Last Name	
Degrees and credentials	
Title	
Department	
Primary Email	
Alternate Email	
Office Phone (including country code)	
Other Contact (e.g., fax with country code; Skype, WeChat, or Line ID)	

Miscellaneous Comments

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

Congratulations on completing your 2024 Annual Report!

When you are ready to submit your final responses, please click "DONE" below. Once you complete the survey, you will not be able to change your responses.

Please contact reporting@aahrpp.org if you have any questions.