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 organizational name would you like to appear on AAHRPP's website?

* 3. What is the address of your Organization?

Street address	
City	
State / Province / Region	
Country	
Zip/Postal Code	

* 4. Does your Organization include any distinct entities (formerly referred to as components) at which human participants research is conducted, which should be identified as part of your Human Research Protection Program (HRPP)? NOTE: Do not include organizations for which the primary relationship between your HRPP and the other organization is reliance upon your IRB/EC.

- ◯ Yes. My Organization has distinct entities (formerly known as components) at which human participants research is conducted.
- ◯ No. My Organization does not have distinct entities (formerly known as components) at which human participants research is conducted.
- ◯ Not Applicable. My Organization is an independent IRB/EC and does not conduct human participants research.

Components/Entities

* 5. Please list each entity (formerly known as components) that should be identified as part of your Organization’s Human Research Protection Program (HRPP).

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

* 6. Where does human participants research that your Organization conducts, reviews, manages and/or sponsors occur?

- ◯ Research activities occur only in my state/province/region within my country
- ◯ Research activities occur in my state and other states/provinces/regions within my country
- ◯ Research activities occur in my state/province/region and countries other than my country
- ◯ Research activities occur in my state/province/region, other states/provinces/regions, and countries other than my country

7. What kind of research does your Organization review, conduct, manage, and/or sponsor? (Note: Estimates are acceptable and must equal 100%).

Percentage of research that is biomedical / clinical

Percentage of research that is social / behavioral / education

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

	Yes	No
Investigational drugs or biologics	◯	◯
Investigational devices	◯	◯

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

- ◯ Yes
- ◯ No

* 10. 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	◯	◯
Employees	◯	◯
Students	◯	◯

Other Vulnerable Populations (please specify)

* 11. Please tell us how the human participant research that your Organization reviews, manages, conducts, and/or sponsors is sponsored (Estimates are acceptable and must equal 100%). What percent of this research is:

Sponsored by the US federal government	
Industry sponsored	
Sponsored by other external sources	
Sponsored by internal sources (including unfunded research)	

* 12. 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)	◯	◯

* 13. Is your Organization based in the United States?

◯ Yes

◯ No

Organizations Outside the US

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

Independent IRBs/ECs

* 15. Is your Organization an independent IRB/EC? NOTE: If your Organization conducts research and also provides IRB/EC review services for other Organizations, your Organization is NOT considered an independent IRB/EC.

- Yes
- No

For Independent IRBs/ ECs (do NOT conduct and/or manage research)

Organizations that are Independent IRBs/ECs

* 16. How many IRBs or ECs does your Organization maintain?

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

* 17. What is the total number of IRB/EC meetings per month for all of your Organization's IRB/ECs combined? If this number varies, please note the approximate number.

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

Total number of FTEs your Organization has dedicated to IRB/EC administration and review functions in the most recent year (the period from January 1 through December 31)

Number of US dollars your Organization has budgeted for IRB/EC administration and review functions 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 new studies:

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

Number of open studies **reviewed at a convened IRB/EC meeting** for 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 outlined in the US Common Rule.

* 20. What was the **number of studies disapproved at initial review** in the most recent year (the period from January 1 through December 31)?

* 21. 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 **unresolved complaints from research participants received**

Number of **new cases of alleged noncompliance evaluated**

Number of **determinations of serious noncompliance made**

Number of **determinations of continuing noncompliance made**

Number of **determinations of unanticipated problems**

* 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 of IRB/EC records/processes conducted internally**

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

Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections conducted at your Organization**

Number of **"for cause" audits of research studies your Organization conducted**

Number of **"not for cause"/random audits of research studies your Organization conducted**

* 23. Please tell us about financial disclosures related to the research your Organization reviewed in the most recent year (the period from January 1 through December 31):

Number of **financial disclosures** made related to research involving human participants

Number of **financial disclosures** made related to research involving human participants that were **determined to indicate a financial conflict of interest**

Number of **studies with a financial conflict of interest management plan** that were reviewed by an IRB/EC

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:

The complete submission to CONVENED BOARD review

The complete submission to CONVENED BOARD approval

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:

The complete submission to the initiation of EXPEDITED REVIEW

The complete submission to approval via EXPEDITED REVIEW

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:

The complete submission to an exemption determination _____

Independent IRB/EC

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

- ◯ Yes
- ◯ No

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

- ☐ My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process.
- ☐ My IRB(s)/EC(s) has a database for tracking IRB/EC submissions.
- ☐ My IRB(s)/EC(s) has an online application for IRB/EC submissions.
- ☐ My IRB(s)/EC(s)'s system has online distribution of review materials to IRB/EC members.
- ☐ My IRB(s)/EC(s)'s system has online IRB/EC review functions.

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

- ◯ Yes
- ◯ No

Use of External IRBs/ECs

For all Organizations that are NOT Independent IRBs/ECs (and conduct and/or manage research)

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

- ◯ Yes
- ◯ No

External IRBs/ECs

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

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

* 35. What is the approximate percentage of your Organization’s human participant research studies reviewed by an external IRB(s)/EC(s)? This percentage should include review of exempt human participants research.

- ◯ < 1-5
- ◯ 6-10
- ◯ 11-20
- ◯ 21-40
- ◯ 41-60
- ◯ 61-80
- ◯ > 80

* 36. Are any of the human participant research studies that your Organization conducts, manages, and/or sponsors reviewed by an external IRB(s)/EC(s) that is not AAHRPP-accredited?

- ◯ Yes
- ◯ No

Not AAHRPP-Accredited External Review

* 37. What is the approximate percentage of human participant research studies that your organization conducts, manages, and/or sponsors is reviewed by an external IRB(s)/EC(s) that is not AAHRPP-accredited? This percentage should include exempt human participants research.

- ◯ < 1-5
- ◯ 6-10
- ◯ 11-20
- ◯ 21-40
- ◯ 41-60
- ◯ 61-80
- ◯ > 80

* 38. 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 Organizations that have internal IRBs/ECs and are NOT Independent IRBs/ECs

Organizations with Internal IRBs/ECs

* 39. How many IRBs/ECs or ECs does your Organization maintain?

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

* 40. What is the total number of IRB/EC meetings a month for all IRBs/ECs combined? If this varies, please note the average during the most recent year (the period from January 1 through December 31).

* 41. Please tell us about the staff and budget for your internal IRBs/ECs. Note this EXCLUDES other components of your HRPP.

Total number of FTEs your Organization has dedicated to IRB/EC administration and review functions in the most recent year (the period from January 1 through December 31)

Number of US dollars your Organization has budgeted for IRB/EC administration and review functions in the most recent year (the period from January 1 through December 31) or last fiscal year

* 42. Please tell us the number of studies that your IRBs/ECs **disapproved** at initial review in the most recent year (the period from January 1 through December 31):

* 43. 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 of IRB(s)/EC(s) records/processes conducted internally**

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

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

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

- [ ] My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process.
- [ ] My IRB(s)/EC(s) has a database for tracking IRB/EC submissions.
- [ ] My IRB(s)/EC(s) has an online application for IRB/EC submissions.
- [ ] My IRB(s)/EC(s)'s system has online distribution of review materials to IRB/EC members.
- [ ] My IRB(s)/EC(s)'s system has online IRB/EC review functions.

* 45. Do you allow other organizations to rely on your internal IRB(s)/EC(s)?

- ◯ Yes
- ◯ No

Veterans Affairs

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

- ◯ Yes
- ◯ No

Veterans Affairs Academic Affiliate

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

- ◯ Yes
- ◯ No

Expedited Review

* 48. 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

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

* 50. 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

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

The complete submission to the initiation of EXPEDITED REVIEW

The complete submission to approval via EXPEDITED REVIEW

Convened Board Review

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

* 53. 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

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

The complete submission to CONVENED BOARD review

The complete submission to CONVENED BOARD approval

For ALL Organizations that are NOT Independent IRBs/

Exempt Human Participants Research

* 55. 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

* 56. 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.

* 57. What is the number of exempt human participants research determinations made, whether by an internal review process (by an internal IRB/EC or other internal HRPP review process) or external IRB/EC, 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.

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

- ◯ Yes
- ◯ No

* 59. Were any of the exemption determinations, regardless of whether they involved the limited IRB review process, made by an internal review process, which could include an internal IRB/EC?

- ◯ Yes
- ◯ No

Timelines for Exemption Determinations

* 60. 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 complete submission to an exemption determination?

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

* 61. 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 **unresolved complaints from research participants received by your HRPP**, which includes any received by an internal IRB/EC

Number of **new cases of alleged noncompliance evaluated through your Organization's internal HRPP process** (which could be by an internal IRB/EC)

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

* 62. 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 that your Organization manages, conducts, reviews, and/or sponsors**

Number of **"not for cause"/random audits your Organization conducted of research studies your Organization manages, conducts, reviews, and/or sponsors**

* 63. Does your Organization centrally track **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, other country regulatory agencies) **inspections of research studies** your Organization manages, conducts, reviews, and/or sponsors?

- ◯ Yes
- ◯ No

Governmental/regulatory agency inspections of researchers

* 64. 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 conducted, managed, reviewed, and/or sponsored in the most recent year (the period from January 1 to December 31)?

Financial Conflicts of Interest

* 65. Can your Organization distinguish between financial disclosures related to research and those made that specifically related to human participants research?

- ◯ Yes
- ◯ No

Financial disclosures were made related to research involving human participants

* 66. In the most recent year (the period from January 1 through December 31), how many financial disclosures were made related to research involving human participants?

Financial Conflicts of Interest

* 67. 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), how many:

Financial disclosures were made related to research involving human participants that were determined to indicate a financial conflict of interest

Studies with a financial conflict of interest management plan were reviewed by an IRB/EC (internal or external)

HRPP Personnel and Budget

* 68. Please tell us about the staff and budget for your HRPP. This EXCLUDES any personnel or budget for internal IRBs/ECs.

Total number of FTEs your Organization has dedicated to the HRPP (excluding IRB/EC)

Number of US dollars your Organization has budgeted for HRPP functions in the most recent year (the period from January 1 through December 31) or last fiscal year

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

Compensation of IRB/EC Members

* 69. Does your Organization provide IRB/EC Chairs with financial or non-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 Compensation

* 70. Please indicate any of the following types of FINANCIAL support your Organization provides IRB/EC 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's home department/clinic for time
- ☐ My Organization does not provide financial support for IRB/EC Chairs.

* 71. Please indicate any of the following types of NON-FINANCIAL support your Organization provides IRB/EC Chairs

- ☐ Food at IRB/EC meetings
- ☐ Thank you or appreciation gifts of nominal value
- ☐ Other, please describe
- ☐ My Organization does not provide any non-financial support for IRB/EC Chairs.

IRB/EC Vice Chair Compensation

* 72. Does your Organization provide IRB/EC Vice Chairs with financial or non-financial compensation?

- ◯ Yes
- ◯ No
- ◯ Not applicable - my Organization's IRBs/ECs do not have Vice Chairs

Type of IRB/EC Vice Chair Compensation

* 73. Please indicate any of the following types of FINANCIAL support your Organization provides IRB/EC 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 Vice Chair's home department/clinic for time
- [ ] My Organization does not provide financial support for IRB/EC Vice Chairs.

* 74. Please indicate any of the following types of NON-FINANCIAL support your Organization provides IRB/EC Vice Chairs

- [ ] Food at IRB/EC meetings
- [ ] Thank you or appreciation gifts of nominal value
- [ ] Other, please describe
- [ ] My Organization does not provide non-financial support for IRB/EC Vice Chairs.

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

* 75. Does your Organization provide Affiliated IRB/EC Members who are not Chairs or Vice Chairs with financial or non-financial compensation?

- ◯ Yes
- ◯ No

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

* 76. 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
- [ ] 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
- [ ] My Organization does not provide financial support for Affiliated IRB/EC Members.

* 77. Please indicate any of the following types of NON-FINANCIAL support your Organization provides for Affiliated IRB/EC Members.

- [ ] Food at IRB/EC meetings
- [ ] Thank you or appreciation gifts of nominal value
- [ ] Other, please describe
- [ ] My Organization does not provide any non-financial support for IRB/EC Affiliated IRB Members.

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

* 78. Does your Organization provide Unaffiliated IRB/EC Members who are not Chairs or Vice Chairs with financial or non-financial compensation?

- ◯ Yes
- ◯ No

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

* 79. 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.

* 80. Please indicate any of the following types of NON-FINANCIAL support your Organization provides for Unaffiliated IRB/EC Members.

- [ ] Food at IRB/EC meetings
- [ ] Thank you or appreciation gifts of nominal value
- [ ] Other, please describe
- [ ] My Organization does not provide any non-financial support for IRB/EC Unaffiliated IRB 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.

* 81. Organizational Changes

- [ ] Change in name of the Organization.
- [ ] Any mergers or acquisitions.
- [ ] Change in the organizational official.
- [ ] 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.
- [ ] No organizational changes.

* 82. 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

* 83. 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

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

Required Reporting

Program Scope Changes

* 85. 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.

* 86. 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

* 87. 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.

88. 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

* 89. 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.

* 90. Person completing this Annual Report

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

* 91. Application Contact

Prefix (Professor, Doctor, Mr., Ms., etc.)	
First Name	
Last Name	
Degrees and credentials	
Title	
Email Address	
Office Phone	
Mailing Street Address	
City	
State/Province	
Zip/Postal Code	
Country	
WeChat ID (if applicable)	
Line ID (if applicable)	
Skype ID (if applicable)	

* 92. Organizational Official

Prefix (Professor, Doctor, Mr., Ms., etc.)	
First Name	
Last Name	
Degrees and credentials	
Title	
Email Address	
Office Phone	
WeChat ID (if applicable)	
Line ID (if applicable)	
Skype ID (if applicable)	

Miscellaneous Comments

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

Congratulations on completing your 2023 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.