

# 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	<input type="radio"/>	<input type="radio"/>
Social / behavioral / education	<input type="radio"/>	<input type="radio"/>

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

	Yes	No
Investigational drugs, biologics, or dietary supplements	<input type="radio"/>	<input type="radio"/>
Investigational devices	<input type="radio"/>	<input type="radio"/>

\* 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	<input type="radio"/>	<input type="radio"/>
Pregnant women	<input type="radio"/>	<input type="radio"/>
Prisoners	<input type="radio"/>	<input type="radio"/>
Adults unable to provide informed consent	<input type="radio"/>	<input type="radio"/>

\* 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	<input type="radio"/>	<input type="radio"/>
Industry sponsored	<input type="radio"/>	<input type="radio"/>
Sponsored by other external sources	<input type="radio"/>	<input type="radio"/>
Sponsored by internal sources (including unfunded research)	<input type="radio"/>	<input type="radio"/>

\* 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)	<input type="radio"/>	<input type="radio"/>
US Department of Education (ED)	<input type="radio"/>	<input type="radio"/>
US Department of Energy (DOE)	<input type="radio"/>	<input type="radio"/>
US Department of Health and Human Services (DHHS)	<input type="radio"/>	<input type="radio"/>
US Department of Justice (DoJ)	<input type="radio"/>	<input type="radio"/>
US Department of Veterans Affairs (VA)	<input type="radio"/>	<input type="radio"/>
US Environmental Protection Agency (EPA)	<input type="radio"/>	<input type="radio"/>
US Food and Drug Administration (FDA)	<input type="radio"/>	<input type="radio"/>

\* 11. 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 adheres to ICH-GCP E6 for all applicable clinical trials
- My organization only adheres to ICH-GCP E6 at a sponsor's request

\* 12. Is your organization based primarily in the United States?

- Yes
- No

### Organizations Outside the US

\* 13. What country-specific laws, regulations, and guidance does your organization apply to research involving human participants?

## Independent IRBs/ECs

\* 14. Is your organization an independent IRB/EC?

NOTE: An independent IRB or EC is an IRB or ethics committee that is not part of an organization that conducts research and 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 or ECs.

Yes

No

**For Independent  
IRBs/ECs**

## Organizations that are Independent IRBs/ECs

\* 15. How many IRBs or ECs does your organization maintain?

1

6

2

7

3

8

4

9

5

10

More than 10 (please specify)

16. 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.

\* 17. 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.

\* 18. Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?

- Yes
- No

\* 19. 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)**

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

\* 20. 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 conducts, reviews, manages, and/or sponsors 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.

\* 21. 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 conducts, manages, reviews, and/or sponsors

Number of **“not for cause”/random/routine post-approval audits of research studies** your organization conducted

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

\* 22. 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** that were reviewed

### Independent IRB/EC - Convened Board

\* 23. 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

\* 24. 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

\* 25. 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

\* 26. 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

\* 27. 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

\* 28. 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

29. 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:*

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

\* 30. 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**



\* 31. 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:**

\* 32. What is the number of open studies (excluding exempt human participants research) reviewed by an external IRB(s)/EC(s)

\* 33. 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.33**

**Not AAHRPP-Accredited External Review**

\* 34. 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.33**

**Non-AAHRPP Accredited External Review - All Human Participants Research**

35. 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

\* 36. 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

\* 37. How many IRBs or ECs does your organization maintain?

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

\* 38. 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)

\* 39. 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

40. 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:*

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

\* 41. Does your organization serve as the reviewing IRB/EC for external organizations conducting research?

- Yes  
 No

## Reviewing IRB/EC

\* 42. 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?

\* 43. Does your organization provide IRB review for a US Department of Veterans Affairs facility?

Yes

No

### Veterans Affairs Academic Affiliate

\* 44. Does your organization serve as the academic affiliate for a Veterans Affairs (VA) facility?

Yes

No

### VA Academic Affiliate

\* 45. My organization serves as an academic affiliate for the following VA facility(ies):

### Expedited Review

\* 46. 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

\* 47. What is the number of open studies reviewed by an internal IRB(s)/EC(s) under **expedited procedures** at initial review?

\* 48. 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**

\* 49. 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**

\* 50. What is the number of open studies reviewed by an internal IRB(s)/EC(s) at a convened meeting at initial review?

\* 51. 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**

\* 52. 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

\* 53. 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

\* 54. 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.

\* 55. 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.

\* 56. Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?

- Yes
- No

\* 57. Does your organization use an internal process to make exempt human participants research determinations?

- Yes
- No

### Exemption Determinations by Internal Review Process

58. 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

\* 59. 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.

\* 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 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  
**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 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

\* 63. 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 studies with a **financial conflict of interest management plan** were reviewed by an IRB/EC (internal or external)?

## Compensation of IRB/EC Chairs

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

\* 64. Does your organization provide IRB/EC 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 Compensation

\* 65. 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

### IRB/EC Vice Chair Compensation

\* 66. Does your organization provide IRB/EC vice chairs with financial compensation?

- Not applicable - my organization's IRBs/ECs do not have vice chairs
- Yes
- No

### Type of IRB/EC Vice Chair Compensation

\* 67. 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

## Compensation for Affiliated 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 **affiliated IRB/EC Members**. (Check all that apply)

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

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

\* 69. Please indicate any of the following types of FINANCIAL support your organization provides for **unaffiliated IRB/EC members**. (Check all that apply)

- |                                                                                                              |                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Salary support (full or partial)                                                    | <input type="checkbox"/> Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees |
| <input type="checkbox"/> Pay for specific activities (e.g., attending IRB meetings, reviews)                 |                                                                                                                                                         |
| <input type="checkbox"/> Stipend/honorarium                                                                  |                                                                                                                                                         |
| <input type="checkbox"/> Other, please describe                                                              |                                                                                                                                                         |
| <input type="text"/>                                                                                         |                                                                                                                                                         |
| <input type="checkbox"/> 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.**

\* 70. Organizational Changes

- |                                                                 |                                                                                                                                                                   |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Change in name of the organization.    | <input type="checkbox"/> Change in the leadership of the Human Research Protection Program (HRPP) (i.e., the individual responsible for the day-to-day operation) |
| <input type="checkbox"/> Any mergers or acquisitions.           |                                                                                                                                                                   |
| <input type="checkbox"/> Change in the organizational official. | <input type="checkbox"/> Change in the application contact.                                                                                                       |
| <input type="checkbox"/> No organizational changes.             |                                                                                                                                                                   |

\* 71. 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

\* 72. 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

\* 73. Please describe the changes in resources in the past 12 months.

## Required Reporting

### Program Scope Changes

\* 74. 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.

\* 75. 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

\* 76. 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.

- |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Catastrophic event that results in an interruption or discontinuance in a component of or the entire HRPP.                                                                                                                                                                                                                                        | <input type="checkbox"/> Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the organization's HRPP. |
| <input type="checkbox"/> 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. | <input type="checkbox"/> No major reportable events.                                                                                                                         |
| <input type="checkbox"/> Any litigation, arbitration, or settlements initiated related to human research protections.                                                                                                                                                                                                                                                      |                                                                                                                                                                              |

77. 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

\* 78. 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.**

**\* 79. Person completing this Annual Report**

Prefix (Professor, Doctor, Mr., Ms., etc.)	<input type="text"/>
First Name	<input type="text"/>
Last Name	<input type="text"/>
Degrees and credentials	<input type="text"/>
Title	<input type="text"/>
Email Address	<input type="text"/>

**\* 80. Application Contact**

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

**\* 81. 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**

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