Guidance on Completing the 2022 Annual Report Form

Question	Explanation of Information Requested
Questions for All Organizations	
What is the legal name of your organization? (Please consult with your general counsel to ensure accuracy and do not use abbreviations)	Please consult with your general counsel to provide the legal name of your Organization.
What organizational name would you like to appear on AAHRPP's website?	If you would like another name other than the legal name of your organization to appear on AAHRPP's website as accredited (https://www.aahrpp.org/learn/find-an-accredited-organization), please provide the name. If the name is the same as your Organization's legal name, please copy the information from the first question here.
What is the address of your organization?	Please provide a central address for your Organization or the address for the office that represents the location of your Organization's leadership (e.g., President, Chancellor, CEO).
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)? (Element I.1.D.)	This question applies only to Organizations that conduct research. AAHRPP previously referred to "Entities" as "Components". Entities are legally separate entities or organizations that are part of your Organization's HRPP. Do not include organizations for which the only relationship is serving as the IRB of record.
Please list each entity (formerly known as components) that should be identified as part of your organization's Human Research Protection Program (HRPP). (Element I.1.D.)	**This question is only presented if the answer selected for the prior question is "Yes. My organization has distinct entities (formerly known as components) at which human participants research is conducted."** Please identify all of the Entities as defined above that are part of your human research protection program. For example, Academic Medical University (AMU) might list AMU Children's Hospital, AMU Psychiatric Hospital, and AMU Rehabilitation Center as Entities because they have distinct leadership and personnel and are sites at which AMU conducts human participants research.
Where does human participants research that your organization conducts, reviews, manages and/or sponsors occur? (Standard I-3)	Select the single option that best describes your Organization. This question is to help AAHRPP identify whether your Organization may need to apply the laws and regulations of other states and countries to research it conducts, reviews, manages, and/or sponsors.
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**	• *Social/behavioral/education research* is defined by topic areas, not methodology. This includes research involving human behavior and social functioning and the social and biological contexts of behavior including such disciplines as sociology, psychology, anthropology, human ecology, history, and communications. Education research is included in this category. • *Biomedical/clinical research* includes research involving human biological function, pathology, or clinical issues, diagnosis, or treatment. Health research, including public health, health services research, and epidemiology should also be included in this category.

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Does your organization review, conduct, manage, and/or sponsor studies involving any of the following? (Element I.7.a) ● **Investigational drugs** ● **Investigational devices**	This question refers to drugs or devices that are investigational or unlicensed test articles. See Element I.7.A. for additional guidance.
Does your organization review, conduct, manage, and/or sponsor planned emergency research? (Element II.4.C.)	**This question only applies to organizations that follow US FDA regulations or US DHHS regulations.** Select "yes" if your Organization conducts, reviews, manages, or sponsors regulated planned emergency research without prior written consent of participants or their legally authorized representatives, even if your Organization does not have an active study of this type but has policies and procedures that permit such research. US FDA guidance describes planned emergency research as investigations that involve human participants who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the research participant and must involve an investigational product that, to be effective, must be administered before informed consent from the research participant or the participant's legally authorized representative can be obtained and in which there is no reasonable way to identify prospectively individuals likely to become eligible for participation.
Does your organization review, conduct, manage, and/or sponsor studies involving any of the following vulnerable participant populations? (Element II.4.A.)	Select the categories based on research your Organization reviews, conducts, manages, or sponsors that permits the inclusion of the populations identified below regardless of whether the research is social, behavioral, education, biomedical, or clinical. • Children • Pregnant women • Prisoners • Adults unable to provide informed consent • Employees • Students If "Other" is selected, please describe the additional population(s) that your Organization identifies as a vulnerable.

Question	Explanation of Information Requested
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)**	• *Sponsored by the US federal government*: this includes research funded in any way by the US federal government or US federal agency. Do NOT include research sponsored by other governments (such as a US state or a government outside the US) in this category. • *Industry sponsored*: this includes research that is funded in any way by a company. • *Sponsored by other external sources*: this includes research funded all or in part by foundations or private donors. Any research not funded in any way by a company, US federal agency, or US federal government. This can also include research sponsored by other governments such as US state government or a government outside the US. • *Sponsored by internal sources (including unfunded research)*: this includes research funded or supported by your Organization or other internal sources. Internal sources include unfunded research that is supported by the Organization by providing space and other resources for infrastructure.
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. ● **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)**	• This question helps AAHRPP identify which US regulations your Organization must apply to research it reviews, manages, conducts or sponsors. AAHRPP recognizes that Organizations may infrequently have research that must comply with certain regulations. Even if your Organization does not have studies that are open that fall under certain regulations, please select those regulations if your Organization may need to apply them to research it reviews, manages, conducts or sponsors. • Note for the **US Department of Defense** regulations: select this regulation if your Organization reviews, manages, or conducts research under a US Department of Defense Addendum from any branch of the military. • Note for the **US Department of Veterans Affairs** regulations and guidance: for VA facilities, this would apply to all research; for academic affiliates, this would apply to VA research only.
Is your organization based in the United States?	This question helps to identify whether an Organization generally reviews, conducts, manages, and/or sponsors research outside of the US and thus needs to comply with other or additional laws and regulations than US-based Organizations.
What country-specific laws, regulations, and guidance does your organization apply to research involving human participants?	**Only Organizations that respond "no" to the prior question will be asked to respond to this question.** Please identify the laws, regulations, and guidance that your Organization must apply to human participants research that it reviews, conducts, manages, and/or sponsors. If your Organization complies with US regulations as well, you do not need to include that information here.
Is your organization an independent IRB/EC?	Select "yes" if your Organization is an IRB or ethics committee that is not owned or operated by the research organization for which it provides review services.

Question	Explanation of Information Requested
Questions for Independent IRBs/ECs - *If you responded "no" to the prior question you will skip these questions.*	
How many IRBs/ECs or ECs does your organization maintain?	This question will help AAHRPP identify the number of committees or panels your Organization supports that conduct IRB/EC review. For most organizations, committees generally have a roster limited to the number of people on the committee, and limited number of alternate members. Most organizations define multiple committees, each of which have separate membership (e.g., a biomedical IRB and a social science IRB). But some organizations define a single IRB, which has many members (e.g., 100 members) where only a small number attend each meeting, and where the membership may vary considerably. In this approach there are often "panels" that meet, or "subcommittees" of the IRB. For example, your Organization might have three IRB panels with different members. In this case, you would report that you have 3 IRBs. Do not include in this number committees that do not review research.
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.	Indicate the number of meetings your IRB(s)/EC(s) holds each month. If you have multiple IRB/EC committees/panels as described above, indicate the approximate number of meetings they hold per month, combined.
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**	• *For the IRB/EC FTEs:* Indicate the estimated total number of full time employees (FTEs) dedicated to supporting IRB(s)/EC(s) functions, including faculty, executives, and administrative staff. Include portions of FTE for IRB/EC members, chairs, and vice chairs who are employees of your Organization and add the portions to obtain a total number of FTEs. • *For the IRB/EC budget:* Indicate the estimated total number of US dollars dedicated to your IRB(s)/EC(s). This should include both personnel and non-personnel costs. Include portions of salaries for IRB/EC members, chairs, and vice chairs that are employees of your Organization. The budget information can be provided for either the last full year or fiscal year, whichever is easier for your Organization to provide.
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.**	• *Open studies* means that studies that your IRB(s)/EC(s) has not closed (e.g., due to lack of action on the part of a sponsor or study team, such as failure to submit a closure report). • *For open studies reviewed via expedited procedures* count the number of open studies reviewed and approved outside of your Organization's convened IRB/EC meeting review process. These are generally minimal risk studies. • *For open studies reviewed at a convened IRB/EC meeting* count the number of open studies reviewed by your Organization's convened IRB/EC when the IRB/EC first reviewed and approved the study. These are generally greater than minimal risk studies. • *For exempt human participants determinations* (Element II.2.A. and III.2.B.) count the number of studies determined to be exempt human participants research in the most recent complete year (e.g., January 1 through December 31, 2021). If your Organization has determined a study to be exempt using the limited IRB review process (Element II.2.C.) permitted under the US Common Rule, include those studies in this count.

Question	Explanation of Information Requested
What was the number of studies disapproved at initial review in the most recent year (the period from January 1 through December 31)?	Count the number of studies a convened IRB/EC voted to disapprove in the most recent complete year (e.g., January 1 through December 31, 2021).
Please tell us about your IRB/EC's review of reportable events within the most recent year (the period from January 1 through December 31) (Element I.5.D.and II.2.G.) **● 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 made**	• *For unresolved complaints*: Provide the number of unresolved complaints from research participants that your Organization has received in the most recent 12 months. A complaint is an expression of dissatisfaction, protest, or outcry related to a research study, researchers or research staff, or the IRB/EC. Unresolved means a complaint that cannot be resolved by the research team or the relying organization. If the complaint is about the IRB/EC, the complaint cannot be resolved by IRB/EC administrative staff and must be reviewed by the IRB/EC. • *For alleged noncompliance:* Indicate the number of new cases of alleged noncompliance investigated by your Organization in the most recent complete year (the period from January 1 through December 31). This includes cases that subsequently were not deemed noncompliance, were deemed noncompliance (whether or not the noncompliance was also determined to be serious or continuing noncompliance). • *For serious noncompliance:* Indicate the number of cases in the most recent complete year (the period from January 1 through December 31) of noncompliance that were determined by your Organization to be **serious**, such as under US federal regulations, other laws or regulations, or institutional policy. • *For continuing noncompliance*: Indicate the number of cases in the most recent complete year (the period from January 1 through December 31) of noncompliance that were determined by your Organization to be **continuing**, such as under US federal regulations, other laws or regulations, or institutional policy. • *For unanticipated problems*: Indicate the number of determinations in the most recent complete year (the period from January 1 through December 31) made by your Organization an event constituted an **unanticipated problem**, such as under US federal regulations, other laws or regulations, or institutional policy.

Question	Explanation of Information Requested
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**	• *For internal "for cause" audits of IRB/EC records*: "For cause" means an audit prompted by some information, a complaint, or an event related to the IRB/EC review. An internal audit is one conducted by personnel within your Organization (e.g., an internal auditing monitoring group or IRB/EC staff). • *For internal "not for cause" audits of IRB/EC records*: "Not for cause" or random means there was no particular reason for choosing records to audit; the studies or records are selected by chance. Not for cause audits are conducted as a part of your Organization's ongoing quality assurance program. • *For governmental or regulatory agency inspections of IRB(s)/EC(s)*: These are audits or inspections of your Organization's IRB(s)/EC(s) conducted by US regulatory agencies or other country regulatory agencies. Include all inspections regardless of the outcome of the inspection. • *For "for cause" audits of research studies*: "For cause" means an audit your Organization conducted prompted by some information, a complaint, or an event related to an investigator or research study overseen by your Organization's IRB(s)/EC(s). • *For internal "not for cause" audits of research studies*: "Not for cause" or random means there was no particular reason for conducting an audit of the conduct of an investigator or research study overseen by your Organization's IRB(s)/EC(s). Not for cause audits are conducted as a part of your Organization's ongoing quality assurance program.
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): (Element I.6.B.) ● **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**	• *For number of financial disclosures*: This refers to financial disclosures collected as part of your Organization's IRB/EC review process. • *For number of financial disclosures determined to indicate a financial conflict of interest*: This refers to financial disclosures your Organization received that were determined to represent a financial conflict of interest through the process your Organization uses to assess financial disclosures. • *For number of management plans*: This refers to management plans for financial conflict of interest that your Organization's IRB(s)/EC(s) reviewed whether the management plan was developed by your Organization or an Organization relying on your Organization's IRB(s)/EC(s).
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)?	Select "yes" if any study was approved by your Organization's IRB(s)/EC(s) at initial review at a committee meeting. This is referred to as a convened board meeting or reviewed by the full IRB/EC.

Question	Explanation of Information Requested
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**	• *For complete submission to convened board review*: This time period is measured from receipt of a complete study application via the designated IRB/EC submission process to the first time the study is reviewed at a convened IRB/ EC meeting. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC. • *For complete submission to convened board approval*: This time period is measured from receipt of a complete study application via the designated IRB/EC submission process to the day all requests made by the IRB/EC to secure approval, if any, has been resolved and the researcher is allowed to conduct the study. If a study is approved without contingencies or modifications at a convened board meeting, this would be the date of convened board approval. If a study is approved with contingencies or modifications that must be made before the researcher is allowed to conduct the study, the date of approval is when all modifications or contingencies have been resolved. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC.
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)?	Select "yes" if any study was approved by your Organization's IRB(s)/EC(s) at initial review outside of a committee meeting, sometimes referred to as a non-committee review process. This does NOT include studies reviewed using the limited IRB review process described in the US Common Rule.
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**	• *For complete submission to initiation of expedited review*: This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s). • *For complete submission to approval*: This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review to when all conditions are met to secure IRB/EC approval and the research can begin to conduct the study. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s).
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)?	Select "yes" if a study was determined by your Organization at initial review to be exempt human participants research. Note that this includes exempt human participants research reviewed using the limited IRB review process.
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**	This time period is measured from when a complete study application is assigned to a designated reviewer and determined to be exempt human participants research. *Complete submission* means the study application received by your Organization has been determined, by whatever process used, to be ready for exempt review.

Question	Explanation of Information Requested
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) has online distribution of review materials to IRB/EC members.** ● **My IRB(s)/EC(s) has online IRB/EC review functions.**	• If your Organization does not use an electronic (computer system) to support any component of the review process, select "**My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process."** • *For database for tracking IRB/EC submissions*: This refers to an online platform or system that allows your Organization to identify on an ongoing basis applications submitted for IRB/EC review. This could include a system that tracks research that is reviewed by an external IRB(s)/EC(s). • *For online application for IRB/EC submissions*: This refers to an online platform or system that allows research teams to prepare and/or submit their applications for IRB/EC review. • *For online distribution of review materials to IRB/EC members*: This refers to an online platform or system that allows IRB/EC members to be assigned or access materials for their review. • *For online application for IRB/EC review functions*: This refers to an online platform or system that allows IRB/EC members and staff to communicate about protocols and other related materials document or record their decisions and study-specific determinations.
Does your IRB(s)/EC(s) compensate any IRB/EC members?	Select "yes" if your Organization provides financial or nonfinancial compensation for any of the following: your IRB/EC Chairs, IRB/EC Vice Chairs, Affiliated IRB/EC Members, Unaffiliated IRB/EC members.
Questions for Organizations that are not Independent IRBs/ECs	
Does your organization use one or more external IRBs/ECs to review some or all of its human participants research? (Standard I-9)	Select "yes" if your Organization uses an IRB/EC that is not operated by your Organization, such as an independent IRB/EC, another university's or hospital's IRB/EC, either for all of its ethics reviews or only some of its ethics reviews.
What is the number of open studies (excluding exempt human participants research) reviewed by an external IRB(s)/EC(s)? (Standard I-9)	Count the number of open studies reviewed by an external IRB(s)/EC(s) (regardless of when the study was first approved). *Open studies* means that studies that have not been closed by the IRB/EC. Do NOT include studies determined by an external IRB(s)/EC(s) to be exempt human participants research.
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. (Standard I-9)	Calculate the percentage of all of the human participants research your Organization conducts, manages, or sponsors that is reviewed by an external IRB(s)/EC(s). AAHRPP views all of your Organization's human participants research as including studies determined to be exempt research.
What is the approximate percentage of external IRBs/ECs that your organization relies upon that are NOT AAHRPP-accredited? (Standard I-9)	Of all the external IRBs/ECs your Organization relies on to review human participants research, including any exempt research, calculate the percentage of IRBs/ECs that have not been accredited by AAHRPP. To find out if an Organization is AAHRPP-accredited, go to https://www.aahrpp.org/learn/find-an-accredited-organization.

Question	Explanation of Information Requested
Please select the statement that best describes your organization's ethical review process: (Standard I-9) ● **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.**	• If your Organization does not have any internal review process for human participants research, select: ***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***. • If your Organization uses an internal review process only to review exempt human participants research, select: **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.** • If your Organization is willing to rely on external IRB(s)/EC(s) for the human participants research including for exempt research determinations, select: **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.** • If your Organization is willing to rely on external IRB(s)/EC(s) for the human participants research except for exempt research determinations, select: **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.**
Questions for Organizations that have internal IRBs/ECs and are not Independent IRBs/ECs	
How many IRBs/ECs or ECs does your organization maintain?	This question is trying to identify the number of committees or panels your Organization supports that conduct IRB/EC review. For example, if your Organization might have three IRB panels with distinct Chairs and distinct meeting schedules but some overlapping membership. In this case, you would report that you have 3 IRBs. Another example would be Organizations that have IRBs/ECs with distinct functions, such as a biomedical IRB, social/behavioral IRB, and a phase 1 IRB, with distinct review portfolios. Each of these committees would be identified as an IRB and could also have panels. In this case, if the biomedical IRB had two panels, the total number of IRBs/ECs would be 4 (two biomedical IRBs, one social behavioral IRB, and one phase 1 IRB). Do not include in this number committees that do not review research.
What is the total number of IRB/EC meetings a month for all IRBs/ECs combined? If this varies, please note the approximate number.	Indicate the number of meetings your IRB(s)/EC(s) holds each month. If you have multiple IRB/EC committees/panels as described above, indicate the average number of meetings they hold per month.

Question	Explanation of Information Requested
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**	• *For the IRB/EC FTEs:* Indicate the estimated total number of full time employees (FTEs) dedicated to supporting IRB(s)/EC(s) functions, including faculty, executives, and administrative staff. Include portions of FTE for IRB/EC members, chairs, and vice chairs who are employees of your Organization and add the portions to obtain a total number of FTEs. • *For the IRB/EC budget:* Indicate the estimated total number of US dollars dedicated to your IRB(s)/EC(s). This should include both personnel and non-personnel costs. Include portions of salaries for IRB/EC members, chairs, and vice chairs that are employees of your Organization. The budget information can be provided for either the last full year or fiscal year, whichever is easier for your Organization to provide.
Please tell us the number of studies that your IRB/EC disapproved at initial review in the most recent year (the period from January 1 through December 31)	Count the number of studies a convened IRB/EC voted to disapprove in the most recent complete year (e.g., January 1 through December 31, 2021).
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 of IRB(s)/EC(s) at your organization**	• *For internal "for cause" audits of IRB/EC records*: "For cause" means an audit prompted by some information, a complaint, or an event related to the IRB/EC review. An internal audit is one conducted by personnel within your Organization (e.g., an internal auditing monitoring group or IRB/EC staff). • *For internal "not for cause" audits of IRB/EC records*: "Not for cause" or random means there was no particular reason for choosing records to audit; the studies or records are selected by chance. Not for cause audits are conducted as a part of your Organization's ongoing quality assurance program. • *For governmental or regulatory agency inspections*: These are audits or inspections of your Organization's IRB(s)/EC(s) conducted by the US government, US regulatory agencies, other country's governments, or other country's regulatory agencies. Include all inspections within the most recent year regardless of their outcome.

Question	Explanation of Information Requested
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) has online distribution of review materials to IRB/EC members.** ● **My IRB(s)/EC(s) has online IRB/EC review functions.**	• If your Organization does not use an electronic (computer system) to support any component of the review process, select "**My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process."** • *For database for tracking IRB/EC submissions*: This refers to an online platform or system that allows your Organization to identify on an ongoing basis applications submitted for IRB/EC review. This could include a system that tracks research that is reviewed by an external IRB(s)/EC(s). • *For online application for IRB/EC submissions*: This refers to an online platform or system that allows research teams to prepare and/or submit their applications for IRB/EC review. • *For online distribution of review materials to IRB/EC members*: This refers to an online platform or system that allows IRB/EC members to be assigned or access materials for their review. • *For online application for IRB/EC review functions*: This refers to an online platform or system that allows IRB/EC members and staff to communicate about protocols and other related materials document or record their decisions and study-specific determinations.
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.	Select "yes" if your Organization's IRB(s)/EC(s) may review human participants research outside of a committee meeting, sometimes referred to as a non-committee review process. This does NOT include the review of exempt human participants research.
What is the number of open studies reviewed by an internal IRB(s)/EC(s) under expedited procedures at initial review?	• *Open studies* means that studies that have not been reported as closed or complete to your IRB(s)/EC(s) or that your IRB(s)/EC(s) has not closed (e.g., due to lack of action on the part of a sponsor or study team, such as failure to submit a closure report). • *For open studies reviewed via expedited procedures* count the number of open studies reviewed and approved outside of your Organization's convened IRB/EC review process. These are generally minimal risk studies.
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**	• *For complete submission to initiation of expedited review*: This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s). • *For complete submission to approval*: This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review to when all conditions are met to secure IRB/EC approval and the research can begin to conduct the study. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s).

Question	Explanation of Information Requested
What is the number of open studies reviewed by an internal IRB(s)/EC(s) at a convened meeting at initial review?	• *Open studies* means that studies that have not been reported as closed or complete to your IRB(s)/EC(s) or that your IRB(s)/EC(s) has not closed (e.g., due to lack of action on the part of a sponsor or study team, such as failure to submit a closure report). • Count the number of open studies reviewed by your Organization's convened IRB/EC at when the IRB/EC first reviewed and approved the study. These are generally greater than minimal risk studies.
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**	• *For complete submission to convened board review*: This time period is measured from receipt of a complete study application via the designated IRB/EC submission process to the first time the study is reviewed at a convened IRB/ EC meeting. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC. • *For complete submission to convened board approval*: from receipt of a complete study application via the designated IRB/EC submission process to the day all requests made by the IRB/EC to secure approval, if any, has been resolved and the researcher is allowed to conduct the study. If a study is approved without contingencies or modifications at a convened board meeting, this would be the date of convened board approval. If a study is approved with contingencies or modifications that must be made before the researcher is allowed to conduct the study, the date of approval is when all modifications or contingencies have been resolved. *Complete submission* means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC.
Questions for Organizations that are not Independent IRBs/ECs	
Do the laws, regulations, codes, and guidance under which your organization conducts or reviews human participants research allow this research to be determined exempt? (Element II.2.A. and Element II.2.B.)	Select "yes" if your Organization can either conduct human participants research or make a determination that human participants research is exempt from the Common Rule or IRB/EC review.

Question	Explanation of Information Requested
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.**	• If your Organization only permits human participants research to be determined exempt research or only conducts exempt research under the categories outlined in the Common Rule or US FDA regulations, select: *My organization solely allows exempt human participants research determinations as outlined within US regulations.* • If your Organization has a policy that creates additional categories of exempt human participants research not found in the Common Rule, select: *My organization allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.* • If your Organization has a policy or applies regulations other than the US Common Rule that permits the conduct of exempt research or the determination that human participants research is exempt, select: *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.*
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.	Count the number of studies determined to be exempt human participants research in the most recent complete year (e.g., January 1 through December 31, 2021). If your Organization has determined a study to be exempt using the limited IRB review process permitted under the US Common Rule, include those studies in this count. This count does not include determinations that activities are not human participants research.
Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?	The limited IRB review process is permitted by the US Common Rule and is only relevant for certain exempt research. Limited IRB review does not require an IRB to consider all of the IRB approval criteria in outlined in the Common Rule. In limited IRB review, the IRB must determine that certain conditions related to privacy protections, which are specified in the regulations, are met.
Were any of the exemption determinations made by an internal review process, which could include an internal IRB/EC?	Select "yes" if individuals within your Organization made some or all determinations that human participants research is exempt. AAHRPP recognizes that in the US, many Organizations require that representatives of an IRB (e.g., an IRB Chair or IRB staff) determine whether research involving human participants meets the criteria for exemption under US federal regulations and/or institutional policy. However, others within an Organization also may make exempt research determinations, such as individuals in a School of Education trained to make such evaluations.

Question	Explanation of Information Requested
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?	*For complete submission to exemption determination*: This time period is measured from when a complete study application is assigned to a designated reviewer and is determined to be exempt human participants research. *Complete submission* means the study application received by your Organization has been determined, by whatever process used, to be ready for exempt review.

Question	Explanation of Information Requested
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**	• *For unresolved complaints*: Provide the number of unresolved complaints from research participants that your Organization has received in the most recent 12 months. A complaint is an expression of dissatisfaction, protest, or outcry related to a research study, researchers or research staff, or the IRB/EC. Unresolved means a complaint that cannot be resolved by the research team or the relying organization. If the complaint is about an IRB/EC that is internal to your Organization, this would be a complaint that cannot be resolved by your Organization's IRB/EC staff and must be reviewed by the IRB/EC. If the complaint is about an external IRB/EC that is your Organization uses, this would be a complaint that the external IRB/EC Organization could not resolve. • *For alleged noncompliance:* Indicate the number of new cases of alleged noncompliance that were investigated by your Organization's noncompliance process, which could be by a local IRB/EC or other Human Research Protection Program function if your Organization does not have an internal IRB/EC. This includes cases investigated in the most recent complete year (the period from January 1 through December 31) that subsequently were not deemed noncompliance, were deemed noncompliance (whether or not the noncompliance was also determined to be serious or continuing noncompliance). If you use any external IRBs/EC(s), include noncompliance cases they investigated related to research your Organization conducts, manages, or sponsors. • *For serious noncompliance:* Indicate the number of cases in the most recent complete year (the period from January 1 through December 31) of noncompliance that were determined by your noncompliance process to be **serious**, such as under US federal regulations, other laws or regulations, or institutional policy. If you use any external IRB(s)/EC(s), include **serious** noncompliance determinations they made on behalf of your Organization. (Element I.5.D.) • *For continuing noncompliance*: Indicate the number of cases in the most recent complete year (the period from January 1 through December 31) of noncompliance that were determined by your noncompliance process to be **continuing**, such as under US federal regulations, other laws or regulations, or institutional policy. If you use any external IRB(s)/EC(s), include **continuing** noncompliance determinations they made on behalf of your Organization. • *For unanticipated problems*: Indicate the number of determinations in the most recent complete year (the period from January 1 through December 31) made by your Organization that an event constituted an **unanticipated problem**, such as under US federal regulations, other laws or regulations, or institutional policy. If you use any external IRB(s)/EC(s), include **unanticipated problems** they made on behalf of your Organization. (Element II.2.G.)

Question	Explanation of Information Requested
Please tell us about other compliance activities 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, other country regulatory agencies) inspections of research studies your organization manages, conducts, reviews and/or sponsors** ● **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**	• *For governmental or regulatory agency inspections of research studies:* These are audits or inspections by the US government, US regulatory agencies, other country's governments, or country's regulatory agencies of studies your Organization manages, conducts, reviews or sponsors. These inspections can be for cause or random. Include all inspections within the most recent year regardless of their outcome. • *For "for cause" audits of research studies*: "For cause" means an audit your Organization conducted prompted by some information, a complaint, or an event related to an investigator or research study overseen by your Organization's IRB(s)/EC(s). • *For internal "not for cause" audits of research studies*: "Not for cause" or random means there was no particular reason for conducting an audit of the conduct of an investigator or research study overseen by your Organization's IRB(s)/EC(s). Not for cause audits are conducted as a part of your Organization's ongoing quality assurance program.
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: (I.6.B) ● **Financial disclosures were made related to research involving human participants** ● **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)**	• *For number of financial disclosures*: This refers to financial disclosures collected as part of the process your Organization uses to identify financial conflicts of interest related to human participants research. • *For number of financial disclosures determined to indicate a financial conflict of interest*: This refers to financial disclosures made researchers or research staff under the purview of your Organization determined by your Organization's process (person or committee) to indicate a financial conflict of interest related to the research. This information is usually provided by the Conflict of Interest Committee or Office staff. • *For number of management plans*: This refers to studies reviewed by internal or external IRB(s)/EC(s) for which a management plan related to financial conflict of interest was put in place.

Question	Explanation of Information Requested
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 the HRPP FTEs:* Indicate the total number of FTEs dedicated to your HRPP, other than the IRB/EC. Include portions of FTE and add the portions to obtain a total number of FTEs. Consider the policies and procedures submitted for your HRPP – include the personnel resources (FTEs) needed to perform those policies and procedures on an annual basis (excluding IRB/EC related personnel). Use the key personnel list that is submitted with the Step 2 application as a basis for counting the total number of FTEs that comprise your HRPP. • *For the HRPP budget:* Indicate the total number of US dollars dedicated to your HRPP, excluding the IRB/EC. This should include both personnel and non-personnel costs. Include portions of salaries for HRPP administrative time for faculty and executives. The budget information can be provided for either the last full year or fiscal year, whichever is easier for your Organization to provide.
Question for All Organizations	
Does your organization provide IRB/EC Chairs with financial or non-financial compensation?	• If your Organization does not have an internal IRB/EC, select "Not applicable - my organization does not have an internal IRB/EC and is not an independent IRB/EC". • If your Organization has an internal IRB(s)/EC(s), but provides neither financial nor non-financial compensation, select "No". Examples of financial compensation include: ○ Salary support (full or partial) ○ Pay for specific activities (e.g., conducting IRB meeting, reviews) ○ Stipend/honorarium ○ 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 Examples of non-financial compensation include: ○ Food at IRB/EC meetings ○ Thank you or appreciation gifts of nominal value

Questions for Organizations that are Independent IRBs/ECs or have internal IRBs/ECs	
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 meeting, reviews)** ● **Stipend/honorarium** ● **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** ● **Other, please describe** ● **My organization does not provide financial support for IRB/EC Chairs**	Please select all forms of financial support that your Organization's IRB/EC chairs may receive. If other forms of financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.
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 non-financial support for IRB/EC Chairs**	Please select all forms of non-financial support that your Organization's IRB/EC chairs may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.
Does your organization provide IRB/EC Vice Chairs with financial or non-financial compensation?	If your Organization does not have Vice Chairs for your IRB(s)/EC(s), select "Not applicable - my organization's IRBs/ECs do not have Vice-Chairs".
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 meeting, reviews)** ● **Stipend/honorarium** ● **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** ● **Other, please describe** ● **My organization does not provide financial support for IRB/EC Vice Chairs**	Please select all forms of financial support that your Organization's IRB/EC Vice Chairs may receive. If other forms of financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.

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**	Please select all forms of non-financial support that your Organization's IRB/EC Vice Chairs may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.
Does your organization provide Affiliated IRB/EC Members who are not Chairs or Vice Chairs with financial or non-financial compensation?	Affiliated members include, but are not limited to, individuals who have the following relationship with your Organization: employee; current student; members of any governing panel or board of the Organization; paid or unpaid consultants; healthcare providers holding credentials to practice at your Organization; and volunteers working at your Organization on business unrelated to the IRB/EC.
Please indicate any of the following types of FINANCIAL support your organization provides Affiliated IRB/EC Members. (Check all that apply) ● **Salary support (full or partial)** ● **Pay for specific activities (e.g., conducting IRB meeting, reviews)** ● **Stipend/honorarium** ● **Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees** ● **Reimbursement of the IRB/EC Affiliated IRB/EC Member's home department/clinic for time** ● **Other, please describe** ● **My organization does not provide financial support for Affiliated IRB/EC Members**	Please select all forms of financial support that your Organization's Affiliated IRB/EC members may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.
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 non-financial support for Affiliated IRB/EC Members**	Please select all forms of non-financial support that your Organization's Affiliated IRB/EC members may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.

Does your organization provide Unaffiliated IRB/EC Members with financial or non-financial compensation?	An individual is considered unaffiliated if they have no affiliation with the Organization other than as an IRB/EC member. Unaffiliated IRB/EC members may include people whose only association with the institution is that of a patient, research participant, or former student at that institution. Paying unaffiliated IRB/EC members for their services would not make the member "otherwise affiliated".
Please indicate any of the following types of FINANCIAL support your organization provides Unaffiliated IRB/EC Members. (Check all that apply) ● **Salary support (full or partial)** ● **Pay for specific activities (e.g., conducting IRB meeting, reviews)** ● **Stipend/honorarium** ● **Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees** ● **Other, please describe** ● **My organization does not provide financial support for Unaffiliated IRB/EC Members**	Please select all forms of financial support that your Organization's Unaffiliated IRB/EC members may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.
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 non-financial support for Unaffiliated IRB/EC Members**	Please select all forms of non-financial support that your Organization's Unaffiliated IRB/EC members may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.

Questions for All Organizations	
Indicate if any of the following changes have occurred in your organization in the last year by checking the box. **Organizational Changes** **● Change in name of the organization.** **● Any mergers or acquisitions.** **● Change in the organizational official.** **● Change in the leadership of HRPP (i.e., the individual responsible for the day-to-day operation)** **● Change in the application contact.** **● No organizational changes.**	If none of the changes on the list have occurred, select: "**No organizational changes.**" Otherwise select all categories of changes that may apply to your Organization. You will be prompted to describe those changes.

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".	• Please provide sufficient detail to allow AAHRPP to understand the potential impact of these changes on your HRPP.
	• For changes in the organizational official or the application contact, please identify who they replaced.
	• For changes in the leadership of HRPP please indicate who was replaced and provide the following for the person now fulfilling that role:
	  ○ First and last name
	  ○ Title
	  ○ Degree(s)
	  ○ Mailing address
	  ○ Email
	  ○ Telephone

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?	• If your Organization has not experienced a change in resources supporting its HRPP, select: "**No.**" Otherwise select all categories that may apply to your Organization. You will be prompted to describe those changes.
Please describe the changes in resources in the past 12 months:	• Please provide sufficient detail to allow AAHRPP to understand the potential impact of any changes in resources on your HRPP.
Indicate if any of the following Program Scope Changes pertaining to the Human Research Protection Program (HRPP) have occurred in your organization in the last year by checking the box. **● Addition of new research programs (e.g., 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 Human Research Protection Program.** **● No program scope changes.**	• This question helps AAHRPP the need for changes in its approach to assessing your Organization's HRPP (e.g., length of site visit or site visitor expertise needed). • If your Organization has not experienced a change in HRPP scope, select: "**No program scope changes.**" Otherwise select all categories of changes that may apply to your Organization. You will be prompted to describe those changes.

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".	Please provide sufficient detail to allow AAHRPP to understand the potential impact of any changes in program scope on your HRPP.
Indicate if any of the following MAJOR EVENTS pertaining to the Human Research Protection Program (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 Human Research Protection Program.** ● **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 Investigators, 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 Human Research Protection Program.** ● **No major reportable events.**	If none of the changes on the list have occurred, select: "**No major reportable events.**" Otherwise select all categories of events that may have occurred related to your HRPP. You will be prompted to describe those events that your Organization has not reported to AAHRPP previously.
Did you already report all of the events checked above to AAHRPP?	
Please provide a summary of the major events that you have not previously reported.	Please provide sufficient detail to allow AAHRPP to understand the potential impact of any events on your HRPP. If you previously reported an event(s), you do not need to describe it here.
Person completing this Annual Report	
Application Contact	
Organizational Official	
Please use this space for additional comments or clarifications.	If you feel like any of your responses in this form require explanation, please describe those here.