Guidance on Completing the 2025 Annual Report Form

Please note that AAHRPP emails organizations with the link to the Annual Report Form, which is now an online survey.

AAHRPP Definitions:

Institutional Review Board (IRB) or Ethics Committee (EC): a body established generally under laws, regulations, codes, and guidance to protect the rights and welfare of human research participants. AAHRPP refers to this as an IRB/EC, but your organization may use a different term.

Independent IRB or EC: 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.

> Note: IRBs embedded within the organization that may conduct research (such as academic organizations, hospitals, or health systems) are NOT considered independent IRBs or ECs.
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> Note: You can check how AAHRPP classifies your organization's "Type" (e.g., hospital, academic institute, independent IRB, etc.) on AAHRPP's website at Find an Accredited Organization.

Timeframes:

- *January 1– December 31*. If submitting the Annual Report in June 2024, an organization would use for these questions the timeframe January 1, 2023 – December 31, 2023. This timeframe is used for most questions.
- Counting the number of convened, expedited, or external protocols: Please provide the number of open studies at the time you submit your Annual Report. *Open studies* means 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).
- In the most recent 12 months: For the Required Reporting Form at the end of the Annual Report, please use the most recent 12 months since the date that you submit your Annual Report.

Question	Explanation of Information Requested
Questions for All Organizations	
What is the legal name of your organization?	Please consult with your general counsel to provide the legal name of your organization.
What is your organization's preferred name?	The preferred name may be used on all correspondence, including your certificate, reports, and the AAHRPP website. (https://www.aahrpp.org/find-an-accredited-organization). If the preferred 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).
Where does human participants research that your organization conducts, reviews, manages and/or sponsors occur? (Standard I- 3) (Select all that apply)	This question helps 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. The location where your organization is primarily based is where its major operations, including their review, management, conduct, or sponsorship of research, are located.

Question	Explanation of Information Requested
What kind of research does your organization review, conduct, manage, and/or sponsor? (Select all that apply) ● **Biomedical/clinical** ● **Social/behavioral/education**	• *Biomedical/clinical research* is defined by topic areas, not methodology, and 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. • *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.
Does your organization review, conduct, manage, and/or sponsor studies involving any of the following? (Element I.7.A.) ● **Investigational drugs, biologics, or dietary supplements** ● **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, and/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. • Select "no" if your organization either a) does not conduct, review, or manage research regulated by the US FDA; or b) conducts, reviews, or manages research regulated by the US FDA but specifically does not conduct, review, or manage planned emergency research. Note: 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

Question	Explanation of Information Requested
What type(s) of funding does your organization receive for the review, management, conduct, and/or sponsorship of human participants research?	• *Sponsored by the US federal government*: this includes research funded in any way by the US federal government or US federal agency or conducted by a federal agency or department. Research sponsored by other governments (such as a US state or a government outside the US) would not apply to this category. • *Industry sponsored*: this includes research that is funded in any way by a company from full to partial monetary support. This does not include cases where the involvement of a company or entity is limited such as to the provision of a drug, biologic, device, or technology for a project. • *Sponsored by other external sources*: this includes research funded all or in part by foundations or private donors. This can also include research sponsored by other governments such as US state government or a government outside the US. This does not include research that is fully funded by a company or the US federal government. • *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)** ● **US National Science Foundation (NSF)**	• This question helps AAHRPP identify which US regulations your organization must apply to research it reviews, manages, conducts and/or sponsors. AAHRPP recognizes that organizations may infrequently have research that must comply with certain regulations. Even if your organization does not have open studies that fall under certain regulations, please select those regulations if your organization may need to apply them to research it reviews, manages, conducts, and/or sponsors. Open studies means 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). • Note for the **US Department of Defense** regulations: select this regulation if the research is conducted or supported by the DoD. • Note for the **US Department of Education** regulations: select this regulation if the research is conducted or supported by the DoE. • Note for the **US Department of Energy** regulations: select this regulation if the research is funded by DOE, conducted at DOE institutions, or performed by DOE employees or their contractors. • Note for the **US Department of Health and Human Services (DHHS)** regulations: select this if your organization conducts human participants research supported or funded by the US DHHS or is a US DHHS Agency conducting human participants research. An organization that holds a Federalwide Assurance (FWA) approved by the Office for Human Research Protections (OHRP) should select that it complies with DHHS regulations. • Note for the **US Department of Justice** regulations: select this regulation if the research is conducted or supported by the National Institute of Justice or Office of Justice Programs. • Note for the **US Department of Veterans Affairs** regulations and guidance: for VA facilities, this would apply to all research; for academic affiliates and independent IRBs, this would apply to VA research only.

Question	Explanation of Information Requested
	• Note for the **US Environmental Protection Agency** regulations: select this regulation if the research is conducted or supported by the EPA. • Note for the **US National Science Foundation** regulations: selects this regulation if the research is conducted or supported by the NSF.
Does your organization have a US Federalwide Assurance (FWA)?	• This would only apply to organizations that comply with US DHHS regulations. More information about FWAs is at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html.
Do you apply: • **The same policies and procedures regardless of funding** • **Different but equivalent policies and procedures for some or all research not covered by regulations**	Only organizations that respond "no" to the prior question will be asked to respond to this question. • Select *"The same policies and procedures regardless of funding"* if your organization indicated on its FWA that voluntarily elects to apply either the Common Rule or the Common Rule and subparts B, C, D, and E of the HHS regulations at 45 CFR part 46 to all of its non-exempt human participants research regardless of source of support, except for research that is covered by a separate assurance issues by another U.S. federal department or agency that has adopted the Common Rule. This is commonly referred to as "checking the box". • Select *"Different but equivalent policies and procedures for some or all research not covered by regulations"* if your organization's FWA only obligates the organization to apply either the Common Rule or the Common Rule and its subparts (B, C, D, and E) to its non-exempt human participants research conducted or supported by a Federal Agency that has adopted the Common Rule. This is commonly referred to as "unchecking the box". In this situation, organizations have the flexibility to apply policies and procedures that provide protections equivalent to the Common Rule to some or all unregulated research.
Does your organization reasonably expect to adhere to the International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP)?	Select the one statement that best describes your organization: • If your organization does not review or conduct clinical trials or does not adhere to the ICH-GCP Guideline, select: *My organization does not adhere to ICH-GCP E6.* • If your organization only adheres to with the US FDA guidance for the implementation of ICH GCP E6 or adheres to a country-specific version of GCP, select: *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.* • If your organization adheres to the full ICH GCP E6 for clinical trials only when a sponsor asks for application of this guideline, and otherwise applies neither the full ICH GCP nor the US FDA or country-specific guideline, select: *My organization only adheres to ICH-GCP E6 at a sponsor's request.* • If your organization applies the full ICH GCP E6 to clinical trials only when a sponsor asks for application of this guideline, and otherwise only applies ICH GCP as adopted by the US FDA or country-specific guidance, select: *My organization adheres to ICH-GCP E6 at a sponsor's request but otherwise adheres to ICH-GCP only as adopted by the US FDA or country-specific GCP (e.g., Japan GCP) for applicable clinical trials.* • If your organization applies the full ICH GCP E6 (as opposed to the US

Question	Explanation of Information Requested
	FDA guidance on ICH GCP E6 implementation) to all clinical trials, select: *My organization adheres to ICH-GCP E6 for all clinical trials.*
Is your organization based primarily 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. Organizations are considered primarily based outside the US if their major operations, including their review, management, conduct, or sponsorship of research, are wholly or for the most part outside the bounds of the territorial jurisdiction of the US.
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?	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. You can check how AAHRPP classifies your organization's "Type" (e.g., hospital, academic institute, independent IRB, etc.) on AAHRPP's website at Find an Accredited Organization (https://www.aahrpp.org/find-an-accredited-organization).
Questions for Independent IRBs/ECs – *If you responded "no" to the prior question you will skip these questions.*	
How many IRBs 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 which members are in attendance 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 (e.g., those that create or review IRB policies).
Please tell us about the staff for your internal IRBs/ECs:	• 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

Question	Explanation of Information Requested
● **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.**	members, chairs, and vice chairs who are employees of your organization and add the portions to obtain a total number of FTEs. Do not include HRPP staff that do not directly support IRB functions.
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.**	• *Open studies* means 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 meeting review process. These are generally minimal risk studies. Please provide the number of open studies at the time you submit your Annual Report. • *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. Please provide the number of open studies at the time you submit your Annual Report. • *For exempt human participants determinations* count the number of new studies determined to be exempt human participants research in the most recent complete year (i.e., January 1 through December 31). 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. This count does not include determinations that activities are not human participants research.

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) (Element I.5.D. and II.2.G.)
 	
● **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)**
	• *For serious noncompliance:* This is the number of determinations of serious noncompliance made by your IRB(s)/EC(s).
	  ○ If the noncompliance is determined to be serious and continuing, include it in this count in addition to the count for noncompliance determined to be continuing.
	• *For continuing noncompliance*: This is the number of determinations of continuing noncompliance made by your IRB(s)/EC(s).
	  ○ If the noncompliance is determined to be serious and continuing, include it in this count in addition to the count for noncompliance determined to be serious.
	• *For unanticipated problems*: This is the number of determinations of unanticipated problems made by your IRB(s)/EC(s).

Question	Explanation of Information Requested
In the most recent year (the period from January 1 through December 31), what was the number of governmental or regulatory agency (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) inspections of research studies your organization reviews that resulted in a finding or a request for an official compliance action (e.g., issuance of a US FDA Form 483 or FDA Warning Letter)? **If your organization does not track this information, please indicate this.**	These are audits or inspections conducted by the US government, US regulatory agencies (e.g., US FDA, VA Office for Research Oversight), other countries' governments, or other countries' regulatory agencies that required a response or action for investigators who conduct research reviewed by your organization that underwent inspection. This number does not include routine monitoring activities performed by federal sponsors. Include all relevant inspections within the most recent complete year. If your organization does not track this information, please indicate this (e.g., "My organization does not track this information.").
Please tell us about other compliance activities in the most recent year (the period from January 1 through December 31): • **Number of "for cause" audits your organization conducted of research studies your organization reviews** • **Number of "not for cause"/random/ routine post-approval audits of research studies your organization reviewed** • **Number of governmental or regulatory agency (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) inspections or reviews of IRB(s)/EC(s)** • **Number of "for cause" audits of IRB/EC records/processes conducted internally** • **Number of "not for cause"/random audits of IRB/EC records/processes conducted internally**	• *For "for cause" audits your organization conducted of research studies*: "For cause" means an audit prompted by some information, a complaint, or an event related to the conduct of the research study overseen by your organization's IRB(s)/EC(s). • *For "not for cause"/random/routine post-approval audits of research studies*: "Not for cause", random, or routine post-approval means there was no particular reason for conducting an 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 and may be conducted by personnel internal to your organization or others your organization designates (e.g., external consultants). Only audits which consist of a comprehensive review of the conduct of a study should be counted (as opposed to spot checks or focused reviews which include limited assessments.) • *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 the US government, US regulatory agencies, other countries' governments, or other countries' regulatory agencies. Include all inspections within the most recent complete year regardless of their outcome. • *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 and focus on general IRB/EC performance rather than reviews related to a particular study. Any systematic review of IRB/EC records with the purpose of determining quality and compliance should be included.

Question	Explanation of Information Requested
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): (Element I.6.B.) ● **Number of studies with a financial conflict of interest management plan for an initial review of a study or a change in research adding a new management plan reviewed by your IRB(s)/EC(s)**	• *For number of studies with management plans*: This refers to studies that either : a) undergo initial review and have financial conflict of interest (COI) management plans or b) for which a change in research is submitted that adds a new COI management plan(s) that the IRB/EC has not previously reviewed If more than one key personnel have a management plan related to the study that the IRB/EC reviewed (either the initial review of a study or review of a change in research), this would only count as one study.
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.
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 approval via CONVENED BOARD REVIEW for initial review of human participants research**	• *For submission to convened board review*: This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when the first convened IRB/EC review occurs. This time period would include any pre-review process your organization has. • *For submission to convened board approval*: This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when all conditions are met to secure IRB/EC approval. This time period would include any pre-review process your organization has.
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 submission to approval via EXPEDITED REVIEW for initial review of human participants research?	• *For submission to approval*: Only include initial reviews and not continuing review or modifications to approved research (e.g., changes in research or amendments). This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when all conditions are met to secure IRB/EC approval. This time period would include any pre-review process your organization has.. • If policies permit administrative withdrawal of submissions after a period of non-response from the researcher, the clock can be "restarted" upon resubmission of the study for purposes of this calculation.

Question	Explanation of Information Requested
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 submission to an EXEMPTION DETERMINATION?	This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the exemption review process to the date when the study is determined to be exempt human participants research. This time period would include any pre-review process your organization has.
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:**	• If your organization does not use an electronic (computer system) to support any component of the IRB/EC review process, select *"My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process."* • Note: Electronic platforms for managing the submission and review process do not refer to the use of email or software/platforms that solely allow document storage and sharing. • *…that allows researchers to prepare and/or submit their applications for IRB/EC review*: This refers to an online platform or system that allows research teams to prepare and/or submit their applications for IRB/EC review. • *…that allows IRB/EC members to review IRB/EC applications and supporting materials*: This refers to an online platform or system that allows IRB/EC members and staff to access studies and other related materials. • *…that allows IRB/EC members and staff to communicate about IRB applications and other related materials:* This refers to an online platform or system that allows IRB/EC members and staff to communicate with each other or research teams about applications submitted through the system. • *…to document or record IRB/EC decisions and study-specific determinations within the system:* This refers to an online platform or system that allows IRB/EC members and/or staff to capture IRB/EC determinations related to a particular study.
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.

Question	Explanation of Information Requested
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 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). • Please provide the number of open studies at the time you submit your Annual Report. • Do NOT include studies determined by an external IRB(s)/EC(s) to be exempt human participants research here. Information about research determined to be exempt human subjects research by an external IRB/EC is asked for later in this survey/form.
Does your organization rely on a non-accredited IRB(s)/EC(s) for the review of some or all of its human participants research? (Standard I-9)	• If your organization relies on one or more IRBs/ECs that are not accredited by AAHRPP (or part of an organization that is accredited) for the review of all of your organization's human participants research: select "**Yes, my organization relies on a non-accredited IRB(s)/EC(s) for the review of ALL of its human participants research**". This would include the review of exempt and non-exempt human participants research. • If your organization can rely (e.g., by policy) or has relied on one or more IRBs/ECs that are not accredited by AAHRPP (or part of an organization that is accredited) for some but not all of its human participants research: select "**Yes, my organization relies on a non-accredited IRB(s)/EC(s) for the review of SOME of its human participants research**". This would include the review of exempt and non-exempt human participants research. • If your organization has not relied or cannot rely (e.g. by policy) on one or more IRBs/ECs that are not accredited by AAHRPP (or part of an organization that is accredited): select "**No, my organization does not rely on any non-accredited IRB(s)/EC(s) for the review of its human participants research**." This would include the review of exempt and non-exempt human participants research.
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)? (Standard I-9)	**Only organizations that respond, "Yes, my organization relies…for SOME" in the prior question will be asked to respond to this question.** This question is being asked because AAHRPP Standards require organizations to have a process to ensure the research is being reviewed appropriately and complies with applicable law and regulations. Consequently, organizations should be aware when they are relying on IRB(s)/EC(s) from organizations that are not AAHRPP-accredited and the proportion of their research portfolio overseen under such reliance arrangements. AAHRPP understands that this metric may be difficult for some organizations to track. Please provide your best estimate.
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.	**Only organizations that respond, "Yes, my organization relies…for ALL", will be asked to respond to this question.**

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 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, 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.

Question	Explanation of Information Requested
Please tell us about the staff for your internal IRBs(s)/EC(s). ● **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)**	• *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. Do not include HRPP staff that do not directly support IRB functions.
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**	• *For internal "for cause" audits of IRB/EC record*s: "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 and focus on general IRB/EC performance rather than reviews related to a particular study. Any systematic review of IRB/EC records with the purpose of determining quality and compliance should be included. • *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. If your organization is a governmental organization or agency, provide audits or inspections conducted by governmental or regulatory agencies that are considered external to your HRPP.

Question	Explanation of Information Requested
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:***	• If your organization does not use an electronic (computer system) to support any component of the IRB/EC review process, select ***"Not Applicable. My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC submission and review process."*** • Note: Electronic platforms for managing the submission and review process do not refer to the use of email or software/platforms that solely allow document storage and sharing. • *…that allows researchers to prepare and/or submit their applications for IRB/EC review*: This refers to an online platform or system that allows research teams to prepare and/or submit their applications for IRB/EC review. • *…that allows IRB/EC members to review IRB/EC applications and supporting materials*: This refers to an online platform or system that allows IRB/EC members and staff to access studies and other related materials. • *…that allows IRB/EC members and staff to communicate about IRB applications and other related materials:* This refers to an online platform or system that allows IRB/EC members and staff to communicate with each other or research teams about applications submitted through the system. • *…to document or record IRB/EC decisions and study-specific determinations within the system:* This refers to an online platform or system that allows IRB/EC members and/or staff to capture IRB/EC determinations related to a particular study.
Does your organization serve as the reviewing IRB/EC for external organizations conducting research?	• Select "yes" if your organization will permit its internal IRB(s)/EC(s) to serve as a reviewing IRB (aka single IRB or IRB of record) for organizations that are separate legal entities from your organization (e.g., your organization is a university and will agree to serve as a reviewing IRB for another university or hospital for a multisite research study that requires single IRB review). • Select "no" if your organization will not permit its internal IRB(s)/EC(s) to serve as a reviewing IRB (aka single IRB or IRB of record) for organizations that are separate legal entities from your organization.
Questions for Organizations that are not Independent IRBs/ECs and serve as the reviewing IRB/EC for external entities	
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?	• Include the total of non-exempt human participants research that your organization's IRB(s)/EC(s) reviewed on behalf of another organization. • *Open studies* means 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). • These studies may be approved by convened or expedited review. • Please provide the number of open studies at the time you submit your Annual Report.
Does your organization provide IRB review for a US Department of Veterans Affairs facility?	• Select "yes" if your organization's IRB(s) will review research that falls under the purview of the US Department of Veterans Affairs. • Select "no" if your organization's IRB(s) will NOT review research that falls under the purview of the US Department of Veterans Affairs.

Question	Explanation of Information Requested
Does your organization serve as the academic affiliate for a Veterans Affairs (VA) facility?	**Only organizations that provide IRB review for a VA facility will be asked to respond to this question.** • Select "yes" if your organization has a formal agreement (e.g., a memorandum of understanding) to serve as the academic affiliate of a VA facility or facilities, including providing IRB review services for the facility(ies). • Select "no" if your organization's IRB(s) does not have a formal agreement (e.g., a memorandum of understanding) to serve as the academic affiliate of a VA facility or facilities, which includes serving as the primary IRB (in addition to the VA Central IRB) for that facility(ies).
My organization serves as an academic affiliate for the following VA facility(ies):	**Only organizations that serve as the academic affiliate for a VA facility will be asked to respond to this question.** List the VA facility(ies) for which your organization has a formal agreement to serve as the academic affiliate.
Questions for Organizations that have internal IRBs/ECs and are not Independent IRBs/ECs	
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?	**Only organizations that respond "yes" to the prior question will be asked to respond to this and the following question.** • *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 and approved outside of your organization's convened IRB/EC review process. These are generally minimal risk studies. • Only include initial reviews and not continuing review or modifications to approved research (e.g., changes in research or amendments). • Please provide the number of open studies at the time you submit your Annual Report.
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)?	Select "no" if your organization's IRB(s)/EC(s) did not review any studies reviewed using the EXPEDITED REVIEW procedures in the most recent year.

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 submission to approval via EXPEDITED REVIEW for initial review of human participants research?	**Only organizations that respond "yes" to the prior question will be asked to respond to this question.** Only include initial reviews and not continuing review or modifications to approved research (e.g., changes in research or amendments). This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when all conditions are met to secure IRB/EC approval. If policies permit administrative withdrawal of submissions after a period of non-response from the researcher, the clock can be "restarted" upon resubmission of the study for purposes of this calculation. This time period would include any pre-review process your organization has.
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 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 when the IRB/EC first reviewed and approved the study. These are generally greater than minimal risk studies. • Please provide the number of open studies at the time you submit your Annual Report.
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 "no" if your organization's IRB(s)/EC(s) did not review any studies reviewed at a convened board meeting in the most recent year.
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 CONVENED BOARD REVIEW for initial review of human participants research:**	**Only organizations that respond "yes" to the prior question will be asked to respond to this question.** • *For Submission to convened board review*: This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when the first convened IRB/EC review occurs. This time period would include any pre-review process your organization has. • *For Submission to convened board approval*: This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the IRB/EC review process to when all conditions are met to secure IRB/EC approval. This time period would include any pre-review process your organization has.
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, or for organizations based outside the US that are exempt from IRB/EC review requirements under governing laws.
Questions for Organizations that Allow Exempt Determinations	

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.* Note: If your organization chooses not to apply exemption categories related to broad consent (#7 and #8), this response should still be selected because your organization otherwise complies with the Common Rule exemption categories. • 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 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.	• Count the number of new studies determined to be exempt human participants research in the most recent complete year (e.g., January 1 through December 31, 2021) by a process external to your organization (e.g., an independent IRB/EC or another organization's IRB/EC office). • Do not include exempt human participants determinations made by an INTERNAL process, such as by an internal IRB/EC office or other internal HRPP office. • If the external 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 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.

Question	Explanation of Information Requested
Does your organization use an internal process to make exempt human participants research determinations?	Select "yes" if individuals within your organization made some or all determinations that human participants research is exempt. This question is asking about all exemption determinations, regardless of whether they involved the limited IRB review process. 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.
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.	**Only organizations that respond "yes" to the prior question will be asked to respond to this question.** • This refers to exemption determinations made for new applications. Do not include determinations made for projects already deemed to be exempt human subjects research (e.g., assessment of changes to projects to ensure the exemption determination is still accurate). • Organizations, not researchers, must make exemption determinations. However, instead of requiring HRPP/IRB staff/IRB members to make determinations, organizations may make these determinations using checklists or other tools completed by researchers. Include exemption determinations made by any HRPP/IRB staff/IRB members or using checklists or other tools in this answer. • Do not include exemption determinations made by an external IRB/EC or other review process external to your organization. • 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 answer. • This count does not consider determinations that activities are not human participants research.

Question	Explanation of Information Requested
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.	**Only organizations that respond "yes" to the previous two questions will be asked to respond to this and the following question.** • Count the number of new studies determined to be exempt human participants research in the most recent complete year (e.g., January 1 through December 31, 2021) by a process internal to your organization. • Organizations, not researchers, must make exemption determinations. However, instead of requiring HRPP/IRB staff/IRB members to make determinations, organizations may make these determinations using checklists or other tools completed by researchers. Include exemption determinations made by any HRPP/IRB staff/IRB members or using checklists or other tools in this count. • Do not include exemption determinations made by an external IRB/EC or other review process external to your organization. • 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.
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?	• Only include exemption determinations made for new applications. Do not include determinations made for projects already deemed to be exempt human subjects research (e.g., assessment of changes to projects to ensure the exemption determination is still accurate). • This time period is measured from the date the investigator/study team submitted the study to the office within your organization that manages the review process to the date when the study is determined to be exempt human participants research. This time period would include any pre-review performed by your organization. DO NOT include exemptions reviewed by an external process.
Questions for Organizations that are not Independent IRBs/ECs	

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 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 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. o If the noncompliance is determined to be serious and continuing, include it in this count in addition to the count for noncompliance determined to be continuing. • *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. o If the noncompliance is determined to be serious and continuing, include it in this count in addition to the count for noncompliance determined to be serious. • *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.

Question	Explanation of Information Requested
Please tell us about other compliance activities related to research 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**	• *For governmental or regulatory agency inspections… that result in a finding or a request for an official compliance action (e.g., issuance of a US FDA Form 483 or FDA Warning Letter)*: These are audits or inspections conducted by the US government, US regulatory agencies (e.g., US FDA, VA Office for Research Oversight), other countries' governments, or other countries' regulatory agencies that required a response or action from your organization for investigators who: o underwent the inspection as an employee, staff member, student or agent of your organization; and/or o conduct research managed or funded by your organization that underwent inspection. For federal agencies that are accredited or seeking accreditation, only include inspections of investigators for human participants research that is overseen by your agency's HRPP and not studies where your agency solely provides funding and HRPP oversight occurs at another organization. This number does not include routine monitoring activities performed by federal sponsors. Include all relevant inspections within the most recent complete year. • *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). "Your organization conducted" means that personnel internal to your organization or others your organization designates (e.g., external consultants) conducted an audit of research it conducts, manages, reviews and/or sponsors. • *For not for cause/random/ routine post-approval audits of research studies*: "Not for cause", random, or routine post-approval 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 and may be conducted by personnel internal to your organization or others your organization designates (e.g., external consultants). Only audits which consist of a comprehensive review of the conduct of a study should be counted (as opposed to spot checks or focused reviews which include limited assessments.) Self-audits or desk audits should be counted only if responses are required from the research team and reviewed by the compliance office.

Question	Explanation of Information Requested
Please tell us about your organization's management of financial conflicts of interest related to human participants research in the most recent year (the period from January 1 through December 31): **What is the number of studies with a financial conflict of interest management plan for an initial review of a study or a change in research adding a new management plan reviewed by an internal or external IRB(s)/EC(s)? (I.6.B)**	• *For number of studies with management plans*: This refers to studies that either: a) undergo initial review and have financial conflict of interest (COI) management plans or b) for which a change in research is submitted that adds a new COI management plan(s) that the IRB/EC has not previously reviewed If more than one key personnel have a management plan related to the study that the IRB/EC reviewed (either the initial review of a study or review of a change in research), this would only count as one study.
Question for All Organizations that have internal IRBs/ECs or are Independent IRBs/ECs	
Does your organization provide IRB/EC chairs/vice chairs with 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: o Salary support (full or partial) o Pay for specific activities (e.g., conducting IRB meeting, reviews) o Stipend/honorarium o Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees o Reimbursement of the IRB/EC chair's home department/clinic for time Examples of non-financial compensation include: o Food at IRB/EC meetings o Thank you or appreciation gifts of nominal value
Questions for Organizations that Provide IRB/EC Chairs with Financial Compensation	

Question	Explanation of Information Requested
Please indicate any of the following types of FINANCIAL support your organization provides IRB/EC chairs or vice chairs (if your organization has vice chairs). (Check all that apply) ● **Salary support (full or partial)** ● **Pay for specific activities (e.g., conducting IRB 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/vice chair's home department/clinic for time** ● **Other, please describe**	Please select all forms of financial support that your organization's IRB/EC chairs and/or 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 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**	• *Affiliated IRB/EC 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. • If your organization provides financial support for affiliated IRB/EC members, please select all forms of financial support they 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. • If your organization does not provide financial support for affiliated IRB/EC members, select: *My organization does not provide financial support for affiliated IRB/EC members*

Question	Explanation of Information Requested
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**	• 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". • If your organization provides financial support for unaffiliated IRB/EC members, please select all forms of financial support they 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. • If your organization does not provide financial support for unaffiliated IRB/EC members, select: *My organization does not provide financial support for unaffiliated IRB/EC members.*
Questions for All Organizations	
Indicate if any of the following changes have occurred in your organization in the last 12 months 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	• If your organization has not experienced a change in resources supporting its HRPP, select: "**No.**" Otherwise select "**Yes**", and you will be prompted to describe those changes.

Question	Explanation of Information Requested
resources in the most recent 12 months?	
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.

Question	Explanation of Information Requested
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 that any of your responses in this form require explanation, please describe those here.