Guidance on Section A of the Application for Accreditation

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/ECs embedded within the organization that may conduct research (such as academic organizations, hospitals, or health systems) are NOT considered independent IRBs or ECs. For accredited organizations: 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 Step 1 Application 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 Step 1 Application. *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).

Question	Explanation of Information Requested
Section I. Organization Information	
All organizations should complete this section regardless of whether the application is for initial accreditation or reaccreditation and should be completed for Step 1 and Step 2	
Section I.A. Identifying Your Organization	
Legal name of your organization applying for accreditation	Please consult with your general counsel to provide the legal name of your organization.
The preferred name for your organization (e.g., the name that should appear on AAHRPP's website and accreditation certificates), if different from above:	If your organization prefers a different name to be displayed on the AAHRPP website (https://www.aahrpp.org/learn/find-an-accredited-organization) or referenced in AAHRPP accreditation certificates, formal reports, and other communications from AAHRPP instead of its legal name, please identify that name here.
Organization address	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).
Section I.B. Entities	
Are there any additional entities associated with your organization (a) at which human participants research is conducted and (b) which you would like to be included for evaluation as part of this application/accreditation?	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.

Question	Explanation of Information Requested
Entity name(s) and location(s) (City, State, Country)	Please identify all of the Entities as defined above that are part of your human research protection program as well as their location. 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 that are part of the AMU HRPP.
Section I.C. Contact Information	
Application Contact Responsible Organizational Official	Note: Signatures for the Application Contact and Organizational Official are only required for a Step 1 application. Electronic signatures are acceptable.
Section II. Information About Your Organization's Human Research Protection Program (complete this section for Step 1 and Step 2)	
For consistency and simplicity, the term "IRB/EC" will be used interchangeably with the terms "IEC" and "REB".	
Section II.A. Location of Research Activities, Types of Research, and Regulations Applied	
1. Where does research involving human participants occur that your organization conducts, reviews, manages and/or sponsors? (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.
2. What kind of research does your organization review, conduct, manage, and/or sponsor?	• *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.
3. Does your organization review, conduct, manage, and/or sponsor studies involving: • 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.

Question	Explanation of Information Requested
4. Does your organization review, conduct, manage, and/or sponsor studies involving any of the following vulnerable participant populations?	Select the categories based on research your organization reviews, conducts, manages, and/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 individuals • Prisoners • Adults unable to provide informed consent
5. Does your organization review, conduct, manage, and/or sponsor planned emergency research?	**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.

Question	Explanation of Information Requested
6. What type(s) of funding does your organization receive for the review, management, conduct, and/or sponsorship of human participants research? (Select all that apply.) • 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 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.

7. Which regulations does your organization reasonably expect could apply to your research portfolio, whether or not you currently have open studies that must comply with those regulations? NOTE: This 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 ED. • 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. • 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: select this regulation if the research is conducted or supported by the NSF.

8. Does your organization reasonably expect to comply with 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 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 FDA guidance on ICH GCP E6 implementation) to all clinical trials, select: *My organization adheres to ICH-GCP E6 for all clinical trials.*
9. 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.
10. Please select the statement that best reflects the terms of your FWA.	Only organizations that respond "no" to the prior question will be asked to respond to this question**.** • Select *"My organization applies 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 *"My organization applies 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.

11. Is your organization primarily based outside of 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.
12. What country-specific laws, regulations, and guidance does your organization apply to research involving human participants?	**Only organizations that respond "yes" 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.
Section II.B. Ethics Review and Total Number of Active Studies	
An IRB or EC is 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 Institutional Review Board (IRB) or Ethics Committee (EC), but your organization may use a different term.	
13. Does your organization have at least one internal IRB/EC or is your organization an independent IRB/EC?	Select "yes" if your organization a) has one or more internal IRB(s)/EC(s) or b) is an independent IRB/EC *Note: An independent IRB or Ethics Committee* is defined as an IRB or ethics committee that is not part of an organization that conduct 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. For accredited organizations, you can check how AAHRPP classifies your organization's "Type" (e.g., hospital, academic institution, independent IRB, etc.) at https://www.aahrpp.org/find-an-accredited-organization.
14. How many IRBs/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 a 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). However, some organizations have one IRB/EC, 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 three IRBs. Do not include in this number committees that do not review research (e.g., those that create or review IRB policies).

15. Does your organization's IRB(s)/EC(s) use electronic (computer) system(s) to manage the submission and review process?	• 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.
16. Do you serve as the reviewing IRB/EC for external organizations conducting research?	• Select "not applicable" if your organization is an independent IRB(s)/EC(s). This question is meant to identify organizations other than independent IRBs/ECs that allow their internal IRBs/ECs to conduct IRB/EC review for external organizations. • Select "yes" if your organization will permit its internal IRB(s)/EC(s) to serve as a reviewing IRB/EC (aka single IRB/EC or IRB/EC 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/EC or IRB/EC of record) for organizations that are separate legal entities from your organization.
17. 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. This question does not apply to organizations that are independent IRBs/ECs. • *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 (as counted in Questions 19 and 20).

18. Does your organization provide IRB review for a US Department of Veterans Affairs (VA) 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.
19. Does your organization serve as the academic affiliate for a VA facility?	• 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).
20. Do the laws, regulations, codes, guidance, or policies under which your organization conducts, manages, sponsors, 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.
21. What is the number of open studies reviewed by an internal IRB(s)/EC(s) under **expedited procedures** 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). • *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. Only include initial reviews and not continuing review or modifications to approved research (e.g., changes in research or amendments).
22. 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 when the IRB/EC first reviewed and approved the study. Only include initial reviews and not continuing review or modifications to approved research (e.g., changes in research or amendments). These are generally greater than minimal risk studies.
23. Do the laws, regulations, codes, guidance, or policies under which your organization conducts, manages, sponsors or reviews human participants research allow some research to be determined **exempt**?	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.

24. Please select the statement that best describes your organization's policies and procedures for **exempt human participants research**.	• If your organization is an independent IRB/EC and makes exempt human participants research determinations on behalf of other organizations, select: *My organization is an independent IRB/EC and makes exempt human participants research determinations as permitted by applicable regulations for a specific study.* • If your organization is NOT an independent IRB/EC and 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 is NOT an independent IRB/EC and 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 is NOT an independent IRB/EC and 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.*
25. 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.

26. 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., 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.	• 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. 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 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.
27. 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?	• 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. DO NOT include exemptions reviewed by an external process. This time period should include any pre-review process your organization has, which might be conducted by an internal IRB/EC. • If your organization has a process to make exemption determinations in place but no studies were determined to be exempt human participants research during the most recent year (the period from January 1 through December 31), select: *My organization did not have any studies determined to be exempt human participants research in the most recent year.* • If your organization does not have an internal process to make exempt human participants research determinations, select: *My organization does not use an internal process to make exempt human participants research determinations.*
28. 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.

Section II.C. Use of External IRBs/ECs	
29. Does your organization rely on one or more external IRBs/ECs to review some or all of its human participants research?	• If your organization is an independent IRB/EC please check the box: *I did not complete this section because my organization is an independent IRB/EC.* • Select "yes" if your organization uses an IRB/EC that is not operated by your organization, such as an independent IRB/EC or another university's or hospital's IRB/EC, either for all of its ethics reviews or only some of its ethics reviews.
30. What is the number of open studies (excluding exempt human participants research) **reviewed by an external IRB(s)/EC(s)**?	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 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). 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 requested above.
31. Does your organization rely on a non-accredited IRB(s)/EC(s) for the review of some or all of its human participants research?	• 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 ALL of its human participants research". This would include the review of exempt and non-exempt human participants research. If your organization relies on a non-accredited IRB(s)/EC(s) for ALL of its human participants research, please identify that IRB(s)/EC(s) because AAHRPP will likely want to include them in the accreditation process for your organization. • 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.
32. 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)?	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.

Section III. Review Timelines and Determinations (complete this section for Step 1 only)	
33. Does your organization have at least one internal IRB/EC OR is it an independent IRB/EC?	Select "yes" if your organization a) has one or more internal IRB(s)/EC(s) or b) is an IRB/EC that is not owned or operated by the research organization for which it provides review services.
34. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from: • The 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. 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 should include any pre-review process your organization has. • If an expedited review process was not used by your organization for the initial review of any studies, select: *My organization's IRB(s)/EC(s) did not review any studies reviewed under EXPEDITED REVIEW procedures in the most recent year.*
35. 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 should 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 should include any pre-review process your organization has. • If a convened board review process was not used by your organization for the initial review of any studies, select: *My organization's IRB(s)/EC(s) did not review any studies reviewed under CONVENED BOARD procedures in the most recent year.*

36. Please tell us about your organization's review of certain events.	• *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 federal regulations, other laws or regulations, or institutional policy. **For independent IRBs/ECs**, 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*: 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 independent IRBs/ECs**, 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*: 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. **For independent IRBs/ECs**, this is the number of determinations of unanticipated problems made by your IRB(s)/EC(s).

Section IV. Review of Reportable Events and Compliance Activities (complete this section for Step 1 only)	
37. Please tell us about your organization's compliance activities related to research studies.	• *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. If your organization is an independent IRB/EC that does not track this information, select "A number was not provided because my organization is an independent IRB/EC and does not track this information." • *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. "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.

38. Please tell us about your organization's compliance activities related to IRB/EC review.	• If your organization a) does not have an internal IRB(s)/EC(s) or b) is not an independent IRB/EC, select: *I did not provide responses to this question because my organization does not have an internal IRB(s)/EC(s) and is not an independent IRB(s)/EC(s).* • *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 countries' governments, or other countries' regulatory agencies. Include all inspections within the most recent complete 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. • *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.
Section V. Review of Conflicts of Interest (complete this section for Step 1 only)	
39. Please tell us about your organization's management of financial conflicts of interest related to human participants research. • 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 a financial conflict of interest management plan:* This refers to studies that either: • undergo initial review and have financial conflict of interest (COI) management plans, or • 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.
Section VI. IRB Staff (complete this section for Step 1 only)	
40. Please tell us about the staff for your internal IRB(s)/EC(s).	• If your organization a) does not have an internal IRB(s)/EC(s) or b) is not an independent IRB/EC, please check: *I did not provide a response to this question because my organization does not have an internal IRB(s)/EC(s) and is not an independent IRB(s)/EC(s).* • *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.

Section VII. Compensation of IRB/EC Members	
• Complete this section for Step 1 only • If your organization does not have internal IRB(s)/EC(s) or are not independent IRB(s)/EC(s) skip this section.	
41. Please indicate any of the following types of FINANCIAL support your organization provides IRB/EC chairs or vice chairs (if your IRB(s)/EC(s) have vice chairs). • My organization does not provide financial support for IRB/EC chairs or vice chairs • 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 or vice chair's home department/clinic for time • Other, please describe	• If your organization provides financial support for IRB/EC chairs and/or vice 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. • If your organization does not provide financial support for IRB/EC chairs and/or vice chairs, select: *My organization does not provide financial support for IRB/EC chairs* or vice chairs
42. Please indicate what type of FINANCIAL support your organization provides affiliated IRB/EC members who are not chairs or vice chairs. • My organization does not provide financial support for affiliated IRB/EC members • Salary support (full or partial) • Pay for specific activities (e.g., attending IRB/EC meetings, 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	• *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*

43. Please indicate any of the following types of FINANCIAL support your organization provides unaffiliated IRB/EC members who are not chairs or vice chairs. • My organization does not provide financial support for unaffiliated IRB/EC members • Pay for specific activities (e.g., attending IRB meetings, reviews) • Stipend/honorarium • Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees • Other, please describe	• 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*