



Question	Explanation of Information Requested
<b>Section I. Organization Information</b>	
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	
<b>Section I.A. Identifying Your Organization</b>	
Legal name of your Organization applying for accreditation	Please consult with your general counsel to provide the legal name of your Organization.
Organization name that should appear on AAHRPP’s website, if different from above	If you would like another name other than the legal name of your Organization to appear on AAHRPP’s website as accredited ( <a href="https://www.aahrpp.org/learn/find-an-accredited-organization">https://www.aahrpp.org/learn/find-an-accredited-organization</a> ), please provide the name. If the name is the same as your Organization’s legal name, please copy the information from the first question here.
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).
<b>Section I.B. Entities (Formerly Components)</b>	
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.
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.
<b>Section I.C. Contact Information</b>	
Application Contact	Note: Signatures for the Application Contact and Organizational Official are only required for a Step 1 application. Electronic signatures are acceptable.
Responsible Organizational Official	
<b>Section II. Information About Your Organization’s Human Research Protection Program (complete this section for Step 1 and Step 2)</b>	
For consistency and simplicity, the term “IRB/EC” will be used interchangeably with the terms “IEC” and “REB”.	
<b>Section II.A. Location of Research Activities, Types of Research, and Regulations Applied</b>	
1. Where does research involving human participants occur that your Organization conducts, reviews, manages and/or sponsors? (Select the option that best describes your Organization.)	Select the single option that best describes your Organization. This question is to help AAHRPP identify whether your Organization may need to apply the laws and regulations of other states and countries to research it conducts, reviews, manages, and/or sponsors.

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<p>2. What kind of research does your Organization review, conduct, manage, and/or sponsor?</p> <p>NOTE: Total percentage should equal 100%.</p>	<ul style="list-style-type: none"> <li>• <i>Biomedical/clinical research</i> 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.</li> <li>• <i>Social/behavioral/education research</i> is defined by topic areas, not methodology. This includes research involving human behavior and social functioning and the social and biological contexts of behavior including such disciplines as sociology, psychology, anthropology, human ecology, history, and communications. Education research is included in this category.</li> <li>•</li> </ul>
<p>3. Does your Organization review, conduct, manage, and/or sponsor studies involving:</p> <ul style="list-style-type: none"> <li>• Investigational drugs</li> <li>• Investigational devices</li> </ul>	<p>This question refers to drugs or devices that are investigational or unlicensed test articles. See Element I.7.A. for additional guidance.</p>
<p>4. Does your Organization review, conduct, manage, and/or sponsor studies involving any of the following vulnerable participant populations?</p>	<p>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.</p> <ul style="list-style-type: none"> <li>• Children</li> <li>• Pregnant Individuals</li> <li>• Prisoners</li> <li>• Adults unable to provide informed consent</li> </ul> <p>If “Other” is selected, please describe the additional population(s) that your Organization identifies as vulnerable.</p>
<p>5. Does your Organization review, conduct, manage, and/or sponsor planned emergency research?</p>	<p><b>This question only applies to organizations that follow US FDA regulations or US DHHS regulations.</b></p> <p>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.</p> <p>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.</p>

Question	Explanation of Information Requested
<p>6. What percent of human participant research that your Organization reviews, manages, conducts, and/or sponsors is:</p> <ul style="list-style-type: none"> <li>• Sponsored by the US federal government</li> <li>• Industry sponsored</li> <li>• Sponsored by other external sources</li> <li>• Sponsored by internal sources (including unfunded research)</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Sponsored by the US federal government</i>: this includes research funded in any way by the US federal government or US federal agency or conducted by a federal agency or department. Do NOT include research sponsored by other governments (such as a US state or a government outside the US) in this category.</li> <li>• <i>Industry sponsored</i>: this includes research that is funded in any way by a company.</li> <li>• <i>Sponsored by other external sources</i>: this includes research funded all or in part by foundations or private donors. Any research not funded in any way by a company, US federal agency, or US federal government. This can also include research sponsored by other governments such as US state government or a government outside the US.</li> <li>• <i>Sponsored by internal sources (including unfunded research)</i>: 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.</li> </ul>
<p>7. Does your Organization have a Federalwide Assurance (FWA)?</p>	<ul style="list-style-type: none"> <li>• Check “yes” if your Organization has a current Federalwide Assurance of compliance (FWA) filed with the US Office for Human Research Protections.</li> <li>• Check “no” if your Organization does not have an assurance. Note that simply registering your IRB with OHRP is not the same as having an FWA.</li> </ul>
<p>8. Please select the statement that best reflects the terms of your FWA.</p>	<ul style="list-style-type: none"> <li>• Under the “Applicability” section of the FWA, an Organization can voluntarily elect to apply the US Common Rule or the Common Rule and its Subparts to all of its non-exempt human participants research regardless of the source of support.</li> <li>• If your Organization has indicated in its FWA that it will apply the Common Rule or the Common Rule and its Subparts, select: <i>My Organization applies the same policies and procedures regardless of whether research is covered by DHHS regulations or the Common Rule</i></li> <li>• If your Organization has not indicated in its FWA that it will voluntarily apply the Common Rule to its non-exempt human participants research, select: <i>My Organization applies different but equivalent policies and procedures for some or all research not covered by regulations</i></li> </ul>

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<p>9. How does your Organization apply the 2018 Common Rule to research?</p>	<ul style="list-style-type: none"> <li>• This question only applies to Organizations that conduct research covered by DHHS regulations, or other US government agency that is a Common Rule agency.</li> <li>• If your Organization applies the updated Common Rule to all non-exempt research and has transitioned all research approved prior to the revised Common Rule went into effect, select: <i>My Organization applies the 2018 Common Rule to all non-exempt human participants research, regardless of when it was approved by an IRB/EC</i></li> <li>• If your Organization decides for each study whether to transition non-exempt research approved before the updated Common Rule went into effect to the new Common Rule, select: <i>My Organization applies the 2018 Common Rule to non-exempt human participants research that was approved by an IRB/EC before the 2018 Common Rule was effective on a study-by-study basis</i></li> <li>• If your Organization will not transition non-exempt research approved before the updated Common Rule went into effect to the new regulation, select: <i>My Organization only applies the 2018 Common Rule to non-exempt human participants research that was approved by an IRB/EC after the 2018 Common Rule was effective</i></li> </ul>
<p>10. Which regulations does your Organization reasonably expect could apply to your research portfolio, whether or not you have open studies that must comply with those regulations? NOTE: This information helps AAHRPP identify the regulations under which it will evaluate your organization.</p> <ul style="list-style-type: none"> <li>• US Department of Defense (DoD)</li> <li>• US Department of Education (ED)</li> <li>• US Department of Energy (DOE)</li> <li>• US Department of Health and Human Services (DHHS)</li> <li>• US Department of Justice (DoJ)</li> <li>• US Department of Veterans Affairs (VA)</li> <li>• US Environmental Protection Agency (EPA)</li> <li>• US Food and Drug Administration (FDA)</li> </ul>	<ul style="list-style-type: none"> <li>• 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 studies that are open that fall under certain regulations, please select those regulations if your Organization may need to apply them to research it reviews, manages, conducts, and/or sponsors.</li> <li>• Note for the <b>US Department of Defense</b> regulations: select this regulation if your Organization reviews, manages, or conducts research under a US Department of Defense Addendum from any branch of the military.</li> <li>• Note for the <b>US Department of Veterans Affairs</b> 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.</li> </ul>

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<p>11. Does your organization reasonably expect to comply with the International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP)?</p>	<ul style="list-style-type: none"> <li>• If your Organization does not review or conduct clinical trials or does not adhere to the ICH-GCP Guideline, select: <i>My Organization does not comply with ICH-GCP.</i></li> <li>• If your Organization only complies with the US FDA guidance for the implementation of ICH GCP E6(R2), select: <i>My Organization only complies with ICH-GCP as adopted by the US FDA.</i></li> <li>• If your Organization applies the full ICH GCP E6(R2) (as opposed to the US FDA guidance on ICH GCP E6(R2) implementation) to clinical trials, select: <i>My Organization complies with the ICH-GCP E6(R2) for all clinical trials.</i></li> <li>• If your Organization applies the full ICH GCP E6(R2) (as opposed to the US FDA guidance on ICH GCP E6(R2) implementation) to clinical trials only when a sponsor asks for application of this guideline, select: <i>My Organization only complies with ICH-GCP E6(R2) at a sponsor's request.</i></li> </ul>
<p>12. Is your Organization based outside of the United States?</p>	<p>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.</p>
<p>13. What country-specific laws, regulations, and guidance does your Organization apply to research involving human participants?</p>	<p><b>Only Organizations that respond “yes” to the prior question will be asked to respond to this question.</b></p> <p>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.</p>
<p><b>Section II.B Ethics Review and Total Number of Actives Studies</b></p>	
<p>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.</p>	
<p>14. Does your Organization have an internal IRB(s)/EC(s) or is your Organization an independent IRB/EC?</p> <p>NOTE: If your Organization conducts research but also provides IRB review services for other Organizations, your Organization is NOT considered an independent IRB/EC.</p>	<p>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.</p> <p>Select “yes” if your Organization does NOT conduct research and is an IRB or ethics committee that is not owned or operated by the research organization for which it provides review services.</p> <p>If your Organization conducts research and provides IRB review services for other Organizations, your Organization is NOT considered an independent IRB/EC.</p>

<p>15. How many IRBs/ECs does your Organization maintain?</p>	<p>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). But some organizations define a single IRB, which has many members (e.g., 100 members) where only a small number attend each meeting, and where the membership may vary considerably. In this approach there are often “panels” that meet or “subcommittees” of the IRB. For example, your Organization might have three IRB panels with different members. In this case, you would report that you have three IRBs.</p> <p>Do not include in this number committees that do not review research.</p>
<p>16. What is the estimated total number of IRB/EC meetings a month for all of your Organization's IRBs/ECs combined?</p>	<p>Indicate the number of meetings your IRB(s)/EC(s) holds each month. If you have multiple IRB/EC committees/panels as described above, indicate the approximate number of meetings they hold per month, combined.</p>
<p>17. Does your Organization’s IRB(s)/EC(s) use electronic (computer) systems for any of these functions? Select all that apply.</p>	<ul style="list-style-type: none"> <li>• If your Organization does not use an electronic (computer system) to support any component of the review process, select <i>“My IRB(s)/EC(s) does not use any electronic (computer) system in support of the IRB/EC review process.”</i></li> <li>• <i>For database for tracking IRB/EC submissions:</i> This refers to an online platform or system that allows your Organization to identify on an ongoing basis applications submitted for IRB/EC review. This could include a system that tracks research that is reviewed by an external IRB(s)/EC(s).</li> <li>• <i>For online application for IRB/EC submissions:</i> This refers to an online platform or system that allows research teams to prepare and/or submit their applications for IRB/EC review.</li> <li>• <i>For online distribution of review materials to IRB/EC members:</i> This refers to an online platform or system that allows IRB/EC members to be assigned or access materials for their review.</li> <li>• <i>For online application for IRB/EC review functions:</i> This refers to an online platform or system that allows IRB/EC members and staff to communicate about protocols and other related materials to document or record their decisions and study-specific determinations.</li> </ul>
<p>18. 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 <b>expedited review</b>.</p>	<p>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.</p>

<p>19. What is the number of open studies reviewed by an internal IRB(s)/EC(s) under <b>expedited procedures</b> at initial review?</p>	<ul style="list-style-type: none"> <li>• <i>Open studies</i> 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).</li> <li>• <i>For open studies reviewed via expedited procedures</i> 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.</li> </ul>
<p>20. What is the number of open studies reviewed by an internal IRB(s)/EC(s) at a <b>convened meeting</b> at initial review?</p>	<ul style="list-style-type: none"> <li>• <i>Open studies</i> 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).</li> <li>• 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.</li> </ul>
<p>21. Do the laws, regulations, codes, and guidance under which your Organization conducts or reviews human participants research allow this research to be determined <b>exempt</b>?</p>	<p>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.</p>
<p>22. Please select the statement that best describes your Organization’s policies and procedures for <b>exempt human participants research</b>.</p>	<ul style="list-style-type: none"> <li>• If your Organization is an independent IRB/EC and makes exempt human participants research determinations on behalf of other Organizations, select: <i>My Organization is an independent IRB/EC and makes exempt human participants research determinations as permitted by applicable regulations for a specific study.</i></li> <li>• 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: <i>My Organization solely allows exempt human participants research determinations as outlined within US regulations.</i> 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.</li> <li>• 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: <i>My Organization allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.</i></li> <li>• 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: <i>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.</i></li> </ul>



<p>23. What is the number of <b>exempt human participants research determinations</b> made, whether by an internal review process (by an internal IRB/EC or other internal HRPP review process) or external IRB/EC, within the most recent year (the period from January 1 through December 31)? Note this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.</p>	<p>Count the number of studies determined to be exempt human participants research in the most recent complete year (e.g., January 1 through December 31, 2021). If your Organization has determined a study to be exempt using the limited IRB review process permitted under the US Common Rule, include those studies in this count. This count does not include determinations that activities are not human participants research.</p>
<p>24. Does your Organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?</p>	<p>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.</p>
<p><b>Section II.C Use of External IRBs/ECs</b></p>	
<p>25. Does your Organization use one or more external IRBs/ECs to review some or all of its human participants research?</p>	<ul style="list-style-type: none"> <li>• If your Organization is an independent IRB/EC please check the box: <i>I did not complete this section because my Organization is an independent IRB/EC.</i></li> <li>• 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.</li> </ul>
<p>26. What is the number of open studies (excluding exempt human participants research) <b>reviewed by an external IRB(s)/EC(s)?</b></p>	<p>Count the number of open studies reviewed by an external IRB(s)/EC(s) (regardless of when the study was first approved). <i>Open studies</i> means studies that have not been closed by the IRB/EC. Do NOT include studies determined by an external IRB(s)/EC(s) to be exempt human participants research here. Information about research determined to be exempt human subjects research by an external IRB/EC should be included with the number of exempt human participants research determinations made, whether by an internal review process (by an internal IRB/EC or other internal HRPP review process) or external IRB/EC, within the most recent year (the period from January 1 through December 31), which is requested above.</p>
<p>27. What is the approximate percentage of your Organization’s human participant research studies reviewed by an external IRB(s)/EC(s)? This percentage should include review of exempt human participants research.</p>	<p>Calculate the percentage of all of the human participants research your Organization conducts, manages, and/or sponsors that is reviewed by an external IRB(s)/EC(s). AAHRPP views all of your Organization’s human participants research as including studies determined to be exempt research.</p>
<p>28. What is the approximate percentage of external IRBs/ECs that your Organization relies upon that are NOT AAHRPP-accredited?</p>	<p>Of all the external IRBs/ECs your Organization relies on to review human participants research, including any exempt research, calculate the percentage of IRBs/ECs that have not been accredited by AAHRPP. To find out if an Organization is AAHRPP-accredited, go to <a href="https://www.aahrpp.org/learn/find-an-accredited-organization">https://www.aahrpp.org/learn/find-an-accredited-organization</a>.</p>
<p><b>Section III. Review Timelines and Determinations (complete this section for Step 1 only)</b></p>	
<p>29. Does your Organization have internal IRBs/ECs OR is it an independent IRB/EC?</p>	<p>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.</p>



<p>30. Number of studies disapproved by your Organization’s IRB(s)/EC(s) at initial review in the most recent year (the period from January 1 through December 31)</p>	<p>Count the number of studies a convened IRB/EC voted to disapprove in the most recent complete year (e.g., January 1 through December 31, 2021).</p>
<p>31. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from:</p> <ul style="list-style-type: none"> <li>• The complete submission to the initiation of EXPEDITED REVIEW</li> <li>• The complete submission to approval via EXPEDITED REVIEW</li> </ul>	<ul style="list-style-type: none"> <li>• <i>For complete submission to initiation of expedited review:</i> This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review. <i>Complete submission</i> means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s).</li> <li>• <i>For complete submission to approval:</i> This time period is measured from when a complete study application is assigned to a designated IRB/EC member(s) who will conduct the expedited review to when all conditions are met to secure IRB/EC approval and the research can begin to conduct the study. <i>Complete submission</i> means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by an IRB/EC member(s).</li> <li>• If an expedited review process was not used by your Organization for the initial review of any studies, select: <i>My Organization’s IRB(s)/EC(s) did not review any studies reviewed under EXPEDITED REVIEW procedures in the most recent year.</i></li> </ul>
<p>32. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from:</p> <ul style="list-style-type: none"> <li>• The complete submission to CONVENED BOARD REVIEW</li> <li>• The complete submission to approval via CONVENED BOARD REVIEW</li> </ul>	<ul style="list-style-type: none"> <li>• <i>For complete submission to convened board review:</i> This time period is measured from receipt of a complete study application via the designated IRB/EC submission process to the first time the study is reviewed at a convened IRB/ EC meeting. <i>Complete submission</i> means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC.</li> <li>• <i>For complete submission to convened board approval:</i> This time period is measured from receipt of a complete study application via the designated IRB/EC submission process to the day all requests made by the IRB/EC to secure approval, if any, have been resolved and the researcher is allowed to conduct the study. If a study is approved without contingencies or modifications at a convened board meeting, this would be the date of convened board approval. If a study is approved with contingencies or modifications that must be made before the researcher is allowed to conduct the study, the date of approval is when all modifications or contingencies have been resolved. <i>Complete submission</i> means the IRB/EC application has been determined, by whatever process the IRB/EC uses, to be ready for review by a convened IRB/EC.</li> <li>• If a convened board review process was not used by your Organization for the initial review of any studies, select: <i>My Organization’s IRB(s)/EC(s) did not review any studies reviewed under CONVENED BOARD procedures in the most recent year.</i></li> </ul>

<p>33. For <b>exemption determinations made through an internal review process</b> (which could include review by an IRB/EC) during the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from the complete submission to an exemption determination?</p>	<ul style="list-style-type: none"> <li>• This time period is measured from when a complete study application is assigned to a designated reviewer and determined to be exempt human participants research. <i>Complete submission</i> means the study application received by your Organization has been determined, by whatever process used, to be ready for exempt review. DO NOT include exemptions reviewed by an external process.</li> <li>• If an exemption review process was not used by your Organization for the initial review of any studies or no studies were determined to be exempt human participants research, select: <i>My Organization did not have any studies determined to be exempt human participants research in the most recent year.</i></li> </ul>
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<p>34. Please tell us about your Organization's review of certain events.</p>	<ul style="list-style-type: none"> <li>• <i>For unresolved complaints:</i> Provide the number of unresolved complaints from research participants that your Organization's HRPP, which includes any received by an internal IRB/EC, has received in the most recent complete year (the period from January 1 through December 31). A complaint is an expression of dissatisfaction, protest, or outcry related to a research study, researchers or research staff, or the IRB/EC. Unresolved means a complaint that cannot be resolved by the research team or the relying organization. If the complaint is about the IRB/EC, the complaint cannot be resolved by IRB/EC administrative staff and must be reviewed by the IRB/EC. <b>For independent IRBs/ECs</b>, this is the number of unresolved complaints from research participants your IRBs/ECs received for review.</li> <li>• <i>For alleged noncompliance:</i> Indicate the number of new cases of alleged noncompliance evaluated through your Organization's HRPP process, which could be by an internal IRB/EC in the most recent complete year (the period from January 1 through December 31). This includes cases that subsequently were not deemed noncompliance or were deemed noncompliance (whether or not the noncompliance was also determined to be serious or continuing noncompliance). <b>For independent IRBs/ECs</b>, this is the number of new cases of alleged noncompliance your IRBs/ECs received.</li> <li>• <i>For serious noncompliance:</i> 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 <b>serious</b>, such as under US federal regulations, other laws or regulations, or institutional policy. <b>For independent IRBs/ECs</b>, this is the number of determinations of serious noncompliance made by your IRB(s)/EC(s).</li> <li>• <i>For continuing noncompliance:</i> 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 <b>continuing</b>, such as under US federal regulations, other laws or regulations, or institutional policy. <b>For independent IRBs/ECs</b>, this is the number of determinations of continuing noncompliance made by your IRB(s)/EC(s).</li> <li>• <i>For unanticipated problems:</i> 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 <b>unanticipated problem</b>, such as under US federal regulations, other laws or regulations, or institutional policy. <b>For independent IRBs/ECs</b>, this is the number of determinations of unanticipated problems made by your IRB(s)/EC(s).</li> </ul>
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**Section IV. Review of Reportable Events and Compliance Activities (complete this section for Step 1 only)**

<p>35. Please tell us about your Organization's compliance activities related to research studies.</p>	<ul style="list-style-type: none"><li>• <i>For governmental or regulatory agency inspections:</i> 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.</li><li>• <i>For internal "for cause" audits of IRB/EC records:</i> "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).</li><li>• <i>For internal "not for cause" audits of IRB/EC records:</i> "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.</li><li>•</li></ul>
<p>36. Please tell us about your Organization's compliance activities related to IRB/EC review.</p>	<ul style="list-style-type: none"><li>• If your Organization a) does not have an internal IRB(s)/EC(s) or b) is not an independent IRB/EC, select: <i>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).</i></li><li>• <i>For governmental or regulatory agency inspections:</i> 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.</li><li>• <i>For internal "for cause" audits of IRB/EC records:</i> "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).</li><li>• <i>For internal "not for cause" audits of IRB/EC records:</i> "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.</li><li>•</li></ul>

**Section V. Review of Reportable Events and Compliance Activities (Complete this section for Step 1 only)**

<p>37. Please tell us about your Organization's management of financial conflicts of interest related to human participants research.</p>	<ul style="list-style-type: none"> <li>• <i>For number of financial disclosures:</i> This refers to disclosures of financial interests by researchers or research staff as required by the laws, regulations, and codes to which your organization must follow, and to any additional disclosure requirements in organization policies (including but not limited to FDA, NSF, PHS, VA requirements, if your organization reviews for VA hospitals, and any state laws). Thus, it applies to all researchers engaged in research involving human participants, not only to those covered by US PHS requirements. <b>For independent IRBs/ECs</b>, this is the number of financial disclosures your Organization received in conjunction with IRB/EC review.</li> <li>• <i>For number of financial disclosures determined to indicate a financial conflict of interest:</i> This refers to financial disclosures made by researchers or research staff under the purview of your Organization determined by your Organization's process (person or committee) to indicate a financial conflict of interest related to the research. This information is usually provided by the Conflict of Interest Committee or Office staff.</li> <li>• <i>For number of management plans:</i> This refers to studies reviewed by internal or external IRB(s)/EC(s) for which a management plan related to financial conflict of interest was put in place.</li> </ul>
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**Section VI. HRPP Staff and Budget (complete this section for Step 1 only)**

<p>38. Please tell us about the staff and budget for your HRPP, EXCLUDING IRB(s)/EC(s).</p>	<ul style="list-style-type: none"> <li>• For Organizations that are independent IRB(s)/EC(s), this would include staff, if any, who do not directly support IRB/EC review or administration functions.</li> <li>• <i>For the HRPP FTEs:</i> Indicate the total number of FTEs dedicated to your HRPP, other than the IRB/EC. Include portions of FTE and add the portions to obtain a total number of FTEs. Consider the policies and procedures submitted for your HRPP – include the personnel resources (FTEs) needed to perform those policies and procedures on an annual basis (excluding IRB/EC related personnel). Use the key personnel list that is submitted with the Step 2 application as a basis for counting the total number of FTEs that comprise your HRPP.</li> <li>• <i>For the HRPP budget:</i> Indicate the total number of US dollars dedicated to your HRPP, excluding the IRB/EC. This should include both personnel and non-personnel costs. Include portions of salaries for HRPP administrative time for faculty and executives. The budget information can be provided for either the last complete year or last fiscal year, whichever is easier for your Organization to provide.</li> </ul>
<p>39. Please tell us about the staff and budget for your internal IRBs/ECs.</p>	<ul style="list-style-type: none"> <li>• If your Organization a) does not have an internal IRB(s)/EC(s) or b) is not an independent IRB/EC, please check: <i>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).</i></li> <li>• <i>For the IRB/EC FTEs:</i> 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.</li> <li>• <i>For the IRB/EC budget:</i> Indicate the estimated total number of US dollars dedicated to your IRB(s)/EC(s). This should include both</li> </ul>

	<p>personnel and non-personnel costs. Include portions of salaries for IRB/EC members, chairs, and vice chairs that are employees of your Organization. The budget information can be provided for either the last full year or fiscal year, whichever is easier for your Organization to provide.</p>
<p><b>Section VII. Compensation of IRB/EC Members</b></p>	
<ul style="list-style-type: none"> <li>• Complete this section for Step 1 only</li> <li>• If your Organization does not have internal IRB(s)/EC(s) or are not independent IRB(s)/EC(s) skip this section.</li> </ul>	
<p>40. Please indicate any of the following types of FINANCIAL support your Organization provides IRB/EC Chairs.</p> <ul style="list-style-type: none"> <li>• Salary support (full or partial)</li> <li>• Pay for specific activities (e.g., conducting IRB meeting, reviews)</li> <li>• Stipend/honorarium</li> <li>• Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees</li> <li>• Reimbursement of the IRB/EC Chair's home department/clinic for time</li> <li>• Other, please describe</li> <li>• My Organization does not provide financial support for IRB/EC Chairs</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization provides financial support for IRB/EC Chairs, please select all forms of financial support that your Organization's IRB/EC Chairs may receive. If other forms of financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.</li> <li>• If your Organization does not provide financial support for IRB/EC Chairs, select: <i>My Organization does not provide financial support for IRB/EC Chairs</i></li> </ul>
<p>41. Please indicate any of the following types of NON-FINANCIAL support your Organization provides IRB/EC Chairs.</p> <ul style="list-style-type: none"> <li>• Food at IRB/EC meetings</li> <li>• Thank you or appreciation gifts of nominal value</li> <li>• Other, please describe</li> <li>• My Organization does not provide non-financial support for IRB/EC Chairs</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization provides non-financial support for IRB/EC Chairs, please select all forms of non-financial they may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.</li> <li>• If your Organization does not provide non-financial support for IRB/EC Chairs, select: <i>My Organization does not provide non-financial support for IRB/EC Chairs</i></li> </ul>

<p>42. Please indicate any of the following types of FINANCIAL support your Organization provides IRB/EC Vice Chairs.</p> <ul style="list-style-type: none"> <li>• Salary support (full or partial)</li> <li>• Pay for specific activities (e.g., conducting IRB meeting, reviews)</li> <li>• Stipend/honorarium</li> <li>• Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees</li> <li>• Reimbursement of the IRB/EC Vice Chair's home department/clinic for time</li> <li>• Other, please describe</li> <li>• My Organization does not provide financial support for IRB/EC Vice Chairs</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization does not have Vice-Chairs for your IRB(s)/EC(s), please check: <i>I did not respond to this question because my Organization's IRB(s)/EC(s) does not have any Vice-Chairs.</i></li> <li>• If your Organization has Vice Chairs for your IRB(s)/EC(s) and provides financial support for them, 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.</li> <li>• If your Organization has Vice Chairs for your IRB(s)/EC(s) but does not provide financial support for them, select: <i>My Organization does not provide financial support for IRB/EC Vice Chairs</i></li> </ul>
<p>43. Please indicate any of the following types of NON-FINANCIAL support your Organization provides IRB/EC Vice Chairs</p> <ul style="list-style-type: none"> <li>• Food at IRB/EC meetings</li> <li>• Thank you or appreciation gifts of nominal value</li> <li>• Other, please describe</li> <li>• My Organization does not provide non-financial support for IRB/EC Vice Chairs</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization does not have Vice Chairs for your IRB(s)/EC(s), please check: <i>I did not respond to this question because my Organization's IRB(s)/EC(s) does not have any Vice Chairs.</i></li> <li>• If your Organization has Vice Chairs for your IRB(s)/EC(s) and provides non-financial support for them, please select all forms of non-financial support they may receive. If other forms of non-financial support are provided that are not on the list, please select "Other, please describe" and explain what that support is.</li> <li>• If your Organization has Vice-Chairs for your IRB(s)/EC(s) but does not provide non-financial support for them, select: <i>My Organization does not provide non-financial support for IRB/EC Vice Chairs</i></li> </ul>
<p>44. Please indicate what type of FINANCIAL support your Organization provides Affiliated IRB/EC Members who are not Chairs or Vice Chairs.</p> <ul style="list-style-type: none"> <li>• Salary support (full or partial)</li> <li>• Pay for specific activities (e.g., attending IRB/EC meetings, reviews)</li> <li>• Stipend/honorarium</li> <li>• Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees</li> <li>• Reimbursement of the IRB/EC Affiliated IRB/EC Member's home department/clinic for time</li> <li>• Other, please describe</li> <li>• My Organization does not provide financial support for Affiliated IRB/EC Members</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Affiliated IRB/EC members</i> 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.</li> <li>• 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.</li> <li>• If your Organization does not provide financial support for Affiliated IRB/EC members, select: <i>My Organization does not provide financial support for Affiliated IRB/EC Members</i></li> </ul>



<p>45. Please indicate any of the following types of NON-FINANCIAL support your Organization provides for Affiliated IRB/EC Members.</p> <ul style="list-style-type: none"> <li>• Food at IRB/EC meetings</li> <li>• Thank you or appreciation gifts of nominal value</li> <li>• Other, please describe</li> <li>• My Organization does not provide non-financial support for Affiliated IRB/EC Members</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization provides non-financial support for Affiliated IRB/EC members, please select all forms of non-financial support they may receive. If other forms of non-financial support are provided that are not on the list, please select “Other, please describe” and explain what that support is.</li> <li>• If your Organization does not provide non-financial support for Affiliated IRB/EC members, select: <i>My Organization does not provide non-financial support for Affiliated IRB/EC Members</i></li> </ul>
<p>46. Please indicate any of the following types of FINANCIAL support your Organization provides Unaffiliated IRB/EC Members.</p> <ul style="list-style-type: none"> <li>• Pay for specific activities (e.g., attending IRB meetings, reviews)</li> <li>• Stipend/honorarium</li> <li>• Support for attendance at HRPP/IRB-related conferences or continuing education activities, such as travel or registration fees</li> <li>• Other, please describe</li> <li>• My Organization does not provide financial support for Unaffiliated IRB/EC Members</li> </ul>	<ul style="list-style-type: none"> <li>• 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”.</li> <li>• 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.</li> <li>• If your Organization does not provide financial support for Unaffiliated IRB/EC members, select: <i>My Organization does not provide financial support for Unaffiliated IRB/EC Members</i></li> </ul>
<p>47. Please indicate any of the following types of NON-FINANCIAL support your Organization provides for Unaffiliated IRB/EC Members.</p> <ul style="list-style-type: none"> <li>• Food at IRB/EC meetings</li> <li>• Thank you or appreciation gifts of nominal value</li> <li>• Other, please describe</li> <li>• My Organization does not provide non-financial support for Unaffiliated IRB/EC Members</li> </ul>	<ul style="list-style-type: none"> <li>• If your Organization provides non-financial support for Unaffiliated IRB/EC members, please select all forms of non-financial support they may receive. If other forms of non-financial support are provided that are not on the list, please select “Other, please describe” and explain what that support is.</li> <li>• If your Organization does not provide non-financial support for Unaffiliated IRB/EC members, select: <i>My Organization does not provide non-financial support for Unaffiliated IRB/EC Members</i></li> </ul>