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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Text  Description automatically generated** | | | | | | | | | |
| **Section A:** | | | | | | | | | |
| Please review the following documents to assist you with preparing and submitting your application:   * Instructions to Apply for Initial Accreditation and Reaccreditation * Instructions for Submitting Materials in Support of Accreditation * Guidance on Completing Section A | | | | | | | | | |
| **Check the appropriate box below to indicate the reason this form is being submitted to AAHRPP (check one)** | | | | | | | | | |
| ***Application for Initial Accreditation*** | | | | **Step 1** | **Step 2** | | | | |
| ***Application for Reaccreditation*** | | | | **Step 1** | **Step 2** | | | | |
| *NOTE*: If submitting an application for Step 2, review the information in Section A from your Step 1 application and update as needed. If no changes are needed or requested in your Step 1 review, it is acceptable to resubmit the Section A you completed for Step 1. | | | | | | | | | |
| 1. **Organization Information (for Step 1 and Step 2)** | | | | | | | | | |
| 1. **For Reaccreditation Applications Only** | | | | | | | | | |
| Please make any changes in organizational name, contacts, and other general organization information in the **AAHRPP Online Accreditation Management System (OAMS)**: [**https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system**](https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system). Additionally, if the legal or website name of your organization changes during the reaccreditation process, please contact us at [reporting@aahrpp.org](mailto:reporting@aahrpp.org). | | | | | | | | | |
| **Identifying Your Organization** | | | | | | | | | |
| Name of organization as it appears on AAHRPP’s [website](https://www.aahrpp.org/find-an-accredited-organization):  Click or tap here to enter text. | | | | | | | | | |
| City:  Click or tap here to enter text. | | | State/Province/Territory:  Click or tap here to enter text. | | | | Country/Region:  Click or tap here to enter text. | | |
| 1. **For Initial Accreditation Applications Only:** | | | | | | | | | |
| **Identifying Your Organization** | | | | | | | | | |
| Legal name of organization applying for accreditation (please consult with your general counsel):  Click or tap here to enter text. | | | | | | | | | |
| The preferred name for your organization (e.g., the name that should appear on AAHRPP’s website and accreditation  certificates), if different from above: Click or tap here to enter text. | | | | | | | | | |
| Organization address:  Street: Click or tap here to enter text. Zip/Postal Code: Click or tap here to enter text. | | | | | | | | | |
| City:  Click or tap here to enter text. | State/Province/Territory:  Click or tap here to enter text. | | | | | Country/Region:  Click or tap here to enter text. | | | |
| **Application Contact** | | | | | | | | | |
| Name and Degree(s): Click or tap here to enter text. | | | | | | | | | |
| Title: Click or tap here to enter text. | | | | | | | | | |
| Department: Click or tap here to enter text. | | | | | | | | | |
| Address, if different from above: Click or tap here to enter text. | | | | | | | | | |
| Telephone (including country code): Click or tap here to enter text. | | | | | | | | | |
| Fax (including country code): Click or tap here to enter text. | | | | | | | | | |
| Primary Email: Click or tap here to enter text. | | | | | | | | | |
| Alternate Email: Click or tap here to enter text. | | | | | | | | | |
| Date: | | | | | | | | | |
| **Responsible Organizational Official** | | | | | | | | | |
| Name and Degree(s): Click or tap here to enter text. | | | | | | | | | |
| Title: Click or tap here to enter text. | | | | | | | | | |
| Department: Click or tap here to enter text. | | | | | | | | | |
| Address, if different from above: Click or tap here to enter text. | | | | | | | | | |
| Telephone (including country code): Click or tap here to enter text. | | | | | | | | | |
| Fax (including country code): Click or tap here to enter text. | | | | | | | | | |
| Primary Email: Click or tap here to enter text. | | | | | | | | | |
| Alternate Email: Click or tap here to enter text. | | | | | | | | | |
| **Billing Contact** | | | | | | | | | |
| Name and Degree(s): Click or tap here to enter text. | | | | | | | | | |
| Title: Click or tap here to enter text. | | | | | | | | | |
| Department: Click or tap here to enter text. | | | | | | | | | |
| Address, if different from above: Click or tap here to enter text. | | | | | | | | | |
| Telephone (including country code): Click or tap here to enter text. | | | | | | | | | |
| Fax (including country code): Click or tap here to enter text. | | | | | | | | | |
| Primary Email: Click or tap here to enter text. | | | | | | | | | |
| Alternate Email: Click or tap here to enter text. | | | | | | | | | |
| List any email addresses that should be carbon copied on invoices (CC): Click or tap here to enter text. | | | | | | | | | |
| 1. **For ALL Organizations: Entities (Formerly Components)** | | | | | | | | | |
| 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?  NOTE: Do not include organizations for which the primary relationship between your HRPP and the other organization is reliance upon your IRB/EC.  My organization does not have any additional entities that will be covered by this application.  My organization has the following additional entities that will be covered by this application.  **Entity name(s) and location(s) (City, State, Country)**  Click or tap here to enter text. | | | | | | | | | |
| 1. **For ALL Organizations: Certification** | | | | | | | | | |
| Applicant certifies that the information contained in this application and thereafter provided to AAHRPP is accurate, complete, and not misleading in any way. Applicant agrees to properly characterize its accreditation status during the application process, the site visit process, and thereafter. Applicant agrees to release AAHRPP and each of its members, directors, officers, employees, and agents (the "AAHRPP Representatives") from any and all claims, and to indemnify and hold harmless AAHRPP and the AAHRPP Representatives from and against any and all liability and costs incurred by them, including attorneys' fees, resulting directly or indirectly from any applications, site visits, evaluations, and decisions regarding the accreditation of the Applicant's Human Research Protection Program. Applicant certifies that it has read the AAHRPP Accreditation Procedures and agrees to abide by those procedures.  **Name of person submitting the application:** Click or tap here to enter text.  **Date application submitted:** Click or tap to enter a date. | | | | | | | | | |
| 1. **Information About Your Organization’s Human Research Protection Program (for Step 1 and Step 2)** | | | | | | | | | |
| 1. **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.) | | Research activities occur in the state/province/region within the country where my organization is primarily based  Research activities occur in other states/provinces/regions within the country where the organization is primarily based  Research activities occur in countries other than the country where the organization is primarily based | | | | | | | |
| 1. What kind of research does your organization review, conduct, manage, and/or sponsor? | | Biomedical/clinical | | | | | | Yes  No | |
| Social/behavioral/education | | | | | | Yes  No | |
| 1. Does your organization review, conduct, manage, and/or sponsor studies involving: | | Investigational drugs, biologics, or dietary supplements | | | | | | Yes  No | |
| Investigational devices | | | | | | Yes  No | |
| 1. Does your organization review, conduct, manage, and/or sponsor studies involving any of the following vulnerable participant populations? | | * Children | | | | | | Yes  No | |
| * Pregnant individuals | | | | | | Yes  No | |
| * Prisoners | | | | | | Yes  No | |
| * Adults unable to provide informed consent | | | | | | Yes  No | |
| 1. Does your organization review, conduct, manage, and/or sponsor planned emergency research\*?   NOTE: This question only applies to organizations that follow US FDA regulations or US DHHS regulations. | | Yes  No  \*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. | | | | | | | |
| 1. 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) | | | | | | | |
| 1. 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) | | | | | | | Yes  No |
| US Department of Education (ED) | | | | | | | Yes  No |
| US Department of Energy (DOE) | | | | | | | Yes  No |
| US Department of Health and Human Services (DHHS) | | | | | | | Yes  No |
| US Department of Justice (DoJ) | | | | | | | Yes  No |
| US Department of Veterans Affairs (VA) | | | | | | | Yes  No |
| US Environmental Protection Agency (EPA) | | | | | | | Yes  No |
| US Food and Drug Administration (FDA) | | | | | | | Yes  No |
| US National Science Foundation (NSF) | | | | | | | Yes  No |
| 1. Does your organization reasonably expect to adhere to the International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP)? (Select the one statement that best describes your organization.) | | My organization does not adhere to ICH-GCP E6.  My organization adheres to ICH-GCP only as adopted by the US FDA or country-specific GCP (e.g., Japan GCP) for all applicable clinical trials.  My organization only adheres to ICH-GCP E6 at a sponsor’s request.  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.  My organization adheres to ICH-GCP E6 for all applicable clinical trials. | | | | | | | |
| 1. Does your organization have a US Federalwide Assurance (FWA)? | | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 11 | | | | | | | |
| 1. Please select the statement that best reflects the terms of your FWA. | | My organization applies the same policies and procedures regardless of funding  My organization applies different but equivalent policies and procedures for some or all research not covered by regulations | | | | | | | |
| 1. Is your organization primarily based outside of the US? | | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 13 | | | | | | | |
| 1. What country-specific laws, regulations, and guidance does your organization apply to research involving human participants? Click or tap here to enter text. | | | | | | | | | |

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| 1. **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.** | | |
| 1. Does your organization have at least one internal IRB/EC OR is your organization an independent IRB/EC (defined in the Guidance document)?   Note: An **Independent IRB or EC** is an IRB or ethics committee that is *not* part of an organization that conducts research and is *not* owned or operated by the research organization for which it provides review services. These organizations are sometimes referred to as commercial IRBs. IRBs/ECs embedded within the organization that may conduct research (such as academic organizations, hospitals, or health systems) are NOT considered independent IRBs or ECs.  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>. | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 23 | |
| 1. How many IRBs/ECs does your organization maintain? | 1  2  3  4  5  6  7  8  9  10  More than 10, please specify: Click or tap here to enter text. | |
| 1. Does your organization’s IRB(s)/EC(s) use electronic (computer) system(s) to manage the submission and review process?   My IRB(s)/EC(s) **does not use any electronic (computer) system** in support of the IRB/EC submission and review process. | *My organization’s IRB(s)/EC(s) uses an electronic system:* | |
| …that allows researchers to prepare and/or submit their applications for IRB/EC review. | Yes  No |
| …that allows IRB/EC members to review IRB/EC applications and supporting materials. | Yes  No |
| …that allows IRB/EC members and staff to communicate about IRB applications and other related materials. | Yes  No |
| …to document or record IRB/EC decisions and study-specific determinations within the system. | Yes  No |
| 1. Do you serve as the reviewing IRB/EC for external organizations conducting research? | Not applicable - my organization is an independent IRB; if you selected this option, skip to question 18  Yes  No; if you answered “no”, skip to question 20 | |
| 1. 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? | Click or tap here to enter text. | |
| 1. Does your organization provide IRB review for a US Department of Veterans Affairs (VA) facility? | Yes  No; if you answered “no”, skip to question 20 | |
| 1. Does your organization serve as the academic affiliate for a VA facility? | Yes; my organization serves as an academic affiliate for the following VA facility(ies): Click or tap here to enter text.  No | |
| 1. Do the laws, regulations, codes, guidance, or policies under which your organization conducts or reviews research involving human participants allow research that is not exempt to be reviewed by a non-committee process? Under the US Common Rule this non-committee review process is referred to as **expedited review.** | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 22 | |
| 1. What is the number of open studies reviewed by an internal IRB(s)/EC(s) under **expedited procedures** at initial review?   Click or tap here to enter text. | | |
| 1. What is the number of open studies reviewed by an internal IRB(s)/EC(s) at a **convened meeting** at initial review?   Click or tap here to enter text. | | |
| 1. Do the laws, regulations, codes, and guidance under which your organization conducts or reviews human participants research allow some research to be determined **exempt**? | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 29 | |
| 1. Please select the statement that best describes your organization’s policies and procedures for **exempt human participants research**.   My organization is an independent IRB/EC and makes exempt human participants research determinations as permitted by applicable regulations for a specific study.  My organization is not an independent IRB/EC and solely allows exempt human participants research determinations as outlined within US regulations.  My organization is not an independent IRB/EC and allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.  My organization is not an independent IRB/EC and 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. | | |
| 1. Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research? | Yes  No | |
| 1. What is the number of **exempt human participants research determinations** made within the most recent year (the period from January 1 through December 31) **by an internal review process** (e.g., by an internal IRB/EC or other internal HRPP review process):   Click or tap here to enter text.  Note: this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.  The question was not answered because my organization does not use an internal process to make exempt human participants research determinations. | | |
| 1. 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? Click or tap here to enter text.   The question was not answered because:  My organization did not have any studies determined to be exempt human participants research in the most recent year.  My organization does not use an internal process to make exempt human participants research determinations. | | |
| 1. 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):   Click or tap here to enter text.  Note: this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.  The question was not answered because my organization does not use an external process to make exempt human participants research determinations. | | |

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| 1. **Use of External IRBs/ECs** | |
| 1. Does your organization rely on one or more external IRBs/ECs to review some or all of its human participants research?   I did not complete this section because my organization is an independent IRB/EC. | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to Section III if you are completing a Step 1 application. If you are completing a Step 2 application, your application is complete after answering this question. |
| 1. What is the number of open studies (excluding exempt human participants research) reviewed by an external IRB(s)/EC(s)?   Click or tap here to enter text. | |
| 1. Does your organization rely on a non-accredited IRB(s)/EC(s) for the review of some or all of its human participants research? | Yes, my organization relies on the following non-accredited IRB(s)/EC(s) for the review of ALL of its human participants research: Click or tap here to enter text.  Yes, my organization relies on a non-accredited IRB(s)/EC(s) for the review of SOME of its human participants research.  No, my organization does not rely on any non-accredited IRB(s)/EC(s) for the review of its human participants research; if you answered “no”, skip to question 33 |
| 1. What is the approximate percentage of human participants research your organization relied on an external IRB(s)/EC(s) that is not AAHRPP-accredited for review during the most recent year (the period from January 1 through December 31)? | < 1-5  6-25  26-50  51-75  76-100 |
| 1. **Review Timelines and Determinations (complete this section for Step 1 only)** | |
| 1. Does your organization have at least one internal IRB/EC OR is it an independent IRB/EC? | Yes; if you answered “yes”, please continue to the next question  No; if you answered “no”, skip to question 36 |
| 1. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from submission to approval via EXPEDITED REVIEW for initial review of human participants research: Click or tap here to enter text.   My organization’s IRB(s)/EC(s) did not review any studies under EXPEDITED REVIEW procedures in the most recent year. | |
| 1. 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: Click or tap here to enter text. * Submission to final approval via CONVENED BOARD REVIEW for initial review of human participants research: Click or tap here to enter text.   My organization’s IRB(s)/EC(s) did not review any studies by the CONVENED BOARD in the most recent year. | |

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| 1. Please tell us about your organization's review of certain events. | For the most recent year (the period from January 1 through December 31): | |
| * Number of **determinations of serious noncompliance**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB(s)/EC(s).   **Note: For independent IRBs/ECs**, this is the number of determinations of serious noncompliance made by your IRB(s)/EC(s). | Click or tap here to enter text. |
| * Number of **determinations of continuing noncompliance**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB(s)/EC(s).   **Note: For independent IRBs/ECs**, this is the number of determinations of continuing noncompliance made by your IRB(s)/EC(s). | Click or tap here to enter text. |
| * Number of **determinations of unanticipated problems**, including those made through your organization’s review process (which could be by an internal IRB/EC) and external IRB(s)/EC(s).   **Note: For independent IRBs/ECs**, this is the number of determinations of unanticipated problems made by your IRB(s)/EC(s). | Click or tap here to enter text. |
| 1. **Review of Reportable Events and Compliance Activities (complete this section for Step 1 only)** | | |
| 1. Please tell us about your organization's compliance activities related to research studies. | For the most recent year (the period from January 1 through December 31): | |
| * Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections of research studies your organization conducts, reviews, manages, and/or sponsors 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)**.   A number was not provided because my organization is an independent IRB/EC and does not track this information. | Click or tap here to enter text. |
| * Number of **“for cause” audits** your organization conducted **of research studies your organization conducts, manages, reviews, and/or sponsors**. | Click or tap here to enter text. |
| * Number of **“not for cause”/random/** **routine post-approval audits** your organization conducted **of research studies your organization conducts, manages, reviews, and/or sponsors**. | Click or tap here to enter text. |

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| 1. Please tell us about your organization's compliance activities related to IRB/EC review.   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 the most recent year (the period from January 1 through December 31): | |
| * Number of **governmental or regulatory agency** (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) **inspections or reviews of IRB(s)/EC(s) at your organization**. | Click or tap here to enter text. |
| * Number of **“for cause” audits** your organization conducted **of IRB(s)/EC(s) at your organization**. | Click or tap here to enter text. |
| * Number of **“not for cause”/random audits** your organization conducted **of IRB(s)/EC(s) at your organization**. | Click or tap here to enter text. |
| 1. **Review of Conflicts of Interest (complete this section for Step 1 only)** | | |
| 1. Please tell us about your organization's management of financial conflicts of interest related to human participants research. | For the most recent year (the period from January 1 through December 31): | |
| * 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 organization’s IRB(s)/EC(s) or external IRB(s)/EC(s) | Click or tap here to enter text. |
| 1. **IRB/EC Staff (complete this section for Step 1 only)** | | |
| 1. Please tell us about the staff for your internal IRB(s)/EC(s).   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 the most recent year (the period from January 1 through December 31) or last fiscal year: | |
| * Number of FTEs your organization has dedicated to your IRB(s)/EC(s) | Click or tap here to enter text. |
| 1. **Compensation of IRB/EC Members (complete this section for Step 1 only)** | | |
| **This section is not completed because my organization does not have an internal IRB(s)/EC(s) and is not an independent IRB(s)/EC(s).** | | |
| 1. Please indicate what type of FINANCIAL support your organization provides IRB/EC chairs or vice chairs (if your IRB(s)/EC(s) have vice chairs). | **Check all that apply.**  My organization does not provide any financial support for IRB/EC chairs or vice chairs.  Salary support (full or partial)  Pay for specific activities (e.g., conducting IRB/EC meetings, reviews)  Stipend/honorarium  Support for attendance at HRPP/IRB/EC-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: Click or tap here to enter text. | |
| 1. Please indicate what type of FINANCIAL support your organization provides affiliated IRB/EC members who are not chairs or vice chairs. | **Check all that apply.**  My organization does not provide any 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/EC-related conferences or continuing education activities, such as travel or registration fees  Other, please describe: Click or tap here to enter text. | |
| 1. Please indicate what type of FINANCIAL support your organization provides unaffiliated IRB/EC members who are not chairs or vice chairs. | **Check all that apply.**  My organization does not provide any financial support for unaffiliated IRB/EC members.  Pay for specific activities (e.g., attending IRB/EC meetings, reviews)  Stipend/honorarium  Support for attendance at HRPP/IRB/EC-related conferences or continuing education activities, such as travel or registration fees  Other, please describe: Click or tap here to enter text. | |