|  |
| --- |
|  |
| **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 the Application (Section A)
 |
| **Check the appropriate box below to indicate the reason this form is being submitted to AAHRPP (check one)** |
| [ ] ***Application Contact or Organizational Official*** ***Update***  **NOTE: If this is the reason for an application, complete Section I only** |
| [ ] ***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, it is acceptable to resubmit the Section A you completed for Step 1.** |
| 1. **Organization Information (complete this section for Step 1 and Step 2)**
 |
| 1. **Identifying Your Organization**
 |
| Legal name of Organization applying for accreditation (please consult with your general counsel): Click or tap here to enter text. |
| Organization name that should appear on AAHRPP’s website, if different from above: Click or tap here to enter text. |
| Organization address line 1Click or tap here to enter text. |
| Organization address line 2Click or tap here to enter text. |
| Organization address line 3Click or tap here to enter text. |
| City:Click or tap here to enter text. | State:Click or tap here to enter text. | Country:Click or tap here to enter text. | Zip/Postal Code:Click or tap here to enter text. |
| 1. **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. **Contact Information**
 |
| **Application Contact** **(Signature only required for a Step 1 application; electronic signatures are acceptable.)** |
| 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: Click or tap here to enter text. |
| Email: Click or tap here to enter text. |
| Signature  | Date: |
| **Responsible Organizational Official** **(Signature only required for a Step 1 application; electronic signatures are acceptable.)** |
| 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: Click or tap here to enter text. |
| Email: Click or tap here to enter text. |
| Signature  | Date: |
| **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: Click or tap here to enter text. |
| 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. **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. |

|  |
| --- |
| 1. **Information About Your Organization’s Human Research Protection Program (complete this section 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 the option that best describes your Organization.)
 | [ ]  Research activities occur only in my state/province/region within my country [ ]  Research activities occur in my state and other states/provinces/regions within my country[ ]  Research activities occur in my state/province/region and countries other than my country[ ]  Research activities occur in my state/province/region, other states/provinces/regions, and countries other than my country |
| 1. What kind of research does your Organization review, conduct, manage, and/or sponsor?

NOTE: Total percentage should equal 100%. | * Percentage of the research that is biomedical/clinical: Click or tap here to enter text.
* Percentage of research that is social/behavioral/education: Click or tap here to enter text.
 |
| 1. Does your Organization review, conduct, manage, and/or sponsor studies involving:
 | Investigational Drugs | [ ]  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 |
| Other vulnerable population(s), please specify: Click or tap here to enter text. |
| 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 |
| 1. What percent of human participant research that your Organization reviews, manages, conducts, and/or sponsors is:
 | * Sponsored by the US federal government
 | Click or tap here to enter text. |
| * Industry sponsored
 | Click or tap here to enter text. |
| * Sponsored by other external sources
 | Click or tap here to enter text. |
| * Sponsored by internal sources (including unfunded research)
 | Click or tap here to enter text. |
| 1. Does your Organization have a Federalwide Assurance (FWA)?
 | [ ]  Yes; if you answered “yes”, please continue to the next question [ ]  No; if you answered “no”, skip to question 10 |
| 1. Please select the statement that best reflects the terms of your FWA.
 | [ ]  My Organization applies the same policies and procedures regardless of whether research is covered by DHHS regulations or the Common Rule[ ]  My Organization applies different but equivalent policies and procedures for some or all research not covered by regulations |
| 1. How does your Organization apply the 2018 Common Rule to research?
 | Please select which statement best describes your Organization.[ ]  My Organization applies the 2018 Common Rule to all non-exempt human participants research, regardless of when it was approved by an IRB/EC[ ]  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 [ ]  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 |
| 1. 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.  | 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 |
| 1. Does your Organization reasonably expect to comply with the International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP)?
 | [ ]  My Organization does not comply with ICH-GCP[ ]  My Organization only complies with ICH-GCP as adopted by the US FDA [ ]  My Organization complies with the ICH-GCP E6(R2) for all clinical trials [ ]  My Organization only complies with ICH-GCP E6(R2) at a sponsor’s request  |
| 1. Is your organization based outside of the US?
 | [ ]  Yes; if you answered “yes”, please continue to the next question[ ]  No; if you answered “no”, skip to question 14 |
| 1. What country-specific laws, regulations, and guidance does your organization apply to research involving human participants?Click or tap here to enter text.
 |
| 1. **Ethics Review and Total Number of Actives 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 an internal IRB(s)/EC(s) OR is your Organization an independent IRB/EC?
 | [ ]  Yes; if you answered “yes”, please continue to the next question [ ]  No; if you answered “no”, skip to question 25 |
| 1. How many IRBs/ECs or 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. What is the estimated total number of IRB/EC meetings a month for all of your Organization's IRBs/ECs combined? If this number varies, please note the approximate number.

 Click or tap here to enter text. |
| 1. Does your Organization’s IRB(s)/EC(s) use electronic (computer) systems for any of these functions?
 | Select all that apply.[ ]  My IRB(s)/EC(s) **does not use any electronic (computer) system** in support of the IRB/EC review process.[ ]  My IRB(s)/EC(s) has a **database for tracking** IRB/EC submissions.[ ]  My IRB(s)/EC(s) has an **online application** for IRB/EC submissions.[ ]  My IRB(s)/EC(s)’s system has **online distribution of review materials** to IRB/EC members.[ ]  My IRB(s)/EC(s)’s system has **online IRB/EC review functions**. |
| 1. Do the laws, regulations, codes, and guidance under which your Organization conducts or reviews research involving human participants allow research that is not exempt to be reviewed by a non-committee process? Under the US Common Rule this non-committee review process is referred to as **expedited review.**
 | [ ]  Yes; if you answered “yes”, please continue to the next question [ ]  No; if you answered “no”, skip to question 20 |
| 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 this research to be determined **exempt**?
 | [ ]  Yes; if you answered “yes”, please continue to the next question [ ]  No; if you answered “no”, skip to question 25 |
| 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 solely allows exempt human participants research determinations as outlined within US regulations.[ ]  My Organization allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.[ ]  My Organization does not follow the US Common Rule but allows exempt human participants research determinations as outlined within my country’s regulations or my Organization’s policy. |
| 1. What is the number of **exempt human participants research determinations** made, whether by an internal review process (by an internal IRB/EC or other internal HRPP review process) or external IRB/EC, within the most recent year (the period from January 1 through December 31)? Note: this includes exemption determinations made using the limited IRB review procedure within the US Common Rule.

Click or tap here to enter text. |
| 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. **Use of External IRBs/ECs**
 |
| 1. Does your Organization use 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. 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.

Click or tap here to enter text. |
| 1. What is the approximate percentage of external IRBs/ECs that your Organization relies upon that are NOT AAHRPP-accredited?

Click or tap here to enter text. |
| 1. **Review Timelines and Determinations (complete this section for Step 1 only)**
 |
| 1. Does your organization have internal IRBs/ECs 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 33 |
| 1. 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)

Click or tap here to enter text. |
| 1. For the most recent year (the period from January 1 through December 31), what is the MEDIAN number of calendar days from
* The complete submission to the initiation of EXPEDITED REVIEW: Click or tap here to enter text.
* The complete submission to approval via EXPEDITED REVIEW: Click or tap here to enter text.

[ ]  My Organization’s IRB(s)/EC(s) did not review any studies reviewed 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
* The complete submission to CONVENED BOARD REVIEW: Click or tap here to enter text.
* The complete submission to approval via CONVENED BOARD REVIEW: Click or tap here to enter text.

[ ]  My Organization’s IRB(s)/EC(s) did not review any studies reviewed by the CONVENED BOARD in the most recent year. |
| 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 complete submission to an exemption determination? Click or tap here to enter text.

[ ]  My Organization did not have any studies determined to be exempt human participants research in the most recent year. |

|  |  |
| --- | --- |
| 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 **unresolved complaints from research participants** received by your HRPP, which includes any received by an internal IRB/EC.

 **For independent IRBs/ECs**, this is the number of unresolved complaints from research participants your IRBs/ECs received for review. | Click or tap here to enter text. |
| * Number of **new cases of alleged noncompliance** evaluated through your Organization’s HRPP process, which could be by an internal IRB/EC.

 **For independent IRBs/ECs**, this is the number of new cases of alleged noncompliance your IRB/EC received. | Click or tap here to enter text. |
| * 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).

**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 IRBs/EC) and external IRB(s)/EC(s).

**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 IRBs/EC) and external IRB(s)/EC(s).

**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, manages, reviews, and/or sponsors**.
 | 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 audits** your Organization conducted **of research studies your Organization conducts, manages, reviews, and/or sponsors**.
 | Click or tap here to enter text. |
| 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 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 financial disclosures made related to research involving human participants

 **For independent IRBs/ECs**, this is the number of financial disclosures your organization received in conjunction with IRB/EC review | Click or tap here to enter text. |
| * Number of financial disclosures related to research involving human participants determined to indicate a financial Conflict of Interest
 | Click or tap here to enter text. |
| * Number of studies with a financial conflict of interest management plan reviewed by an internal or external IRB(s)/EC(s)
 | Click or tap here to enter text. |

|  |
| --- |
| 1. **HRPP Staff and Budget (complete this section for Step 1 only)**
 |
| 1. Please tell us about the staff and budget for your HRPP, EXCLUDING IRB(s)/EC(s).

NOTE: 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. | 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 the HRPP (excluding IRB(s)/EC(s))
 | Click or tap here to enter text. |
| * Number of US dollars your Organization has budgeted for HRPP functions (excluding IRB(s)/EC(s))
 | Click or tap here to enter text. |
| 1. Please tell us about the staff and budget for your internal IRBs/ECs.

 [ ]  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. |
| * Number of US dollars your Organization has budgeted for IRB/EC administration and review functions
 | 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.
 | **Check all that apply.**[ ]  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 home department/clinic for time[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any financial support for IRB/EC Chairs. |
| 1. Please indicate what type of NON-FINANCIAL support your Organization provides IRB/EC Chairs. (Check all that apply)
 | **Check all that apply.**[ ]  Food at IRB/EC meetings[ ]  Thank you or appreciation gifts of nominal value[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any non-financial support for IRB/EC Chairs. |
| 1. Please indicate what type of FINANCIAL support your Organization provides IRB/EC Vice Chairs.

[ ]  I did not respond to this question because my Organization’s IRB(s)/EC(s) does not have any Vice-Chairs. | **Check all that apply.**[ ]  Salary support (full or partial)[ ]  Pay for specific activities (e.g., conducting 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 Vice-Chair's home department/clinic for time[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any financial support for IRB/EC Vice Chairs. |
| 1. Please indicate what type of NON-FINANCIAL support your Organization provides IRB/EC Vice Chairs.

[ ]  I did not respond to this question because my Organization’s IRB(s)/EC(s) does not have any Vice-Chairs. | **Check all that apply.**[ ]  Food at IRB/EC meetings[ ]  Thank you or appreciation gifts of nominal value[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any non-financial support for IRB/EC Vice Chairs. |
| 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.**[ ]  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.[ ]  My Organization does not provide any financial support for Affiliated IRB/EC Members. |
| 1. Please indicate what type of NON-FINANCIAL support your Organization provides Affiliated IRB/EC Members who are not Chairs or Vice Chairs
 | **Check all that apply.**[ ]  Food at IRB/EC meetings[ ]  Thank you or appreciation gifts of nominal value[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any non-financial support for Affiliated IRB/EC Members. |
| 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.**[ ]  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.[ ]  My Organization does not provide any financial support for Unaffiliated IRB/EC Members. |
| 1. Please indicate what type of NON-FINANCIAL support your Organization provides Unaffiliated IRB/EC Members who are not Chairs or Vice Chairs
 | **Check all that apply.**[ ]  Food at IRB/EC meetings[ ]  Thank you or appreciation gifts of nominal value[ ]  Other, please describe: Click or tap here to enter text.[ ]  My Organization does not provide any non-financial support for Unaffiliated IRB/EC Members. |