Guidance on Completing the Application/Annual Report Forms

The purpose of this application is to provide AAHRPP with information to help tailor the review to your Organization and to promote the use of quality indicators by Organizations. These quality indicators can be used as benchmarks by an Organization to compare its performance over time or with other Organizations. Some of this information was previously required in the Overview section of the application. If any questions need clarification or qualification, you can do so in the Overview section.

Instructions:

For the Step 1 Application complete ALL questions: 1-36

For the Step 2 Application, complete ONLY questions 1-11

For the Annual Report, complete question 1 AS WELL AS 12-35 and the Required Reporting Form

Title and Guidance	Item Requested	Explanation of Information Requested
1. Total Number of Active Protocols:	Review by the limited review procedure	Provide the current (current means on the day you complete the application form) number of active protocols (new and continuing) reviewed by the limited review procedure. Include all protocols reviewed by external IRBs. External means IRBs that are outside of your own organization (e.g. commercial IRBs).
	Exemptions in most recent 12 months	Provide the number of protocols determined to be exempt in the most recent 12 months. Do not include exempt protocols prior to 12 months that are still active, even if they undergo annual continuing review. Include all protocols reviewed by external IRBs. External means IRBs that are outside of your own organization (e.g. commercial IRBs).
	Review by the expedited procedure	Provide the current (current means on the day you complete the application form) number of active protocols (new and continuing) reviewed by the expedited procedure. Include all protocols reviewed by external IRBs. External means IRBs that are outside of your own organization (e.g. commercial IRBs).
	Convened IRB Review	Provide the current (current means on the day you complete the application form) number of all active protocols (new and continuing) reviewed by the convened IRB. Include all protocols reviewed by external IRBs. External means IRBs that are outside of your own organization (e.g. commercial IRBs).
	Total number of active protocols	Provide a sum of the preceding four categories.

2. Does your Organization routinely conduct, review, or manage research:	Research activities occur ONLY in your state, province or region within your country	Check if your Organization routinely conducts, reviews or manages research only in the state/province region within the country in which your Organization resides.
	Research activities occur in your state PLUS other states, provinces, regions within your country	Check if your Organization routinely conducts, review, or manages research in your state plus other states/provinces/regions within your country
	Research activities occur in your state, province, or region PLUS countries other than your own country	Check if your Organization routinely conducts reviews, or manages research in your state/province/region, plus countries other than the resident country of your Organization
	Research activities occur in your state, province, or region, other states, provinces, regions PLUS countries other than your country	Check if your Organization routinely conducts reviews or manages research in your state, other states/provinces/regions, plus countries other than the resident country of your organization.
3. Percentage of types of research conducted, reviewed, or managed at your Organization	Social/Behavioral/Education	Indicate the estimated percentage of social/behavioral/education research (SBER) conducted at your Organization. Social/behavioral/education research is defined by topic areas, not methodology. This includes research involving human behavior and social functioning and the social and biological contexts of behavior including such disciplines as sociology, psychology, anthropology, human ecology, history, and communications. Education research is included in this category
	Biomedical/Clinical	Indicate the estimated percentage of biomedical/clinical research being conducted at your Organization. Biomedical/clinical research 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.
	• Investigational Drugs	Check if your Organization conducts, review, or manages research involving investigational drugs (no % needed)
	• Investigational Devices	Check if your Organization conducts, reviews, or manages research involving investigational devices (no % needed)
	• Other Biomedical	Check if your Organization conducts, review or manages other biomedical research not included in the above
	Other – specify	If your Organization performs research in areas that do not fit into the categories above, check this box and specify the type of research conducted.

4. Types of research involving participant populations that <u>are</u> allowed, conducted, or reviewed at your organization.	Employees	Check if research involving employees of your Organization is conducted, managed, or reviewed at your Organization.
	Pregnant Women	Check if research involving pregnant women is conducted, managed, or reviewed at your Organization.
	Prisoners	Check if research involving prisoners is conducted, managed, or reviewed at your Organization.
	Students	Check if research involving students is conducted, managed, or reviewed at your Organization.
	Children	Check if research involving children is conducted, managed, or reviewed at your Organization.
	Adults unable to consent	Check if research involving adults unable to consent is conducted, managed, or reviewed at your Organization
	Other- specify	Check if there are other populations involved in research that your Organization conducts, manages or reviews, and specify the additional populations.
5. Does your Organization:	Have its own IRB/EC(s)	Check if your Organization has one or more IRB/EC(s).
	Number of IRBs/EC(s)	Indicate the number of IRB/EC(s) operated by your Organization.
	Number of meetings per IRB/EC per month	Indicate the number of meetings your IRB/EC holds each month. If you have multiple IRB/ECs, indicate the average number of meetings per month held by your IRBs or ECs.
	Rely on external IRB/EC(s)	Check if your Organization relies on an external IRB/EC to review one or more of your research protocols.
	For some but < 10% of total protocols	Check if your Organization relies on an external IRB/EC to review at least one, but fewer than 10% of your research protocols.
	For some but $\geq$ 10% of total protocols	Check if your Organization relies on an external IRB/EC to review more than 10%, but not all of your research protocols.
	For all (100%) of protocols	Check if your Organization relies on an external IRB/EC to review all of your research protocols.
	For multi-site clinical trials only	Check if your Organization relies on an external IRB/EC to review multi-site clinical trials only.
	Percentage that rely on AAHRPP-accredited IRBs or ECs	If your Organization relies on external IRB/EC(s) to review any number of research protocols provide the percentage that rely on AAHRPP-accredited IRB/EC(s).
6. What regulations or guidance pertaining to human research apply to your <u>active</u> protocols: ***It is assumed that selected requirements will only be applied to the Department or Agency that is selected/checked. For example, if the Department of**	US Department of Defense	Check if your Organization reviews, manages, or conducts research under a US Department of Defense Addendum from any branch of the military.
	US Department of Education	Check if your Organization reviews, manages, or conducts research under the US Department of Education regulations.
	US Department of Energy	Check if your Organization reviews, manages, or conducts research under the US Department of Energy regulations and guidance.
	US Department of Health and Human Services	Check if your Organization reviews, manages, or conducts research under the US Department of Health and Human Services regulations.
	US Department of Justice	Check if your Organization reviews, manages, or conducts research under the US Department of Justice regulations.
	US Department of Veterans Affairs	Check if your Organization reviews, manages, or conducts research under the US Department of

Education is selected, the requirements will be applied only to Department of Education-funded research		Veterans Affairs regulations and guidance. For VA facilities this would apply to all research; for academic affiliates this would apply to VA research only.
	US Environmental Protection Agency	Check if your Organization reviews, manages, or conducts research under the US Environmental Protection Agency regulations.
	US Food and Drug Administration	Check if your Organization reviews, manages, or conducts research regulated by the US Food and Drug Administration.
	State, regional, and local laws	Check if your Organization reviews, manages, or conducts research to which state, regional, or local laws must apply.
	ICH-Good Clinical Practice Guideline (E6)	Check if your Organization follows the ICH-Good Clinical Practice Guideline (E6).
	Country-specific regulations and laws (outside of the US) - Specify	Check if your Organization reviews, manages, or conducts research to which country or provincial laws apply.
7. In the most recent 12 months, did your Organization conduct, manage or IRB review planned emergency research without consent per 21 CFR 50.24?	Yes or No	Check yes if you conduct, review, or manage regulated planned emergency research without consent of participants or their legally authorized representatives, or if you want to have these policies and procedures to conduct such research in the future (within the next two years).
8. Does your Organization conduct, manage or review classified research using human participants:	Yes or No	Check yes if you conduct, review, or manage classified research that involves human research participants.
9. Sources of sponsorship for research: (Note: Total should add up to 100%)	Percent of human participant research that is governmentally/federally sponsored	Indicate the percent of your human participant research portfolio that is sponsored (funded in any way) by a governmental/federal agency. Specify if funding is from the U.S. government or non-U.S./other government.
	Percent of human participant research that is industry sponsored	Indicate the percent of your human participant research portfolio that is sponsored (funded in any way) by a company
	Percent of research that is sponsored by other external sources	Indicate the percent of your human participant research portfolio that is sponsored (funded in any way) by entities other than a federal agency or company such as a foundation or private donor.
	Percent of research that is sponsored by internal sources	Indicate the percent of your human participant research portfolio that is sponsored by your institution or other internal sources. Internal sources include unfunded research that is supported by the Organization by providing space and other resources for infrastructure.

10. Does your Organization have a Federal-Wide Assurance?	Yes or No	Check yes if your Organization has a current federal wide assurance of compliance (FWA) filed with the Office for Human Research Protections. Check no, if your Organization does not have an assurance. Note that simply registering your IRB with OHRP is not the same as having a FWA.
	Do you apply: ☐ The same policies and procedures regardless of funding ☐ Different but equivalent policies and procedures for some or all research not covered by regulations	If your Organization has not checked one or both of the Subpart boxes, but your Organization applies all of its policies and procedures to all research, regardless of funding check ☐ The same policies… If your Organization has not checked one or both of the Subpart boxes, and your Organization applies different but equivalent policies and procedures to research not covered by the regulations (e.g. DHHS), check ☐ Different but equivalent…
	Do you plan to apply the updated Common Rule to: ☐ No existing research ☐ All existing research ☐ Existing research on a protocol-by-protocol basis	*This question applies to organizations that conduct research covered by DHHS regulations, or other US government agency regulations.* Check "no existing research" if you do not plan to apply the updated Common Rule to any research prior to the implementation date. Check "all existing research" if you plan to apply the updated Common Rule to all research regardless of the date of research was approved. Check "Existing research on a protocol-by-protocol basis as approved by the IRB" if you plan to apply the updated Common Rule to all new research initiated after the implementation date, and some previous research as determined by your organization.
11. Does your IRB or EC use the following electronic (computer) systems:	Database for protocol tracking	Check yes if your Organization uses an electronic database to track protocols. If yes, indicate whether all of your protocols are tracked electronically or only some.
	Online application submission	Check yes if your Organization uses an electronic system for researchers to submit protocols or applications. If yes, indicate whether all or some of your protocols are submitted electronically.
	Online protocol or materials distribution to IRB or EC members	Check yes if your Organization uses an electronic system to distribute documents to IRB members. If yes, indicate whether all or some of your documents are distributed to IRB or EC members.
	Online review functions	Check yes if your Organization uses an electronic system for IRB or EC members and staff to review or communicate about protocols and other related materials. If yes, indicate whether the IRB or EC members and staff use the electronic system to communicate for all or some of the protocols.
12. Number of FTEs dedicated to:	HRPP (other than IRB or EC) - **Total**	Indicate the total number of FTEs dedicated to your Human Research Protection Program (HRPP), other than the IRB. 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 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.
	IRB or EC – **Total**	Indicate the total number of FTEs dedicated to your IRB(s), including faculty, executives, and administrative staff. Include portions of FTE for IRB or EC members, chairs, and vice-chairs who are employees of your Organization and add the portions to obtain a total number of FTEs.

13. Number of US dollars budgeted in the most recent 12 months or last fiscal year for: *Answer only the HRPP portion if your Organization does not have an IRB.*	HRPP (other than IRB or EC)	Indicate the total number of US dollars dedicated to your human research protection program, excluding the IRB or EC. This should include both personnel and non-personnel costs. Include portions of salaries for HRPP administrative time for faculty and executives.
	IRB or EC	Indicate the total number of US dollars dedicated to your IRB(s) or EC(s). This should include both personnel and non-personnel costs. Include portions of salaries for IRB or EC members, chairs and vice-chairs that are employees of your Organization.
14. Do you compensate your: *Leave blank if your Organization does not have an IRB.*	IRB or EC chair – No or Yes, amount of compensation	Indicate whether your IRB or EC chair(s) receives any compensation for their service to the IRB. If they are compensated, indicate the US dollar amount. If they receive non-financial compensation indicate what the compensation is such as release time or reduced teaching load.
	IRB or EC vice chairs – No or Yes, amount or type of compensation	Indicate whether your IRB or EC vice chair(s) receives any compensation for their service to the IRB If they are compensated, indicate the US dollar amount. If they receive non-financial compensation indicate what the compensation is such as release time or reduced teaching load.
	Affiliated IRB or EC members – No or Yes, amount or type of compensation	Indicate whether your affiliated IRB or EC members receive any compensation for their service to the IRB or EC. If they are compensated, indicate the US dollar amount. If they receive non-financial compensation indicate what the compensation is such as release time or reduced teaching load.
	Non-affiliated IRB or EC members – No or Yes, amount or type of compensation	Indicate whether your non-affiliated IRB or EC members receive any compensation for their service to the IRB. If they are compensated, indicate the US dollar amount. If they receive non-financial compensation indicate what the compensation is).
15. Number of researchers:		Indicated the number of researchers (responsible researchers, principal researchers, co-researchers) who conduct research involving humans and are employed by your Organization. Do not include students in the count.
16. Number of research coordinators and staff:		Indicate the number of research staff who conduct research involving humans and are employed by your Organization. Do not include students in the count unless they are paid as employees.
17. For new protocols reviewed in the most recent 12 months by the convened IRB or EC, what is the median number of calendar days from complete submission to: *Leave blank if your Organization does not have an IRB.*	Review at meeting	This time period is measured from submission of a complete application to the IRB or EC office to the first time it is reviewed at a convened IRB or EC meeting. Date of submission is the day the IRB office receives a complete application. Complete means the IRB application contains all required materials and is ready for review by a convened IRB.
	Approval	This time period is measured from submission of a complete application to the IRB or EC office to the approval of the study by the convened IRB or EC. Date of submission is the day the IRB or EC office receives a complete IRB application. Approval is the day the study is approved by the convened IRB or EC and the researcher is allowed to conduct the research.

		Complete means the IRB application contains all required materials and is ready for review by the convened IRB or EC.
18. For new protocols reviewed in the most recent 12 months by the expedited procedure, what is the median number of calendar days from complete submission to: *Leave blank if your Organization does not have an IRB.*	Review	This time period is measured from submission of a complete application to the IRB or EC office to the first time it is reviewed by an IRB or EC member. Date of submission is the day the IRB or EC office receives the complete application. Complete means the application contains all required materials and is ready for review by the expedited procedure.
	Approval	This time period is measured from submission of a complete application to the IRB or EC office to the approval of the application using the expedited procedure. Date of submission is the day the IRB or EC office receives the complete application. Approval is the day that the reviewer approves the research and the researcher is allowed to conduct the research. Complete means the application contains all required materials and is ready for review by the expedited procedure.
19. For new protocols reviewed in the most recent 12 months by the limited review procedure, what is the median number of calendar days from complete submission to: *Leave blank if your Organization does not have an IRB.*	Review	This time period is measured from submission of a complete application to the IRB or EC office to the first time it is reviewed by an IRB or EC member. Date of submission is the day the IRB or EC office receives the complete application. Complete means the application contains all required materials and is ready for review by the expedited procedure.
	Approval	This time period is measured from submission of a complete application to the IRB or EC office to the approval of the application using the expedited procedure. Date of submission is the day the IRB or EC office receives the complete application. Approval is the day that the reviewer approves the research and the researcher is allowed to conduct the research. Complete means the application contains all required materials and is ready for review by the expedited procedure.
20. Median number of calendar days from protocol submission to exempt determination in last year: *Leave blank if your Organization does not have an IRB.*		This time period is measured from the submission of a complete application to the determination that the application is exempt and the researcher is allowed to conduct the research. Date of submission is the day the IRB office receives the complete protocol. Complete means the application contains all required materials and is ready for a determination regarding exempt status.
21. Number of protocols reviewed by the IRB/EC and disapproved in the most recent 12 months		Provide the number of protocols that your IRB/EC reviewed and disapproved in the most recent 12 months.
22. Number of unresolved complaints from research participants received in the most recent 12 months:		Provide the number of unresolved complaints from research participants that your Organization has received in the most recent 12 months. A complaint is an expression of dissatisfaction, protest, or outcry related to a research protocol, researchers or staff, or the IRB or EC. Unresolved means a complaint that cannot be resolved by staff and must be reviewed by

	the IRB or EC. If you use an external IRB or EC, include complaints that were submitted to the IRB or EC.
23. Number of new cases of alleged non-compliance investigated in the most recent 12 months:	Indicate the number of new cases of alleged non-compliance that were investigated by your non-compliance process in the most recent 12 months. This includes cases that subsequently were not deemed non-compliance, were deemed minor non-compliance, or were deemed serious or continuing non-compliance. If you use an external IRB or EC, include non-compliance cases investigated by the IRB or EC of your Organization's protocols.
24. Number of determinations of serious non-compliance in the most recent 12 months:	Indicate the number of cases of non-compliance that were determined to be serious by your non-compliance process in the most recent 12 months. If you use an external IRB or EC, include non-compliance determinations by the IRB of your Organization's protocols.
25. Number of determinations of continuing non-compliance in the most recent 12 months:	Indicate the number of cases of non-compliance that were determined to be continuing by your non-compliance process in the most recent 12 months. If you use an external IRB or EC, include non-compliance determinations related to your protocols made by the external IRB or EC.
26. Number of unanticipated problems involving risks to participants or others in the most recent 12 months:	Indicate the number of unanticipated problems involving risks to participants or others that were reported to regulatory agencies in the most recent 12 months.
27. Number of internal and Sponsor "for cause" audits of investigator protocols conducted in the most recent 12 months: *This parameter should be part of an HRPP quality improvement program.*	Indicate the number of "for cause" audits of investigator protocols conducted in the most recent 12 months. "For cause" means an audit prompted by some information, a complaint, or an event.
28. Number of internal and Sponsor random audits of investigator protocols conducted in the most recent 12 months: *This parameter should be part of an HRPP quality improvement program.*	Indicate the number of random audits of investigator protocols conducted in the most recent 12 months. Random means there was no particular reason for choosing an investigator to audit; the investigator or protocol was selected by chance.
29. Number of internal "for cause" audits of IRB or EC records conducted in the most recent 12 months: *This parameter should be part of an HRPP quality improvement program.*	Indicate the number of "for cause" audits of IRB or EC records conducted in the most recent 12 months. "For cause" means an audit prompted by some information, a complaint, or an event.
30. Number of internal random audits of IRB or EC records conducted in the most recent 12 months: *This parameter should be part of an HRPP quality improvement program.*	Indicate the number of random audits of IRB or EC records conducted in the most recent 12 months. Random means there was no particular reason for choosing records to audit; the protocols or records are selected by chance.
31. Number of US FDA, other US regulatory agencies, or other country regulatory agencies inspections of *investigators* conducted at your Organization in the most recent 12 months: *Leave blank if your Organization does not conduct, review or manage FDA regulated research.*	Indicate the number of US FDA inspections, inspections by other US regulatory agencies, or other country regulatory agencies (e.g., Chinese FDA or other drug regulatory bodies) of investigators conducted at your Organization in the last year. Include all inspections regardless of the outcome of the inspection.

32. Number of US FDA inspections, other US regulatory agencies, or other country regulatory agencies (e.g., EMA) of the IRB(s) conducted at your Organization in the most recent 12 months: *Leave blank if your Organization does not conduct, review or manage FDA regulated research.*	Indicate the number of FDA inspections, inspections by other US regulatory agencies, or other country regulatory agencies (e.g., Chinese FDA or other drug regulatory bodies) of the IRB(s) or EC(s) conducted at your Organization in the last year. Include all inspections regardless of the outcome of the inspection.
33. Number of financial disclosures related to research involving human participants.	Indicate the number of financial disclosures related to research involving human participants in the most recent 12 months.
34. Number of financial disclosures related to research involving human participants that were determined to indicate a financial conflict of interest.	Indicate the number of financial disclosures related to research involving human participants in the most recent 12 months that were 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.
35. Number of protocols with a financial conflict of interest management plan that were reviewed by the IRB or EC.	Indicate the number of protocols reviewed by the IRB or EC in the last year with a management plan for a financial conflict of interest.