AAHRPP Association for the Accreditation of Human Research Protection Programs, Inc.®

2024 Section A and Annual Report Changes

AAHRPP convened a working group to look at the metrics it publishes. As part of that effort, the working group reviewed the information AAHRPP collects as part of its Application for Accreditation and Annual Report and made several recommendations, including the elimination of several questions, that are reflected in the 2024 forms and relevant guidance. Some of the questions added to the Annual Report are to obtain information in anticipation of transitioning that data to an online accreditation management system in the future.

The following list identifies the significant changes made to the Section A form and Annual Report survey. Guidance has also been updated where needed. The page numbers in parentheses below refer to the question number in Section A, if applicable.

- Where research involving human participants occurs was revised to allow organizations to select all that apply. (1)
- No longer ask for organizations' percentage of biomedical and social/behavior/educational research; only that they specify whether these categories apply to their research. (2)
- Included biologics and dietary supplements with "investigational drugs" to clarify what this category encompasses. (3)
- Removed the request to provide information on other vulnerable populations. (4)
- No longer require the percentages of research funded by different sources, only to list the different overall sources of funding. (6)
- Removed from Section A questions about Federalwide Assurances (FWAs) and application of the 2018 Common Rule.
- Rephrased the options for organizations to select that adhere to International Conference on Harmonisation-Good Clinical Practice Guideline (ICH-GCP) (8) and added this question to the Annual Report.
- Added to Annual Report: "Does your organization permit the use of limited IRB review as described in the US Common Rule for exempt human participants research?"
- Removed the question, "What is the total number of IRB/EC meetings a month for all IRBs/ECs combined?"
- Rephrased the options for the type of electronic (computer) system(s) organizations use to manage the IRB/EC submission and review process. (13)
- **Added question:** *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 entities conducting research?* (15)
- For exempt determinations, separated the count into exemption determinations made through an internal process or external process. (24 & 26)
- Removed the request to provide the approximate percentage of studies organizations reviewed by an IRB/EC external to the organization.
- Rephrased questions about the use of non-accredited IRBs/ECs. (29 & 30)
- Removed the question about the number of studies that your IRB(s)/EC(s) disapproved at initial review.
- The review timeframes have been redefined to be more in line with what organizations track and want to know. For example, we no longer request the timeline for submission to initiation of

expedited review and request time from submission to convened board and submission to final approval via convened board for initial review of human participants research.

- We no longer request the number of unresolved complaints or the number of cases of alleged noncompliance evaluated. (34)
- We added instructions to only count government or regulatory agency inspections of research studies "*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)*." (35)
- Guidance for the questions about reportable events and compliance activities has been updated. (35 & 36)
- For financial conflicts of interest, we are only requesting "Number of **studies with a financial conflict of interest management plan** that were reviewed by an IRB/EC", and not the number of disclosures or disclosures determined to indicate a conflict. (37)
- Removed the question about budget so that we only ask for the number of FTEs dedicated to your organization's IRB(s)/EC(s) (if applicable) in the most recent year. (38)
- Removed questions about number of FTEs and budget for HRPP staff that do not support IRBs/ECs.
- Removed the questions about the types of non-financial support that your organization provides IRB/EC chairs and members.

We made the following additional changes to the Section A and Annual Report guidance:

- Included a list of definitions and timeframes at the beginning.
    - An Independent IRB/EC is defined as, "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/ECs."
- For the question, "Where does research involving human participants occur that your organization conducts, reviews, manages and/or sponsors?", the guidance has been updated to clarify that the location where your organization is primarily based is "where its major operations, including their review, management, conduct, or sponsorship of research, are located." (1)
- For the question about funding, added clarification that "Industry sponsored" "does not include cases where the involvement of a company or entity is limited such as to the provision of a drug, biologic, device, or technology for a project." (6)
- Added notes to clarify when regulations could apply to an organization's research portfolio. (7)
- For the question "What is the number of exempt human participants research determinations made within the most recent year" by an internal review process, guidance was added to specify:
    - Organizations, not researchers, must make exemption determinations. However, instead of requiring HRPP/IRB staff/IRB members to make determinations, organizations may make these determinations using checklists or other tools completed by researchers. Include

exemption determinations made by any HRPP/IRB staff/IRB members or using checklists or other tools in this count. (24)

- Added clarifications about how to answer questions about relying on non-AAHRPP accredited organizations and clarified AAHRPP's purpose for this question. (29 & 30)
- Clarified the timeframe that is requested for Convened Review and Exemption Determinations. (25 & 33)
    - These timeframes begin when the application is received by the office or entity that manages the IRB/EC review process or that will evaluate the application.
- Added clarification that noncompliance determined to be both serious and continuing should be counted twice (once for serious noncompliance and once for continuing noncompliance). (34)
- Corrected guidance regarding compliance activities related to research studies and added clarifications regarding governmental or regulatory agency inspections of research studies organizations conduct, review, manage, and/or sponsor. (35)