

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.

- For organizations that adhere to ICH-GCP E6, asked if organization may adhere to R2, R3, or either (9).
- Added options for organizations to note if they do not calculate the timeframes for initial submission to convened board review and final approval (36) (Annual Report and Section A), and also for exempt determinations (28) and expedited review (26) (Section A only)
- For the 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 (39), added notes:
  - **For organizations that are not independent IRB(s)/EC(s)**, only count studies for which your organization has issued conflict of interest management plans for your researchers.
  - **For organizations that are independent IRB(s)/EC(s)**, count studies for which your IRB(s)/EC(s) have reviewed a COI management plan, regardless of whether the plan was received from the relying organization or issued by your organization's IRB(s)/EC(s).
- Added option in Annual Report to note if organization does not track the number of governmental or regulatory agency inspections of research studies that resulted in a finding or a request for an official compliance action (e.g., issuance of a US FDA Form 483 or FDA Warning Letter)
- Some changes to Required Reporting Form section near end of Annual Report, to more closely match AAHRPP's Accreditation Procedures ([Issues Requiring Prompt Reporting and Annual Reports](#)) including:
  - Request for summary of reporting to AAHRPP in the past 12 months
  - Request for any updates requested by AAHRPP in the past 12 months to be submitted
  - Added a question about changes in a) whether your organization uses external IRBs/ECs; b) Contracting for services from another organization; c) Other changes in method of providing services

Changes made June 2025:

- Clarified that accredited organizations should update their organizational name, contacts, and other general organizational information in the **AAHRPP Online Accreditation Management System (OAMS)**: <https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>. Organizations applying for their initial accreditation should complete the Section A Form as indicated and contact [reporting@aahrpp.org](mailto:reporting@aahrpp.org) if the above fields change after submitting the Step 2 Application and before the organization is accredited and granted access to AAHRPP's online system.
- (June 3, 2025) Replaced requirement for signatures both in Step 1 and Step 2 applications with a certification (includes typed name and date).

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

- For the number of open studies for which your organization serves as a reviewing IRB/EC (17), noted, “If your organization does not track this number, please provide an estimate.”
- For the number of FTEs your organization has dedicated to your IRB(s)/EC(s), added the following note (40):
  - “Of note, organizations have discretion about how to categorize whether reliance staff are considered IRB/EC staff or other HRPP staff, because of differences in how organizations implement reliance workflows and the budgets. For instance, if a reliance person who does not otherwise conduct IRB/EC reviews is paid out of an IRB/EC budget, that person could be listed as IRB staff.”