

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

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.

- Added to list of regulations an organization might follow: "US National Science Foundation (NSF)" (7)
- Added back question: "Do you have a Federalwide Assurance (FWA)?" (9) Organizations that answer yes will be asked (question 10) whether they apply:
 - The same policies and procedures regardless of funding
 - Different but equivalent policies and procedures for some or all research not covered by regulations
- For the question about ICH-GCP, reordered and added an answer option to show all possible levels, hopefully with a logical order (8).
- Several organizations have misidentified themselves as independent IRBs. To help clarify what AAHRPP means by an independent IRB, added link to AAHRPP's <u>website</u>, which lists accredited organizations' "type", to the definition of an independent IRB (13).
- Revised question to specify to count studies a) that undergo initial review and have financial conflict of interest (COI) management plans or b) for which a change in research is submitted that adds a new COI management plan(s) that the IRB/EC has not previously reviewed (39).
- Combined questions about compensating IRB/EC chairs with vice chairs (41).
- (June 3, 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 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:

- Added for management of financial conflicts of interest (39):
 - Specified should be counting studies with management plans as part of the initial review of a research study or a new plan included as part of a change in research reviewed by the IRB/EC in the specified timeframe.
 - Added, "If more than one key personnel have a management plan related to the study that the IRB/EC reviewed (either the initial review of a study or review of a change in research), this would only count as one study."

• Where counting studies' timeframes from submission, specified that the timeframe should include pre-review (27, 34, 35)