



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 [website](#), 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).

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 **any pre-review process your organization’s has**, which might be conducted by an internal IRB(s)/EC(s). (27, 34, 35)