2023 Section A and Annual Report Changes

We made the following changes to the Section A form and Annual Report survey. Guidance has also been updated where needed.

- Added the following clarification for the question "Is your Organization an independent IRB/EC?": *If your Organization conducts research and also provides IRB/EC review services for other Organizations, your Organization is NOT considered an independent IRB/EC.*
- Added the question "Do you allow other organizations to rely on your internal IRBs/ECs?" to identify organizations that are not independent IRBs/ECs that provide IRB review for external organizations.
- Added questions to identify when organizations conduct IRB review of research conducted by a US Department of Veterans Affairs facility and serve as academic affiliates for VA facilities:
    - Does your organization provide IRB review for a US Department of Veterans Affairs (VA) facility?
    - Does your organization serve as the academic affiliate for a VA facility?
- For organizations that rely on external IRBs/ECs:
    - Instead of an open text box for the response to the question, "What is the approximate percentage of your Organization's human participant research studies **reviewed by an external IRB(s)/EC(s)**?", we provided options that would allow organizations to provide estimated ranges.
    - Changed the question "What is the approximate percentage of external IRBs/ECs that your Organization relies upon that are NOT AAHRPP-accredited?" to "What is the approximate percentage of human participant research studies that your Organization conducts, manages, and/or sponsors that is reviewed by an external IRB(s)/EC(s) that is not AAHRPP-accredited? This percentage should include exempt human participants research." The intent of this change is to determine how much of an organization's research portfolio is reviewed by IRBs/ECs that are not accredited rather than the percentage of IRBs/ECs relied upon that are not accredited.
- For the number of governmental or regulatory agency (e.g., US FDA, other US regulatory agencies, or other country regulatory agencies) inspections of research studies that organizations conduct, manage, review, and/or sponsor, added an option for organizations to indicate they cannot track these audits centrally, instead of providing a number.
- Added an option to account for organizations that cannot separate out human participants research from all disclosures related to research.

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

- For the question, "Does your Organization review, conduct, manage, and/or sponsor planned emergency research?", updated the guidance to read:
    - Select "yes" if your Organization conducts, reviews, manages, and/or sponsors regulated planned emergency research without prior written consent of participants or their legally authorized representatives, even if your Organization does not have an active study of this type but has policies and procedures that permit such research.

    - Select “no” if your Organization either a) does not conduct, review or manage research regulated by the US FDA; or b) conducts, reviews, or manages research regulated by the US FDA but specifically does not conduct, review, or manage planned emergency research.
- Clarified that for the number of governmental or regulatory agency inspections of research studies an organization manages, conducts, reviews and/or sponsors that, if the Organization is a governmental organization or agency, they should provide audits or inspections conducted by governmental or regulatory agencies that are considered external to their HRPP.
- For “Please tell us about your Organization's management of financial conflicts of interest related to human participants research”, revised the guidance as follows:
    - *For number of management plans:* This refers to studies reviewed by internal or external IRB(s)/EC(s) for which a management plan related to financial conflict of interest was put in place, whether by the IRB/EC or another entity such as a Conflict of Interest Committee. This question is meant to identify the number of studies an internal or external IRB/EC reviews that have been given a management plan for a potential or actual conflict of interest.