



**AMERICAN
PSYCHOLOGICAL
ASSOCIATION**
SERVICES, INC.

April 16, 2025

NIH Unsolicited Clinical Trials Application Form Working Group
National Institutes of Health

Re: Request for Information: Inviting Input on a Proposed Clinical Trial Specific Application Form
Notice Number: [NOT-OD-26-058](#)

Submitted Electronically via Email: CTForms@mail.nih.gov

Dear Working Group members:

The American Psychological Association (APA) appreciates the opportunity to provide input to the NIH Unsolicited Clinical Trials Application Form Working Group's Request for Information Inviting Input on a Proposed Clinical Trial Specific Application Form. The APA is the nation's largest scientific and professional nonprofit organization representing the discipline and profession of psychology, as well as more than 190,000 members and affiliates who are clinicians, researchers, educators, consultants, and students in psychological science.

APA appreciates the opportunity to provide feedback on the proposed revisions to the clinical trials reporting form. The association's comments reflect particular attention to potential impacts on social and behavioral science research and address the following issues and questions:

- Systemic biases in the form that favor biomedical over social and behavioral science
- Would the form unintentionally discourage social and behavioral science clinical trials or distort how they are designed and presented
- Gaps in addressing ethical issues unique to behavioral research (e.g., deception)
- Specific revisions APA should recommend (e.g., new fields, flexibility language, examples)

The association offers the following comments on the Proposed Clinical Trial Specific Application Form.

Potential for Systematic Bias

APA is pleased that the revised form does not appear to introduce explicit structural bias favoring biomedical research. The required fields generally align with elements common to both biomedical and social/behavioral studies. However, the association is concerned bias could emerge through implementation details, particularly in the instructions (which are not yet developed). For example:

- If Section 2.1 relies on restricted pull-down menus (e.g., based on Medical Subject Headings), available options may not adequately capture constructs central to social and behavioral research.
- The outcomes field may implicitly prioritize quantifiable biological markers over behavioral, cognitive, or social outcomes.

Ensuring flexibility in descriptors and terminology will be important to avoid unintended bias.

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Impact on Social and Behavioral Clinical Trials

The proposed revised form is unlikely to discourage social and behavioral clinical trials or distort their design or presentation. APA identified several changes that represent improvements:

- Elimination of sections specific to DSM Boards, study team structure, and enrollment procedures
- Introduction of page limits to improve clarity and reduce administrative burden

The proposed revisions make the form more streamlined and applicable across disciplines.

Ethical Considerations

No major gaps are evident in addressing ethical issues specific to behavioral research. The form appropriately requires:

- Identification of the reviewing IRB
- Description of informed consent procedures
- Assessment of risks and benefits

These elements align with established ethical standards and ensure adequate oversight. Issues such as deception fall within IRB purview and do not require additional form-specific requirements. Although consent processes in social **and** behavioral research may be more flexible, the requirement to clearly describe them is appropriate and not burdensome. Additionally, the absence of requirements to justify “scientific importance” in strictly biomedical terms is advantageous for social **and** behavioral researchers.

Recommended Revisions

To further strengthen the form and ensure inclusiveness across research domains, APA recommends the following revisions:

- **Clarify the definition of “clinical trial”**
Provide guidance distinguishing clinical trials from basic experimental studies involving humans (BESH), particularly when such studies include health-related outcomes.
- **Ensure flexible terminology and descriptors**
Avoid overly restrictive controlled vocabularies. Include open-text fields or expanded options to capture social, behavioral, and contextual constructs.
- **Broaden outcome definitions**
Explicitly recognize behavioral, psychological, social, and functional outcomes in addition to biological markers.
- **Provide social and behavioral examples**
Include sample entries illustrating how social/behavioral trials can be appropriately described.
- **Add flexibility in instructions**
Clarify that sections should be interpreted broadly to accommodate diverse methodologies, including qualitative, mixed-methods, and adaptive designs.

APA commends the Working Group on its thoughtful proposed revisions. The revised form represents a meaningful improvement and does not inherently disadvantage social and behavioral science. The Association’s concerns are primarily limited to implementation details. With targeted refinements, particularly regarding definitions, flexibility, and illustrative examples, the form can effectively support both biomedical and social and behavioral research.

Thank you again for the opportunity for APA to provide input on the proposed changes to the clinical trial specific application form. Please do not hesitate to contact Angela Sharpe, Senior Director, Congressional & Federal Relations (asharpe@apa.org) if you have questions.

Sincerely,

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