Association for Psychological Science

Response to NIH NOT-OD-18-217 Request for Information

The US National Institutes of Health (NIH) is attempting to classify basic behavioral science and other basic research with human subjects as clinical trials. Per a directive from Congress, NIH has delayed implementation of the new definition and has released a Request for Information (RFI) inviting members of the scientific community to offer feedback on a series of topics. Although the title of the RFI implies that it is solely about registration and reporting, there's something much larger at stake—the way that basic research with human subjects is recognized at NIH. You can read more on this on the APS website.

The Association for Psychological Science (APS) strongly opposes NIH's efforts to classify basic research with human subjects as clinical trials, and has told NIH this in its response to the RFI, submitted on October 11, 2018. You can read APS's response to the RFI topics below. The blue text indicates the topic prompt appearing in the NIH RFI, and the block text shows APS's response.

RFI Topic: Specific examples of prospective basic science studies involving human participants that pose the greatest challenges in meeting the registration and results information submission requirements at ClinicalTrials.gov, including specific reasons for these challenges (e.g., specific data elements);

> **APS:** The questions in this RFI assume that the scientific community accepts NIH's redefinition of basic research with human subjects as clinical trials and that such basic research should be subject to identical registering and reporting standards as clinical trials. The Association for Psychological Science (APS) does not agree with this assumption, and neither does the basic human subjects research community, evidenced by the strong and unanimous opposition to this redefinition previously conveyed to NIH by thousands of individual scientists and numerous scientific and academic organizations in addition to APS.
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> Clinical trials and basic research with human subjects are recognized across all of science as distinct spheres, involving different methods and designs, terminologies, publication outlets, and, importantly, different best practices for registration and reporting. Critically, ClinicalTrials.gov was not designed with basic research with human subjects in mind and is not an appropriate platform for registering and reporting these types of studies.
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> APS urges NIH to evaluate existing platforms for reporting basic research with human subjects and/or consider establishing a new platform that is appropriate for these types of studies, rather than attempting to retrofit ClinicalTrials.gov for this purpose. Forcing basic research to fit a mold designed for clinical trials disregards the immutable differences between these types of studies.

RFI Topic: Strengths and weaknesses of potential alternative platforms that might function as conduits for timely registration and reporting of prospective basic science studies involving human participants;

APS: A wide variety of platforms exists for timely registration and reporting of basic research with human subjects. As one example, APS advises its journal submitters to visit the Registry of Research Data Repositories (re3data.org) to find the right repository for their data. We have found that setting expectations for data and materials reporting and registration and letting researchers use the platform that is right for them has been effective in encouraging increased registration and reporting. Alternatively, NIH could develop a new portal for registration and reporting of the outcomes and findings of basic research, including basic research with human subjects.

We recommend that NIH consult APS's current initiatives supporting transparent reporting and registration of basic research with human subjects. Further information is available on our website (https://www.psychologicalscience.org/publications/open-science). Preliminary evidence (e.g., Kidwell et al., 2016, *PLOS Biology*; Giofrè, Cumming, Fresc, Boedker, & Tressoldi, 2017, *PLOS One*) suggests that APS policies introduced in 2014 are linked with improved rates of reporting within our journals. We have since seen similar organizations adopt similar policies modeled after our own.

Given our experience in encouraging registration and reporting, we further recommend that NIH undertake a comprehensive, broad survey of the basic human subjects research community to determine what platforms currently are being used for the purposes of registering and reporting research. This survey should not be connected to current NIH clinical trials definitions and policies, which we believe to be a separate topic. A panel of experts should be convened to determine the criteria for assessing these platforms, and the quality of the platforms should be thoroughly examined. APS would be willing to facilitate a convening of such a panel. The results of this survey should be made publicly available at the earliest opportunity.

RFI Topic: Additional data elements or modification to existing data elements that could be applied to ClinicalTrials.gov to better meet the needs of the public and of researchers in assuring timely registration and results information submission of prospective basic science studies involving human participants;

APS: As noted in our response to the first prompt, we do not believe that ClinicalTrials.gov is an appropriate platform for registering and reporting basic research with human subjects, given that APS and the basic human subjects research community do not agree that basic research should be subject to the current clinical trials policies at NIH.

We are willing to engage in a discussion about appropriate data elements for inclusion in existing platforms for reporting basic research findings, or about elements for inclusion in potential new platforms that are appropriate for basic research with human subjects.

Fundamentally, APS believes that the question of which data elements are appropriate for reporting and registration of basic research with human subjects is entirely separate from the issue of whether basic research with human subjects should be classified as clinical trials. As always, APS is supportive of efforts to strengthen registration and reporting of basic research with human subjects, which we believe is a core aspect of ensuring rigorous and reproducible science.

RFI Topic: Other existing reporting standards for prospective basic science studies involving human participants and how such standards would fulfill the aims described in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information; and

APS: It is inappropriate to address this question in the context of this RFI, which needlessly combines the question of whether basic research with human subjects should be defined as clinical trials—which APS and the entire basic research community opposes—with recommended reporting and registration standards for basic science research. Please see our answers to the second and third prompts for more.

RFI Topic: Any other point the respondent feels is relevant for NIH to consider in implementing this policy for timely registration and reporting of prospective basic science studies involving human participants.

APS: NIH must halt its efforts to define basic research with human subjects as clinical trials. The basic human subjects research community, academic institutions and organizations, and other groups are unanimous in opposing this definition. It is entirely unclear to APS and the community why NIH is persisting in its efforts, especially given that including basic research with human subjects in the definition of clinical trials will not solve the problem of the underreporting and lack of registration of true clinical trials.

Moreover, APS requests that NIH's clinical trials definition and associated policies, case studies, and other guidance be reverted to their 2014 status, prior to the introduction of the expanded definition of clinical trials to include basic research with human subjects, and not permit directly or indirectly by implication or reference a definition of clinical trials that includes basic research with human subjects. The definition of clinical trials must be clear so as to not automatically classify basic research with human subjects as clinical trials.

As noted by Congress in its message to NIH, "Fundamental research is critical to the NIH mission and of value to the public, and there is concern that policy changes could have long-term, unintended consequences for this research." We agree with this assessment and ask that NIH make a fresh start and engage in a process that is focused on designing policies that are appropriate for basic research with human subjects to meet the goals that we share with NIH with regard to ensuring transparency and rigor in research.