

Make Your Voice Heard on NIH Proposal

October 31, 2018



BASIC RESEARCH ≠ CLINICAL TRIALS

The US National Institutes of Health (NIH) is still at it: [If you've been following along](#), you know that NIH has been attempting to classify basic behavioral science research as clinical trials. Just on principle, this reclassification is offensive. But there are practical implications as well. Among other things, psychological scientists funded by NIH will have to satisfy many additional rules and regulations that may make sense for true clinical trials — but not for basic research. And NIH has tried to justify this move by connecting it to efforts to increase registering and reporting of research studies. Simply put, this makes no sense.

APS and many other scientific and academic organizations and thousands of individual scientists were unanimous in telling NIH that they opposed the definition. But NIH was unreceptive to the community's concerns and continued to move ahead with implementing the objectionable redefinition amid widespread confusion within and outside NIH about its purpose.

At a loss, APS and other groups turned to Congress to express our disappointment with NIH's policy changes; Congress, recognizing our concerns were valid, [instructed NIH to delay its policies and consult with the scientific community](#).

And that's where we are now. At the direction of Congress, NIH has issued a [Request for Information](#)

[\(RFI\)](#) asking the community to weigh in on a number of questions related to basic behavioral science. The title would lead you to believe that the focus of the RFI is on registration and reporting, but you'll see that NIH has used the RFI to double down and is treating the redefinition of basic research as clinical trials as a done deal.

NIH needs to hear from individual scientists like you that basic human subjects research should not be classified as clinical trials.

APS has weighed in, and you can read our response to NIH's RFI below. Feel free to use it as a model for your own RFI response; the bottom line is that it is critically important to let NIH know you do not accept a redefinition of basic research with human subjects as clinical trials.

To respond individually to NIH's RFI, you should:

- Read APS's response to NIH's RFI, shown on the next page
- Access NIH's RFI — don't be distracted by the title, which only captures part of the broader issues raised by the RFI
- Enter your comments into whichever individual comment boxes that you feel you are able to address
- Submit the RFI form **prior to November 12, 2018, 11:59 PM EDT**
- Encourage your colleagues to weigh in as well
- Feel free to share your response with APS by emailing it to aps@psychologicalscience.org with the subject line "NIH RFI."

After submitting your response to NIH's RFI, treat yourself to "[The Basic Research Blues](#)," a song on this issue written and performed by Sarah Brookhart, APS Executive Director. You may even want to do your own version of the song — be sure to share it with APS if you do!

Below follows APS's response to the NIH RFI on clinical trails.

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](#) 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](#). 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

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.