FASEB
Federation of American Societies for Experimental Biology

Representing Over 130,000 Researchers

301.634.7000
www.faseb.org

9650 Rockville Pike
Bethesda, MD 20814

The National Institutes of Health (NIH) issued a Request for Information (RFI), "Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants (NOT-OD-18-217), on August 10, 2018. NIH sought input on five specific topics related to the registration and reporting of results of studies that meet its definition of "clinical trial." These topics included:

- 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);

- 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;

- 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;

- 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

- 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.

The Federation of American Societies for Experimental Biology (FASEB) discussed these topics at length. The discussions were distilled into the following response to Topic #2 on strengths and weaknesses of potential alternative platforms to clinicaltrials.gov:

TEXT SUBMITTED THROUGH RFI WEBSITE ON NOVEMBER 8, 2018

FASEB proposes that NIH utilize its Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) system as an alternative to the clinicaltrials.gov database to facilitate research reporting requirements for all studies it funds involving human participants that **do not** meet the criteria outlined in FDAAA for applicable clinical trials. NIH-funded clinical studies that **do** qualify as applicable clinical trials should be expected to meet all registration and reporting requirements mandated through 42 CFR Part 11 (i.e., the "Final Rule," which clarifies reporting requirements in FDAAA Section 801).

One of the primary drivers of the NIH Dissemination Policy is responsible stewardship of taxpayer funds. Mandating clinical trials to be registered and to report results in a public database like clinicaltrials.gov allows other researchers to see what studies have already been done and those being conducted. This should minimize duplication of effort and reduce waste. Furthermore, when it is providing the funds, the

public should be able to identify clinical trials that are currently recruiting and obtain summary results from those that have concluded. FASEB agrees with both of these premises. However, for the many exploratory, mechanistic, observational, and other types of basic research studies now classified as clinical trials, the most useful information—for both other researchers and the public—about a given study would be a short summary of the purpose, hypotheses tested, and basic findings.

RePORTER is a searchable, public database maintained by NIH that is continually updated with all current NIH grant awards. For each grant the system displays a project description, key terms, award amount and history, project start and end dates, and any resulting publications and patents, among other information. Recently, NIH updated its policies such that Project Outcomes—concise, lay-language summaries of research findings taken directly from principal investigators' (PIs') interim or final Research Performance Progress Reports—will be included in RePORTER. As the number of grants for which outcomes are available increases so, too, will RePORTER's utility as a registration and reporting platform. Additionally, RePORTER provides contact information for the PI, so that interested parties could ask for more detailed information or data, should they choose.

Adding a few search features to the existing RePORTER database would enhance the retrieval of information about basic research that involves human participants. For example, now that all grants proposing clinical trials must be submitted through specific Funding Opportunity Announcements (FOAs), there should be a way in the RePORTER query form to refine a search by FOA type (i.e., clinical trial allowed, optional, or not allowed). In addition, or alternatively, since all grants involving research with human participants must submit a Human Subjects and Clinical Trials Information form, there could be a check box in the query form to only search awards with a corresponding Human Subjects form.

Although not created as a research registration and reporting platform, using RePORTER in this manner could confer a number of advantages for NIH, researchers, and the public. (487/500 words)