



Society for Research in Child Development

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Society for Research in Child Development (SRCD) Response to the National Institutes of Health (NIH) Request for Information

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).

Many basic research studies with humans, especially those in the behavioral science involve experimental manipulations or comparisons of groups –for example, among members of the Society for Research in Child Development, there are studies examining learning, social interactions, motor development, communication styles, memory, reading, reasoning, emotion and motivation. These studies directly compare different ages or different contexts with the goal of understanding how such factors impact and modulate children’s behavior. These are not outcome-based in the sense of seeking the efficacy of a particular intervention or attempting to optimize well-being. These studies are at least several steps upstream from clinical trials, designed to understand how and why behavioral trajectories occur the ways that they do, and how and why contexts and environmental factors impact how behaviors are expressed in any given moment. The goals are often to test theoretical models for how and why humans behave as they do rather than to enhance outcomes per se. For these studies, many of the questions asked in standard registration and reporting processes for clinical trials are simply non-applicable. Furthermore, many basic behavioral science studies involve a series of many smaller studies rather than a single large sample. These series are important because they allow incremental changes in the experimental manipulations and/or the populations being investigated to construct a more comprehensive understanding of the dynamics driving behavior and its development. The presumption behind the clinical trials registration and reporting process is that each funded project is a single study with a single protocol and a single participant sample. Federal estimates are that reporting on clinical trials requires an average of 40 hours per study. Taken to scale for a research project with 10-12 experiments, this is an extraordinary and prohibitive PI burden, requires months of effort dedicated exclusively to reporting. Furthermore, data reporting tends to be much more complicated and nuanced for basic research including analytics involving data visualization techniques and complex modeling of multiple factors and experimental conditions. A framework designed to report in a more binary fashion on the success of an intervention is simply not relevant or able to accommodate these types of findings.

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.

There is a strong open science movement within the basic research community, with high motivation and incentive to develop and utilize reporting platforms. The platforms used for reporting by basic researchers in the behavioral science must be flexible enough to accommodate the diversity of research designs, models, and analytic approaches reflected in this research community’s approaches. In the absence of broad consultation with representatives from a diverse range of disciplines and research communities conducting basic research with human participants, NIH leadership cannot hope to

developing a platform that can anticipate and accommodate the diversity of research activities currently supported in its portfolio for basic research with humans. A flexible model for comprehensive reporting can be achieved by 1) establishing an Advisory Group with representation from across the range of basic research approaches, 2) systematic consultation with Associations and Societies from relevant disciplines, and/or 3) comprehensive surveys of current and prospective PIs conducting basic research with humans. What is required is a detailed and comprehensive understanding of the basic research designs, participant pools, analytic tools, and data representation formats represented in NIH's basic research portfolio with humans. It is likely that some existing Federal resources could be adapted to accommodate basic research approaches, and/or that tailored versions of other existing reporting platforms outside of the Federal Government (such as the Open Science Framework) could be employed for these purposes.

Additional data elements or modification to existing data elements that could be applied to [ClinicalTrials.gov](https://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.

Although SRCD strongly endorses data sharing and public access to research, we assert that basic research is, by definition, not designed to be directly applied. By posting such research on ClinicalTrials.gov, NIH is creating the incorrect and potentially harmful impression that the results of these projects can be used by the public to inform future decision making. There are rarely clear and direct implications for the public from the outcomes of research beyond inherent interest in the outcomes, but there is enormous potential for public misunderstanding of the purposes of the reported data if it is intermixed with reports that actually directly inform public well-being. Responsible reporting requires transparency about whether and how the data can be used to impact individuals' own lives. Requiring enormous numbers of basic science projects to post results to ClinicalTrials.gov also has the potential to obscure the public's ability to navigate to those studies that ARE definitively testing the outcomes of clinical interventions.

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.

As stressed above, reporting and dissemination standards for Clinical Trials are simply not relevant to many basic research studies with humans and are therefore inadequate to achieve NIH's goal of increasing transparency and accountability for this particular segment of NIH's portfolio.

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.

SRCD, along with many other associations and societies supporting basic science with human subjects, embraces the goal of increasing timely registration and reporting of all science, and applauds NIH for recognizing and seeking redress for PI failures to do so in a timely and comprehensive fashion. However, the proposed remedy reflects an oversimplified understanding of the full extent of the NIH portfolio of studies involving human subjects. As a result, 2016 and 2017 revisions to the posted case studies exemplifying clinical trials resulted in many studies being inadvertently subsumed in the definition that are not designed to be clinical trials and have not historically been regarded by NIH as such. Program staff, of course, have no choice but to use the case studies as a basis for determining whether a project is a clinical trial and therefore requiring registration and reporting guidelines for clinical trials, even though

the extramural staff who handle these projects are well aware that the clinical trial designation is not relevant or appropriate. We urge NIH 1) to reinstate the October 2014 case studies which exemplified all and only those studies designed to be clinical trials, 2) to continue to enforce the enhanced registration and reporting processes proposed for clinical trial research, and 3) to develop alternative processes for enhancing registration and reporting of basic science studies with human participants that better reflect the nature and the goals of the science being supported. This requires starting from the solicitation of specific knowledge regarding the nature and breadth of science being represented in the portfolio which this RFI is presumably designed to help address. Until due diligence has been performed and new approaches have been developed to appropriately accommodate ALL human subjects research and not only the narrow research type that is apparently most salient to NIH leadership, all parent funding opportunities should avoid designations for basic research that suggest it is part of the clinical trials framework for registration and reporting.