



FLORIDA STATE UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR RESEARCH

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Michael S. Lauer, M.D.
Deputy Director for Extramural Research
National Institutes of Health
9000 Rockville Pike
Building 1
Bethesda, MD 20892

Dear Dr. Lauer:

On behalf of Florida State University, thank you for dedicated and thoughtful service to our nation and its biomedical research enterprise. Despite challenging fiscal conditions at both the state and federal levels, FSU research is in the midst of an exciting period of growth that has helped power our recognition as a *Preeminent Florida University*. We are pleased to actively partner with the National Institutes of Health and other federal agencies in an efficient manner to seek answers to questions that are fundamental to our understanding of the world around us. With that objective in mind, I write to express concern with the recent NIH decision to utilize an expanded definition of *clinical trial* as a means of promoting quality and transparency in research that directly engages human participants. **While we share the NIH goal of accountability, we believe that a better approach is needed to avoid the inclusion of basic research that is not aimed at testing an intervention or treatment. The new policy is already proving to be an unnecessary and considerable tax on some NIH-supported investigators.**

As you are aware, the NIH has stated that “[The agency] has had difficulty in reporting how many clinical trials it has funded and results from many NIH-funded clinical trials are never published or reported in a public database.” As a result, the Government Accountability Office recommended that NIH improve its clinical trial data collection and dissemination practices. The Notice of Proposed Rulemaking that resulted, “Clinical Trials Registration and Results Submission,” failed to capture input from large swaths of the basic science research community as they had not previously identified with the subject matter described by the notice title. The NPRM was ultimately followed by a policy that significantly expands the definition of clinical trial to include basic research.

The new clinical trial designation imposes a raft of new requirements on basic research studies that have already passed ethics review, such as following different standards for funding applications and reporting results on clinicaltrials.gov – a public database. If the rationale, as reported by NIH, is to increase reporting to the database site as a new protocol on clinicaltrials.gov, this not only adds considerable administrative burden but fails to provide patients with any information about clinical trials that do benefit health outcomes. In part, the broad definition of behavioral intervention covers what can be best described as not approaching minimal risk.

FSU scientists report confusion over the case studies that NIH recently updated to clarify the determination of what is to now be considered a clinical trial. Our researchers have articulated a concern

that they will be limited to respond to clinical-trial specific funding opportunity announcements even though they may conduct basic research. We are also experiencing a considerable strain on resources to comply with the new policy.

NIH case study example 18c, involving “the recruitment of healthy volunteers who are randomly assigned to one of two experimental conditions to enhance or interfere with cognitive performance...”¹ demonstrates the challenge for basic research. Users of the state-of-the-art FSU Magnetic Resonance Imaging Facility, point out that a substantial amount of cognitive research uses Sternberg’s additive factors logic² to elucidate basic mental processes. This involves using experimental manipulations that enhance or interfere with cognition for the purpose of inferring what mental operations are involved. These are “in the moment” manipulations that are typically not used for the purpose of altering cognition on a long-term basis. For example, if one wanted to understand the basic operations involved in maintaining letters when they are no longer available to the senses (i.e. verbal short-term memory), they might hypothesize that there is a sub-vocal articulation process that is critical. To test this hypothesis, they might have participants repeat “the” over and over (i.e. articulatory suppression), thereby occupying sub-vocal articulation, with the expected result being that memory performance would be reduced if verbal short-term memory indeed relies on sub-vocal articulation. If they scanned participants under conditions with and without articulatory suppression, using example 18C, this would be considered a clinical trial. But most would agree that this classification does not reflect the work taking place. This example represents a considerable amount of FSU basic research in young and healthy adults.

As another example, a member of the FSU faculty was recently notified by an NIH program officer that one of his funded studies was now considered a clinical trial. He now has significant extra reporting and tracking to perform, in addition to completing a site visit from NIH to determine if his procedures are in line with the stringent requirements for clinical trials. The researcher’s study doesn't involve clinical patients or interventions.

Once again, we appreciate the NIH commitment to demonstrating effective use of federal resources. However, we ask that you reengage stakeholders on a new clinical trials policy in a manner that generates input from a broad collection of scientists. We believe that such a process will lead to practices that meet the NIH transparency goals while allowing basic research to continue forward unfettered by this unnecessary and inappropriate regulatory framework.

Sincerely,



Gary K. Ostrander, Ph.D.
Vice President for Research
Florida State University

CC: Francis Collins, Director, National Institutes of Health
FSU Congressional Delegation

¹ Available at <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>, revised September 8, 2017.

² Available at <http://www.jstor.org/stable/pdf/27828738.pdf>.