Dear NIH Clinical Research and Bioethics Policy Team,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the National Institutes of Health’s (NIH’s) draft Policy regarding dissemination of NIH-funded clinical trial information (NOT-OD-15-019). FASEB is composed of 27 scientific societies, collectively representing over 120,000 biological and biomedical researchers. The Federation recognizes the importance of transparent reporting for clinical trial information for the medical, research, and patient communities, and we applaud the efforts of NIH and the National Library of Medicine (NLM) to develop the ClinicalTrials.gov website into a robust resource. Sharing information about clinical trials, including high-level demographics of the subject population and summary results, can help the scientific community avoid unnecessary duplication of studies and increase detection of adverse events across trials. Despite these major social benefits, FASEB has several concerns about the draft Policy, some of which were also articulated in our comments in response to the Department of Health and Human Services’s (HHS’s) Notice of Proposed Rulemaking (NPRM) “Clinical Trials Registration and Results Submission.”

The proposed Policy would require registration and results reporting for all NIH-funded clinical trials on ClinicalTrials.gov. Some NIH-funded clinical trials are already subject to these requirements through Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). These trials include controlled, interventional studies of drugs, biological products and devices regulated by the Food and Drug Administration (FDA). FDAAA excludes phase 1 trials, which represent initial assessments of drug or device safety and aid in determining appropriate dosage and potential side-effects. The proposed NIH Policy, however, would require registration and reporting of all NIH-funded clinical trials, including phase 1. While this would certainly increase the amount of information available to patients, clinicians, and researchers through ClinicalTrials.gov, we are concerned about several potential unintended consequences associated with posting the results of early stage clinical assessments in such a public forum. Therefore FASEB recommends that NIH A) exclude Phase 1 clinical trials from this Policy or B) limit data reporting for Phase 1 clinical trials to adverse events.
Reporting results from Phase 1 clinical trials may lead to premature interpretation of outcomes

Much of the proposed Policy is focused on improving reporting and communication of clinical trial information to the public. FASEB believes that posting accurate data from trials that assess efficacy (e.g., Phase 2 or 3) provides more utility to patients and physicians. However, mandatory reporting of Phase 1 clinical trials – which, are by nature assessments of safety rather than efficacy – could mislead clinicians and patients, inadvertently reducing patient safety.

If not implemented in a manner that ensures appropriate financial and staffing resources, the proposed substantial changes could result in large volumes of data with low utility for both the scientific community and the public

One of FASEB’s greatest concerns is the capability of NLM to receive, store, and process clinical trial data assuming full compliance for both the HHS proposed rule and NIH Policy. The proposed rule and the draft NIH companion policy expand the types of clinical trial types required to register and report data to ClinicalTrials.gov and will increase substantially the volume and frequency of data uploaded to the database. Similarly, although Title VIII of FDAAA already provides enforcement actions for non-compliance, we anticipate that increased awareness of these provisions will increase vigilance of institutions and investigators to report clinical trial data. Therefore, it is critical that HHS and NLM ensure that existing resources – both digital and human – are capable of managing high volume data uploads, customer service requests, and enforcement procedures prior to full implementation of the proposed policy or proceeding with enforcement actions.

FASEB appreciates the opportunity to provide comments on this proposed rule. The efforts of NIH and NLM to develop ClinicalTrials.gov into a robust information source for clinicians, patients, and researchers are commendable and the proposed rule would build upon this success. However, we encourage NIH to address the concerns outlined in this letter prior to finalizing and implementing this Policy.

Sincerely,

Joseph R. Haywood, PhD
FASEB President