Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

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Subject: NIH Request for Public Comments on the Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

To Whom this May Concern:

The Council on Governmental Relations (COGR) is an association of 190 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We and our members appreciate the opportunity to comment on the Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.

We support the interest of the NIH to advance the translation of research results into knowledge, products, and procedures that improve human health. We recognize that transparency of information concerning clinical trials is critical to researchers, physicians, patients, and the general public (“stakeholders”) in order to reduce bias, avoid duplication, and expedite scientific discoveries. However, we are concerned that the NPRM as currently written and NIH’s proposed plan to apply this policy to all NIH funded clinical studies regardless of study phase, type of intervention, or whether they are subject to the FDA regulations will not only increase burden for our member institutions, but will be very difficult for them to maintain compliance within the timeframes cited. We believe that in order to achieve successful outcomes to proposed policy and any resultant regulation, consensus and harmonization of data must be obtained among all stakeholder groups including federal agencies prior to any further proposed changes and implementation. Further, we see no evidence that the proposed NIH policy as currently drafted supports the mission to advance the translation of research results into knowledge, products, and procedures that improve human health for reasons cited below.

Unique to academia, unlike other entities, researchers wear many hats often balancing their administration duties, with those of teaching, research, consulting, clinical practice, and service to their communities, all of which bear significance and importance. If the additional reporting and compliance requirements (and subsequent short turnaround deadlines) will be applicable to all NIH clinical studies, there will be a stark increased need for additional administrative support and other resources to comply. As you are aware, Institutions of Higher Education continue to be subject to an administrative cost cap of 26% making this another costly unfunded mandate IHE’s must address. The additional administrative burden and lack of resources to add administrative support for our investigators creates an environment that opposes the advancement of public health and detracts from advances in clinical research. Further indirect implications include the encroachment on already pressed time spent in writing proposals for new and innovated research and mentorship activities.
While the cost impact to enter all clinical studies into clinical trials.gov is minimal and takes one quarter of the time it takes for results reporting, monitoring and quality assurance, we believe that the costs of implementing the NIH policy (including the NPRM) far outweigh the benefits when the vast majority of researchers already register their studies due to the desire to publish in journals. The NPRM outlines costs tied to the regulation, these costs are not recognized in the NIH Draft Policy: i.e. additional National Library of Medicine (NLM) staff required to process 600 trials per year, 24,000 hours per year to input results, thousands of hours of institutional time to reconfigure/redesign systems to manage, support, and monitor compliance with the policy, and additional NLM and institutional time to account for other special circumstances including but not limited to behavioral trials for which the systems were not initially designed.

While we agree that journal publication is not always possible and that many clinical trials are not being published or published in a timely manner, we ask that you exclude from reporting small pilot studies. The small pilot studies designed to examine the feasibility of an approach that is intended to be used in a larger scale study, might confuse rather than heighten public understanding (the reason for issuance of the NPRM and NIH Draft Policy), thereby diverting resources that could more usefully be devoted to larger studies. Similarly, studies with multiple screen failures or enrollment problems add little to results reporting for the patient population, but may add value for physicians or researchers, again, adding merit to COGR’s stance that a “one-size-fits-all” model to data sharing will be less efficient for promoting public understanding. Given that contact information is already available in clinicaltrials.gov for interested parties wanting more information for these types of situations, we ask that you re-consider results reporting for certain studies and the costs and burden that would be eliminated for institutions should these trials be eliminated.

The Draft NIH Policy (and the NPRM) does not recognize the current onerous website interface, and the resources it will require of our member institutions to properly train current and new staff, and to communicate, manage and monitor the abundance of data being requested within the timelines cited. We ask that you consider this in context with the increased applicability of studies and devices and the burden it will add to an already onerous system interface difficult to navigate if improvements aren’t made before implementing additional requirements.

We implore you to partner with patient stakeholders and the broader community alike in determining a thoughtful and carefully planned approach of data sharing and storage that can be more easily understood and broadly shared. We ask that DHHS work with the stakeholder community to develop a data sharing plan(s) specific to generating successful outcomes mutually beneficial to satisfy all stakeholder groups and to recognize the risks placed on institutions and faculty as a result of accepting federal funds, that subject them to scrutiny for non-compliance including breaches of patient records.

In closing, we appreciate the opportunity to provide our comments and we support the need to provide patients with more data and transparency necessary to inform good decisions. We advocate for additional analysis and to consider all stakeholders input before implementing arduous regulations that add extensive burden to institutions. We ask that you harmonize with other agencies and acknowledge efforts currently underway to promote public awareness ensuring efforts aren’t duplicated unnecessarily.

Thank you for your willingness to review COGR’s recommendations. Please contact me or Jackie Bendall at (202) 289-6655. We look forward to working with you to address these important issues.

Sincerely,

Anthony P. DeCrappeo
President