Proposed Clinical Trials Registration and Results Submission

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Dear Mr. Moore:

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 Department of Health and Human Services (DHHS) NPRM entitled, “Clinical Trials Registration and Results Submission.”

We support the interest of the DHHS to expand results reporting to the general public, medical and researcher communities (“stakeholders”) through ClinicalTrials.gov. We also recognize that transparency of information concerning clinical trials is critical to all stakeholders in order to reduce bias, avoid duplication, and expedite scientific discoveries. However, we are alarmed after hearing from our COGR members that the NPRM as currently written will generate concerns surrounding privacy protection with the potential that de-identified data can eventually be traced to a human being. Other concerns include the fear of non-compliance and stricter penalties within the short timeframes imposed, inadequate resources to provide the volume of data and documentation required to adequately and properly institute monitoring and quality control mechanisms, and distress that the information potentially required by the rule when it becomes final (i.e., lay summaries, full protocols, adverse events reporting, and possibly expanded statistical analysis requirement etc.) within the persistent timeframes required could inadvertently create erroneous or incomplete data. Such errors, as well as the already present risks of misinterpretation of apparently “neutral data” would be detrimental to the patient community and all stakeholders thus having unintended consequences which diverge from what the NPRM sets out to achieve. These concerns will be further noted in the separate comment letters of our membership.

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 with proposed short turnaround deadlines in fact become final in the regulation, 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.
Just as “there is no such thing as a free lunch”, there is no regulation that will come without additional cost and burden 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.

The additional administrative burden and lack of resources to add administrative support for our investigators creates an environment that could actually detract from rather than advancing public health. Thus, across the board, we recommend that you expand the time frames allowed for each additional sort of reporting to the maximal reasonable choices. Urgent updates could uniformly face a 30 day requirement, non-urgent updates could be done annually to coincide with researchers’ IRB scheduled continuing reviews, and results reporting could be given the 18 month window after study completion that the statute Food and Drug Administration’s Amendments Act (FDAAA) allowed you to authorize.

While the NPRM does outline the hourly costs tied to data input in the proposed regulation, historically these time estimates have been lower than actual time involved, and with all the new requirements added by the NPRM, we fear that these estimates are once again lower than the true time that will be required. Moreover, the NPRM does not recognize 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 proposed increased applicability of the results reporting requirements to more studies of drugs and devices that are not FDA approved and the burden it will add 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 to data collection 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 particular, we ask that the National Library of Medicine not publicly post data that has not been through its own Quality Assurance process completely and successfully just for the sake of meeting 30 day posting goals. Bad data shared publicly is worse that delayed data, and even with caveats posted on the website, the risk that people will jump to (and share broadly) inaccurate conclusions which will be impossible to recapture or retract is very serious indeed.

While we agree that there are important benefits to providing clinical data necessary to advance scientific discovery, we are less confident that each of the current suggested approaches called for in the NPRM will meet multiple stakeholder needs. Providing the more generous time-frames listed above would provide the extra cushion necessary to improve quality and reduce fears and incidents of regulatory non-compliance, as well as giving researchers and NLM staff greater opportunities to consider when waivers of results reporting are appropriate to avoid disclosing patient’s individual data.

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. In fact, without these patient volunteers risking their daily lives and routines on behalf of all of us, scientific discoveries could not move forward. We advocate for additional analysis to consider all stakeholders input before implementing regulations that potentially detract rather than enhance clinical trial transparency. We ask that you harmonize with other agencies and acknowledge efforts currently underway to promote public awareness and transparency 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. DeCrappa
President