ENDOCRINE SOCIETY
Hormone Science to Health

Acting Director Sarah Carr
Office of Clinical Research and Bioethics Policy, Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

February 10, 2015

Dear Acting Director Carr,

The Endocrine Society appreciates the opportunity to provide comments on the draft policy on Dissemination of NIH-Funded Clinical Trial Information, and also to the Notice of Proposed Rulemaking (NPRM) for Clinical Trials Registration and Results Submission under Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Endocrine Society's membership of over 18,000 includes many clinical researchers who conduct clinical trials with the participation of human subjects. We support the intention of the NPRM and draft policy to improve the management and utilization of data from clinical trials sponsored by the National Institutes of Health (NIH); however we have several concerns that we urge the NIH to address prior to the release of the final policy.

Endocrine Society researchers report that submitting results to clinicaltrials.gov is a tedious and complicated process. For example, form fields and checklists require the completion of items that do not apply unambiguously to the investigator's specific study, suggesting that the processes on clinicaltrials.gov may not be readily tailored to each specific investigator. Additionally, the administrative burden placed on clinical researchers in order to implement the draft policy activities would require a significant percent effort allocation which is currently neither accommodated by current grant budget structure nor necessarily in accordance with university policy regarding effort requirements. Furthermore, the draft policy activities may be redundant to current processes; for example, published manuscripts that include the required information could be submitted directly to clinicaltrials.gov without having to re-enter these data element into form fields. **We therefore strongly urge the NIH to make clinicaltrials.gov a more user-friendly experience through solicitation of specific feedback from users of the website and the development of more streamlined processes**.

The Endocrine Society appreciates and supports NIH efforts to require the submission of negative results so that they can contribute to our understanding of drug efficacy and underlying physiology. We are concerned, however, that the draft policy does not include explicit data curation standards and policies to ensure that research results are robust and reproducible. Specifically, the inclusion of unpublished research results may introduce data that have not been subject to strict peer-review. Additionally, the NIH should provide oversight to ensure that end users of the data are responsible parties that can appropriately interpret the data. **We therefore recommend that the final policy**

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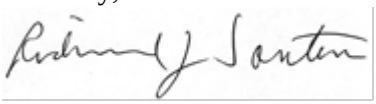
**incorporate guidelines for data curation and content management, such as peer review for unpublished results as a requirement for the inclusion of data in clinicaltrials.gov.**

Finally, **the Endocrine Society recommends that the final policy include the following considerations to ensure that investigators are given sufficient time to submit results**:

1. A provision should be added to defer submission for investigators with manuscripts under review for the study in question, so that the publication can be released prior to posting results on clinicaltrials.gov.
2. A more thoughtful approach should be given to the definition of the end of a study. As we understand the NPRM, the end of a study is defined as the last clinical intervention. However, this definition does not consider the need for subsequent analysis of samples and processing of data acquired during the study, which continue well after a patient's final visit. For example, if a trial involves whole exome sequencing, the final clinical endpoint does not accurately capture the end of a significant portion of the experimental work.

The Endocrine Society appreciates that the results of clinical trials funded by the NIH should be made more transparent and accessible for researchers and the public. However, due to the concerns articulated above, we urge the NIH to incorporate our recommendations into the final policy. We believe that, after taking the recommendations into account, the new policy will facilitate the NIH mission to "advance the translation of research results into knowledge, products, and procedures that improve human health." Thank you for considering the Endocrine Society's comments. If we can be of any assistance in your efforts, please do not hesitate to contact Dr. Joseph Laakso, Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,



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