Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

November 12, 2018

Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: NOT-OD-18-217 "Request for Information (RFI): Registration and Results Reporting Standards for Prospective Basic Science Studies"

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the NIH's request for information regarding registration and results reporting standards for prospective basic science studies. The AAMC is a not-for-profit association representing all 151 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC shares the NIH's commitment to ensuring transparency in research, particularly via the registration and reporting of studies involving human participants. We have actively reached out to institutions and researchers in attempts to provide the NIH with a meaningful response to this narrowly tailored RFI. However, we have also found that there are still significant concerns within the research community about the creation of a new category of NIH-funded research: prospective basic science studies involving human participants that do not meet the definition of an *applicable clinical trial*[1] but do meet the definition of *clinical trial*[2] under NIH policy. There remains a lack of clarity and consistency in determining which studies would fit into this category, as opposed to prospective basic science studies involving human participants that meet neither the definition of an *applicable clinical trial* nor the definition of *clinical trial* under NIH policy.

The AAMC, with other higher education institutions, raised concerns about the definition of a clinical trial in 2017[3]. In light of the fact that AAMC continues to hear from institutions regarding the difficulty in clearly determining the scope and applicability of the NIH definition of a clinical trial, we are concerned about the sustainability of the framework as it has been set forth. Without clarity on which policies apply to which research, there is both a risk of inadvertent noncompliance and a likelihood of overinclusion of research that does not meet this new third category of research.

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[1] https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf
[2] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html
[3] https://www.aamc.org/download/482960/data/associationssubmitcommentstonihonthedefinitionofaclinicaltrial.pdf

We offer the following comments in response to the specific questions posed in the RFI:

Specific examples of prospective basic science studies involving human participants that pose the greatest challenges in meeting the registration and results information submission requirements at ClinicalTrials.gov, including specific reasons for these challenges (e.g., specific data elements):
AAMC constituents have noted that the pre-set fields in ClinicalTrials.gov are not conducive for the reporting of results of many basic science research studies conducted across disciplines, especially those for which the addition of qualitative data, images, and other formats are not readily supported. AAMC-member institutions conduct the majority of NIH-funded clinical trials, and we have strongly encouraged researchers to directly respond to this RFI and provide the NIH with additional specific and detailed examples of basic science studies from medical schools that would be challenging to report on ClinicalTrials.gov.

Additional data elements or modification to existing data elements that could be applied to ClinicalTrials.gov to better meet the needs of the public and of researchers in assuring timely registration and results information submission of prospective basic science studies involving human participants:
Including prospective basic science studies involving human participants on ClinicalTrials.gov may lead to confusion for users of the site, which, as described by the NIH, was created in response to legislation "to broaden the public's access to information about clinical trials." Should the outcome of these deliberations and public comments result in the inclusion of basic science research studies in ClinicalTrials.gov, we encourage the agency to consider a bifurcation of the site to clearly identify those studies that fall under the traditional definition of a clinical trial from basic research studies, and to simplify the input process. We note that although it is possible to list "basic science" as the primary purpose of a study in ClinicalTrials.gov, the public-facing interface includes no way to separate those studies from the traditional clinical trials in the database. In fact, in an attempt to search ClinicalTrials.gov for the 10,199 "basic science" study records referenced in the RFI, we were unable to identify them or to exclude them from a search of clinical trials using the search options on the site. We urge the NIH to consider the different needs of the public and scientists in using ClinicalTrials.gov and understand that adding these research studies that were not the types of research the site was designed to catalogue requires a revised outward-facing interface and researcher entry portal that are usable and useful for the correct audiences.

The AAMC also commends to NIH the expertise of the Clinical Trials Registration and Results Reporting Task Force[4], a prodigiously active, expert group comprised of PRS Administrators and other individuals working directly with ClinicalTrials.gov at over 150 institutions. Although NIH has already been engaged with this group, the members of the Task Force would be an excellent resource for identifying specific data types that may be challenging to enter into ClinicalTrials.gov.

[4] https://ctrrtaskforce.org/

Other existing reporting standards for prospective basic science studies involving human participants and how such standards would fulfill the aims described in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information:
We have not been able to identify widely accepted reporting standards for many of these study types and caution that creating them will be a heavy lift for the NIH, and one that is necessary to enable researchers to comply with agency policy. We also note that these standards will be different depending on the research discipline.

Strengths and weaknesses of potential alternative platforms that might function as conduits for timely registration and reporting of prospective basic science studies involving human participants:
While we agree that alternative platforms might be better suited to accommodate the types and format of data produced during basic science studies, and do so in a discipline-specific manner, we note that the NIH will still have to create standards and requirements for these various platforms. We are concerned that any lack of clarity in what needs to be reported to NIH will result in a greater administrative burden and not accomplish the goal of providing meaningful results reporting from studies with human participants.

The AAMC understands the impetus for the NIH's goal of increased transparency around research with human participants. However, we are not convinced that the broad registration and reporting requirements will be effective in furthering this goal without creating undue burden for investigators and institutions.

This RFI itself is raising new questions, and to the extent that the responses received to this request do not provide a clear path forward, or should the NIH be open to further discussion, AAMC would be happy to facilitate engagement with our member institutions. For further questions or discussion, please contact me or my colleague Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926.

Sincerely,

Ross E. McKinney, Jr., MD
Chief Scientific Officer