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International Committee of Medical Journal Editors
c/o Annals of Internal Medicine
American College of Physicians
190 North Independence Mall West
Philadelphia, PA 19106-1572

The Association of American Medical Colleges (AAMC) is pleased to submit the following comments in response to the proposal of the International Committee of Medical Journal Editors (ICMJE) for sharing of de-identified, patient-level data as a prerequisite for publication. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. These institutions and organizations include 148,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences. We have discussed the ICMJE proposal with research leaders at our member institutions. The AAMC supports sharing de-identified individual patient-level data from published clinical trials in general, with appropriate safeguards for protection of patient privacy, assignment of credit to originating investigators, assurance of transparency in how data are used, and other qualifications. We would like to comment on the following points of the proposal:

- 1) *“As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the de-identified individual patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material)...”*

The AAMC believes that meaningful data sharing can: catalyze further research and maximize results from the nation’s extensive research investment; increase the impact of volunteer human subjects; enable comprehensive meta-analyses and timely re-examination or confirmation of critical findings; and leverage networks of researchers and information technology to solve complex medical and biological problems.

Our central concern in implementing the proposal is to ensure protection of privacy and other obligations to patients/human subjects. While standard HIPAA or other identifiers can be removed, the ability to reconstruct patient identities from other information remains a concern, particularly from trials involving small numbers of individuals, sensitive information, or vulnerable populations. It should be recognized that asking certain variables and developing

constructs to hide others could interfere with the ability to reproduce a study. Nevertheless, investigators and institutions must be permitted to exercise judgment in posting such information. The ICMJE should help researchers and institutions identify and disseminate use cases and best practices for sharing sensitive patient data. The community at large should support promulgation of regulations that would penalize re-identification of individual subjects from anonymized data. Because the proposal may require adjustment of subject consent forms, journals should help disseminate model forms or provisions.

- 2) *Proposed 6 month timeframe following publication for sharing de-identified individual patient data*

The AAMC is concerned that requiring sharing of patient level data within 6 months of publication is not always the most feasible or appropriate timeframe. Allowing later posting could help adjust the burden on investigators, and could be particularly helpful for trials of products that may be submitted for regulatory approval (such as FDA in the United States). In fact, the impact of the proposal on regulatory review may create other issues that we are unaware of. We are concerned that the requirements could create disincentives for publishing results from particularly large or complex trials in a timely manner, as investigators assess the burdens and significant costs of complying within the proposed six month deadline. The limitations of currently available platforms for sharing the data create additional logistic challenges which we hope will resolve over time. A timeframe tied to one year after publication would promote compliance by institutions and authors. It would also allow time for other studies to begin. We also urge the creation of a process for creating reasonable exceptions or extensions of this timeframe.

- 3) *“The ICMJE will also require that authors include a plan for data sharing as a component of clinical trial registration.”*

The AAMC supports a requirement to develop and make available a data sharing plan prior to publication. To effectively implement this requirement, authors and institutions will need clear guidance on how journal editors will evaluate the plan in the context of a manuscript submission. The AAMC observes that the proposal does not address the modification of a data sharing plan post registration other than in its level of restrictiveness and urges the ICMJE to articulate how such a revision, especially one that improves the data sharing plan, could be implemented. Since the need for effective data sharing is increasingly encouraged in many contexts, the community including the ICMJE should work to communicate the advantages of this movement, and how it serves patients, investigators, and science.

- 4) *“...those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. However, because collaboration will not always be possible, practical or desired, an alternative means of providing appropriate credit needs to be developed and recognized in the academic community. We welcome ideas about how to provide such credit.”*

The AAMC strongly supports providing recognition and credit for use of data, although when investigators make use of several secondary sources, it may be difficult and unproductive to require contact or collaborations with the originating authors. Researchers have noted that papers related to genomics or other highly collaborative fields could generate hundreds of additional names. At a minimum, there should be an expectation of recognizing the originators of a data set; higher levels of contact or collaboration should result from authors' discretion. Data sharing practices currently vary across disciplines and specialties; the AAMC hopes that community norms for citation would evolve as data sharing practices become established. The AAMC notes that using universal identifiers, such as ORCID ID, can facilitate accurate citation. Journals should help ensure that data are used only by qualified researchers, and that original contributors are notified when further research is published or utilized. True transparency is bi-directional: the AAMC has opposed proposed "data access" regulations that would require researchers to make data underlying their research available to un-named third parties; such tactics have been used to harass or undermine investigators' work for purposes other than scientific advancement.

The AAMC envisions an environment where comprehensive medical records and other individual health-related data resources are also available to investigators, with appropriate approval and oversight, in a learning health system. Our support for sharing research data is an extension of this vision, where both anonymized patient records as well as data from clinical studies are available for research. Finally, the ICMJE must recognize that, like many socially beneficial activities undertaken by our community, implementation of this proposal will require significant effort and expense, and may generate risks to individual researchers, their institutions, and their patients. Although we believe the efficiency and effectiveness of research will be improved through data sharing, medical research leaders, sponsors, and members of the public who support data sharing proposals should also encourage increased public funding to cover its costs and resources.

The AAMC is grateful to the ICMJE for its leadership on this important public health topic, and for the opportunity to comment. Please contact me (akommaya@aamc.org) with any questions or for clarification on these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "A. Ommaya".

Alexander Ommaya, DSc
Acting Chief Scientific Officer