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February 12, 2021

The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Ave S.W.
Washington D.C., 20201

RE: Proposed Rule: Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue (RIN 0991-AC15)

Dear Acting Secretary Cochran:

The Association of American Medical Colleges (AAMC) urges the Department of Health and Human Services (HHS) to withdraw the proposed rule (RIN 0991-AC15) drafted to further restrict important and ethical research involving human fetal tissue (HFT). The AAMC is a not-for-profit association dedicated to transforming health through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 115,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC's members conduct biomedical research and training activities across the research enterprise, from fundamental science to clinical and community engaged research and receive the majority of extramural research funding through the National Institutes of Health (NIH). We have long recognized the life-saving potential of research using HFT to better understand and address diseases affecting millions of people.

When HHS issued a statement halting the use of fetal tissue in NIH intramural research in June 2019 and announced it would take subsequent steps to restrict or make more difficult the use of fetal tissue by extramural grantees, the AAMC issued a statement expressing concerns with the impact of these

restrictions. Subsequent actions taken to implement the intentions expressed in HHS' 2019 statement, including NIH guide notices, have erected unnecessary barriers to the conduct of ethical and meritorious research with fetal tissue and have resulted in the failure to fund research found through the NIH peer review process to be scientifically promising and worthy of funding.

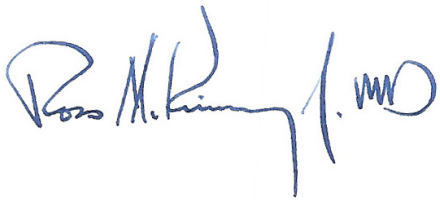
On several occasions the AAMC has urged HHS and the administration to rescind the June 2019 statement and related policy changes. The proposed rule issued on January 13, 2021 is the result of the Department's promise in June 2019 to "undertake changes to its regulations and NIH grants policy to adopt or strengthen safeguards and program integrity requirements applicable to extramural research involving human fetal tissue." No such additional safeguards were needed at the time the misguided and harmful statement was issued and none are needed now.

The proposed rule seeks a number of changes to the federal regulations for the protection of human subjects and to the uniform administrative requirements, cost principles, and audit requirements for HHS awards. The proposed changes range from unnecessary or redundant with existing rules to harmful restrictions on the available sources of tissue for researchers. In addition to other issues raised by the specific language in the proposal, the AAMC has fundamental concerns with the proposed rule that support its immediate withdrawal.

- **The rule would "provide that expenses associated with the acquisition of human fetal tissue for use in research are not allowable expenses under Federal awards from an HHS awarding agency," an unjustifiable restriction.** The acquisition of biospecimens for use in research designed to study its structure or function is an essential component of such a research grant and federal grant funds should be available for this purpose.
- **The rule would, without meaningful justification, prohibit federal grantees from acquiring biospecimens from certain types of entities.** The source of the biospecimens and materials for federal grantees should be determined by the entity's procedures and compliance with existing federal and state laws, not by the type of entity. This provision would only serve to make the material deemed essential for particular research more difficult to acquire, without affording any additional protections or safeguards than already exist in the sound legal and ethical framework for HFT donation and research.
- **The proposed rule would add informed consent language for tissue donation to regulations meant to protect and inform research participants.** This proposed language would be mandated for consent forms used in the context of tissue donation, conflating procedures for ensuring that *research subjects* are informed about the purpose and process of research with those ensuring that *biospecimen donors* are informed about donating tissue for later research.

On January 7, 2021, the AAMC joined almost 100 organizations in a letter to President-elect Biden asking that the incoming administration move swiftly to end the HHS policies and related NIH guide notices from 2019 that served only to restrict important and already highly regulated research. This proposed rule should also be withdrawn. Please feel free to contact me or my colleague Heather Pierce, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org) with any questions.

Sincerely,



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