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Rockville, MD 20852

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**Re: Protection of Human Subjects and Institutional Review Boards; Docket No. FDA- 2021-N-0286**

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide these comments to the Food and Drug Administration (FDA) in response to the Notice of Proposed Rulemaking (NPRM), *Protection of Human Subjects and Institutional Review Boards* (87 Fed. Reg. 58733 to be codified at 21 C.F.R. Parts 50, 56, and 812) and has also submitted a response to the companion NPRM, *Institutional Review Boards; Cooperative Research* (87 Fed. Reg. 58752 to be codified at 21 C.F.R. Part 56).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 156 accredited U.S. medical schools; 14 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and nearly 80 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

**I. General Comments**

Since finalization of the revisions to the *Federal Policy for the Protection of Human Subjects* in 2017 ("revised Common Rule," 45 C.F.R. Part 46, Subpart A), the AAMC has worked with the research community through the implementation and compliance changes necessitated by the change (e.g., updates to training materials, policies, processes, and electronic systems).<sup>1</sup> Because the FDA is not a Common Rule agency, the revision increased inconsistency between the revised Common Rule and FDA's human subject protection regulations (21 C.F.R. Part 50). This NPRM marks an important step in making the FDA's regulations more closely align with the revised Common Rule, a change the research community has awaited and is mandated by Section 3023 of the 21<sup>st</sup> Century Cures Act.<sup>2</sup>

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<sup>1</sup> This burden was especially apparent during the transition from the pre-2018 requirements to the revised Common Rule, see: AAMC Comments on the *Delay of the Revisions to the Federal Policy for the Protection of Human Subjects* (Docket No. HHS-OPHS-2017-0011, <https://www.aamc.org/media/12251/download?attachment>).

<sup>2</sup> 21<sup>st</sup> Century Cures Act, Pub. L. 114-255, § 3023 (2016).

The AAMC notes that although the FDA has undertaken substantial harmonization efforts “to help ensure clarity and enhance both human subject protection and the IRB review process [while also reducing] regulatory burden for IRBs, sponsors, and investigators,”<sup>3</sup> the proposed rule does not address all provisions in the revised Common Rule, and has provided a rationale for when it has not proposed adoption of certain aspects of the revised Common Rule.

**We believe the areas FDA has prioritized for harmonization are the right places to begin and have identified below additional areas that are ripe for harmonization or in need of clarification through guidance (Section VI, Additional Considerations).** We note that some areas the FDA did not address in this proposed rule are areas which have raised implementation concerns in the regulated community, such as the posting of informed consent forms, public health surveillance activities, exempt research, limited IRB review, and the complicated issue of broad consent—which AAMC, in response to the Common Rule NPRM (80 Fed. Reg. 53933), characterized as having “the greatest impact on institutions with the least benefit to individuals whose biospecimens may be used in future research.”<sup>4</sup>

The AAMC supports the agency’s interest in ensuring that “clinical trial participants [are] at the forefront of [...] the FDA’s oversight of clinical research.”<sup>5</sup> In the revised Common Rule, HHS also highlights the need to “modernize, simplify, and enhance the current system of oversight”<sup>6</sup> using the 1979 Belmont Report’s key ethical principles of respect for persons, beneficence, and justice<sup>7</sup> as a fundamental basis for its revisions. The AAMC expressed concern for whether the Common Rule’s proposed revisions “strike a reasonable balance” between the Belmont Report’s ethical principles, noting that “few individual proposals seem to strike such a balance, but fall entirely on one principle to the exclusion of the other two.”<sup>8</sup>

## II. New and Revised Definitions

The proposed rule makes revisions to the definitions for “legally authorized representative,” “written or in writing,” “private information,” “identifiable private information,” and “identifiable biospecimen.” **While we support the proposed changes to harmonize with the definitions in the revised Common Rule and recognize that increased alignment will help minimize confusion, we recommend evaluation of other definitions and terminology that might benefit from alignment and/or clarification (e.g., see Section IV. Activities Preparatory to Research) such as terms in the revised Common Rule that are broader in scope than those in the FDA’s regulations.** For example, in the proposed rule the FDA notes that the terms “sponsor” and “investigator” are used throughout its regulations “to describe the responsibilities that apply to certain parties involved in FDA-regulated research.”<sup>9</sup> The FDA goes on to reference HHS’ Office of Human Research Protection’s (OHRP) 2008 guidance (*Coded Private Information or Specimens Use in Research*) which states that OHRP “considers the term ‘investigator’ to

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<sup>3</sup> Protection of Human Subjects and Institutional Review Boards, 87 Fed. Reg. 58734 (Sep. 28, 2022).

<sup>4</sup> AAMC Comments on HHS Common Rule NPRM (January 4, 2016), <https://www.aamc.org/media/11936/download?attachment>.

<sup>5</sup> FDA Press Release, FDA Takes Steps to Further Harmonize Clinical Research Regulations with HHS Common Rule (Oct. 6, 2022), <https://www.fda.gov/news-events/fda-voices/fda-takes-steps-further-harmonize-clinical-research-regulations-hhs-common-rule> (Accessed Dec 20, 2022).

<sup>6</sup> Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (January 19, 2017).

<sup>7</sup> The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c\\_FINAL.pdf](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf) (Accessed November 11, 2022).

<sup>8</sup> Supra Note 4, Also see AAMC Comments on the Common Rule Advance Notice of Proposed Rulemaking (October 25, 2011), <https://www.aamc.org/media/24296/download?attachment>.

<sup>9</sup> 87 Fed Reg. 58737.

include anyone involved in conducting the research, which is broader than the definition of an ‘investigator’ under FDA’s regulations.”<sup>10</sup> Taking into account OHRP’s position, FDA explains that the basis for the proposed adoption of “identifiable” (i.e., “information for which a subject’s identity is or may readily be ascertained by the sponsor of FDA-regulated research”) is to better harmonize the two regulations.

Notably, the terms “identifiable private information” and “identifiable biospecimen” received significant attention from the research community during the revisions to the Common Rule, especially related to the proposed changes to the definition of “human subject” to include all biospecimens regardless of identifiability.<sup>11</sup> While this controversial proposed change was not adopted, the revised regulations do require Common Rule Departments and Agencies to reexamine the meaning of the terms “identifiable private information” and “identifiable biospecimen” within 1 year and at least every 4 years after (45 C.F.R 46.102 (e)(7)(i)), and they “may alter the interpretation of these terms, including through the use of guidance.”<sup>12</sup>

We appreciate FDA’s explicit indication that it will participate in these reexamination activities, yet this convening has not yet taken place. Given the proposed additions to FDA’s regulations pertaining to identifiability, in addition to the significant changes to the research landscape since publication of the revised Common Rule (e.g., increased access to electronic health data and biospecimens for research), we recommend that this convening take place in coordination with the regulated community, including diverse perspectives from individuals and organizations that participate in federally-regulated research. We also recommend the broad dissemination of related meeting announcements to ensure the inclusion of those that are unaware of opportunities proffered in the Federal Register.

### III. Informed Consent

#### *Key Information Requirement*

The FDA has proposed harmonization with the revised Common Rule’s general requirements for informed consent, including the content, organization, and presentation of information (i.e., “key information”) to assist a prospective subject or legally authorized representative with understanding whether to participate in the research. **In the interest of such harmonization, the AAMC supports FDA’s proposed changes to mirror the key information requirements found at 45 C.F.R 46.116(a)(1)-(6).**

The key information requirement was one of the more significant changes to the revised Common Rule intended to support the Belmont Report’s principle of respect for persons—respecting an individual’s right to voluntarily make an informed decision about what should or should not happen to them in a research setting. **While we recognize the benefits from having a paper form include key information at the outset, we remain concerned that the regulations’ sole emphasis on the format and structure of a document undermines HHS’ important perspective that “informed consent is a process, not just a form.”**<sup>13</sup> The informed consent process, whether in a form or other medium, should ensure that

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<sup>10</sup> *Id.*, also see: OHRP Guidance, *Coded Private Information or Specimens Use in Research, Guidance* (2008), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html> (Accessed Dec 20, 2022).

<sup>11</sup> *Supra* Note 4. In AAMC’s comments to HHS on the Common Rule NPRM, the AAMC strongly recommended “removing the proposed additional provision to the definition of human subject and retaining the definition of identifiable private information or augmenting to clarify that when the identity of the individual from whom a biospecimen was derived becomes readily ascertainable by the investigator, the research would be subject to the Common Rule.”

<sup>12</sup> *Supra* Note 9.

<sup>13</sup> Office for Human Research Protections. *Informed Consent Tips* (Rockville, MD 1993), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html> (Accessed Dec. 20, 2022).

“information about the study, including its putative risks and benefits, [...] be presented in a fair, balanced, and unbiased manner.”<sup>14</sup> The AAMC expressed similar concerns about the informed consent process in our response to the Common Rule NPRM:

With the major revisions to the Common Rule, there is an opportunity to re-envision the informed consent process and provide investigators and institutions with the flexibility to ensure that critical information is delivered in a way that is understandable to the research subject. Although the proposed changes to the informed consent document are not harmful, they are focused on rearranging and adding to a written document, not setting forth the types of information that it is important for prospective subjects to know and giving investigators and IRBs the flexibility to determine how best to communicate the information and ensure understanding, given the research design, level of inherent risk to participants, target study population, and best evidence for effective communications.<sup>15</sup>

The FDA, in collaboration with OHRP and the research community, should identify and develop tools that reinforce the flexibility in the regulations and provide examples of acceptable language, similar to the approach taken in the joint OHRP/FDA *Guidance on Exculpatory Language in Informed Consent*.<sup>16</sup>

### *New Elements of Informed Consent*

In addition to the above, the proposed rule adds three new elements of informed consent that are consistent with the same elements in the revised Common Rule: whether a subject’s biospecimens may be used for commercial profit and whether the subject would share in that profit; whether clinically relevant research results will be disclosed to subjects; and whether the research would include whole genome sequencing. Notably, FDA proposes a fourth element (at 21 CFR 50.25(a)(9)) that “would require a description of how information or biospecimens may be used for future research or distributed to another investigator for future research.”<sup>17</sup>

**The AAMC does not see a benefit in modifying the existing Common Rule element on informed consent and recommends that FDA instead harmonize with the current language in the revised Common Rule at 45 C.F.R 46.116(b)(9). The language as proposed makes implementation and compliance in some circumstances impossible.**

Under the revised Common Rule, research subjects must be provided with one of two statements pertaining to the collection of identifiable private information or identifiable biospecimens and whether their information and biospecimens could be identified and used for future research.<sup>18</sup> Justifying the departure from the revised Common Rule, the FDA indicates that “while [its] proposed element is not limited to the two situations addressed by the statements required under the corresponding element of the revised Common Rule, the research community would be able to develop informed consent forms and processes that comply with both sets of regulations.”<sup>19</sup> Such an approach would likely result in informed consent documents that are more complicated and confusing than informative, as sponsors, institutions, and investigators attempt to both create a study-specific description regarding future research as required by the FDA and also choose one of the two required statements under the revised Common Rule.

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<sup>14</sup> McKinney RE Jr, Beskow LM, Ford DE, Lantos JD, McCall J, Patrick-Lake B, Pletcher MJ, Rath B, Schmidt H, Weinfurt K. *Use of altered informed consent in pragmatic clinical research*. Clin Trials. (October 2015).

<sup>15</sup> AAMC Comments on Common Rule NPRM, Supra Note 4.

<sup>16</sup> *Id.*, also see: *Guidance on Exculpatory Language in Informed Consent*: <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/guidance-exculpatory-language/index.html> (Accessed Nov. 11 2022).

<sup>17</sup> 87 Fed Reg 58749.

<sup>18</sup> 45 C.F.R 46.116(b)(9).

<sup>19</sup> 87 Fed Reg. 58738.

The FDA’s new proposed element would require researchers to provide a description of how information or biospecimens might be used for *future* research purposes. Notably, future research often is not readily apparent at the clinical design stage, putting researchers in the precarious position of having to make imprecise predictions about what would or would not happen with a subject’s information or biospecimens.

#### **IV. Activities Preparatory to Research**

Regarding activities that are preparatory to research, including obtaining information or biospecimens to identify and recruiting potential subjects, the FDA proposes that its regulations depart from the revised Common Rule’s related provision at 45 C.F.R 46.116(g), suggesting that the FDA instead maintain its longstanding policy that “some specific activities are not considered to fall within the definition of clinical investigation, and therefore do not require IRB review or informed consent.”<sup>20</sup>

**In the spirit of harmonization, we recommend that FDA adopt the revised Common Rule language at 45 CFR 116(g) to relieve existing confusion between the two regulations. If the FDA maintains its current policy, researchers would have to continue navigating two different approaches for activities preparatory to research.**

In 2011, the HHS Secretary’s Advisory Committee on Human Research Protections (SACHRP) released recommendations on activities that take place prior to subject consent to research participation, recommending that “OHRP and FDA [...] take the necessary steps to issue a single joint guidance on recruitment of subjects so that IRBs have a single source of information regarding the agencies’ viewpoint on this issue.”<sup>21</sup> Notably, during the revisions to the Common Rule, HHS took into account SACHRP’s harmonization recommendations, specifically adopting the FDA’s approach in the 1998 guidance, *Screening Tests Prior to Study Enrollment*.<sup>22</sup> If the FDA maintains its current policy, this would be a missed opportunity to harmonize with HHS on an issue the Department has already carefully examined for purposes of creating clarity and consistency with the FDA’s screening guidance.

#### **V. Waiver of Documentation of Informed Consent**

The AAMC agrees with the FDA’s proposal to add the Common Rule’s exception permitting an IRB to waive documentation of informed consent if the subject or legally authorized representative is a member of “a distinct cultural group or community in which signing forms is not the norm” as long as the study is no more than minimal risk to the subjects and there is an alternative mechanism to document informed consent.<sup>23</sup> However, we are not in agreement with the proposal not to adopt the Common Rule’s exception to the documentation requirements allowing a waiver of consent in situations where the informed consent form is the only record connecting the subject and the research and the primary risk would result from a breach of confidentiality.<sup>24</sup> In support of this proposal, the FDA indicates that its regulations have not “historically” included an analogous exception, but does not offer its current thinking on why the revised Common Rule’s exception may not be applicable to FDA-regulated research which

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<sup>20</sup> 87 Fed. Reg. 58739.

<sup>21</sup> SACHRP Attachment C, *Recommendation regarding application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects and recruiting subjects*, (July 20, 2011), <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-c/index.html> (Accessed Nov. 11, 2022). Also see, SACHRP Letter to HHS Secretary: Recommendations from SAS & SOH (Oct. 13, 2011).

<sup>22</sup> *Information Sheet, Screening Tests Prior to Study Enrollment Guidance for Institutional Review Boards and Clinical Investigators* (January 1998), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/screening-tests-prior-study-enrollment> (Accessed Dec. 20, 2022).

<sup>23</sup> 87 Fed Reg. 58740.

<sup>24</sup> 45 C.F.R. 46.117(c)(1)(i).



would have been helpful to guide public comment on this topic. **The AAMC does not agree that this exception is inapplicable to FDA-regulated research and recommends adoption of the revised Common Rule language.**

During SACHRP's October 2022 public meeting,<sup>25</sup> the committee rejected FDA's viewpoint that the revised Common Rule's exception to the documentation requirement is not relevant to FDA-regulated research, recommending that FDA adopt the new regulatory language found at 46.117 (c)(1)(i). The committee also pointed to circumstances where real world evidence and data would increase the need for research protections and the revised Common Rule's waiver requirement would allow for better protection of confidentiality and privacy when conducting clinical investigations among certain study populations. We agree with SACHRP that FDA should adopt the language at 46.117(c)(1)(i) for purposes of harmonization.

## **VI. Additional Considerations**

Differences between the FDA's human subject protection regulations and those adopted and revised by the sixteen Common Rule departments and agencies have created unnecessary complexity for IRBs, investigators, institutions, and sponsors. As the research environment becomes increasingly more complex, ensuring effective protections for research participants becomes paramount, as does promoting and maintaining public trust in a consistent framework for human subject protections regardless of the source of funding or oversight. Thus, we anticipate continued efforts to harmonize or clarify aspects of the revised Common Rule that were not addressed in this rulemaking and encourage the FDA to work closely with HHS in support of this mission, whether through regulatory reform or joint clarification through guidance. As AAMC wrote in its response to the Common Rule NPRM:

It is essential that a regulatory framework to protect human subjects provide institutions, investigators, and research subjects with clarity to ensure consistency of interpretation from institution to institution and study to study, and flexibility to allow the rule to be applied to atypical situations, emerging technologies, and complex research methods. [...] In many cases the proposed revisions attempt to reduce ambiguity by reducing flexibility, imposing rigid mandates on all research regardless of structure, design, or actual risk to subjects. The AAMC questions whether too many issues that could have been addressed through guidance were addressed through regulation, leaving the Common Rule less able to adapt and respond to evolving research design and technology.<sup>26</sup>

### ▪ ***Effective Date***

The FDA has proposed an effective date of 180 days after the date of publication of the final rule. We recommend revising this to a one year implementation period to permit the research community to amend relevant policies, procedures, and forms to align any changes to FDA-regulated research.

### ▪ ***Avenues for Stakeholder Input***

We recommend FDA develop additional opportunities for continued research community engagement to help the agency identify aspects of the regulations that would benefit from harmonization and simplification, including the development of joint FAQs or tools to assist the regulated community with implementation. We also urge FDA to engage a broad spectrum of the research community, recognizing that engagement methods must extend beyond the Federal Register in an attempt to reach diverse communities. This should also include the active solicitation of feedback from individuals and

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<sup>25</sup> October 19-20, 2022 SACHRP Meeting, <https://www.hhs.gov/ohrp/sachrp-committee/meetings/october19-20-2022/index.html> (Accessed December 20, 2022).

<sup>26</sup> AAMC Comments on Common Rule NPRM, Supra Note 4.

community organizations that are closest to injustice and inequity. As stated by AAMC to HHS in response to the Common Rule NPRM: “only through collaboration with the public can we regain and maintain the public trust in the ethics, importance, and promise of the research mission.”<sup>27</sup>

▪ ***Quality Improvement and Evaluation***

In addition to developing additional avenues for continued input, FDA should seek to assess regularly (with HHS and other Common Rule departments and Agencies) the effect and effectiveness of this proposed rule and the companion Cooperative Research proposed rule (if finalized). The AAMC has extensive experience in regulatory evaluation through projects like the *AAMC Conflict of Interest Metrics Project* ([www.aamc.org/metricsproject](http://www.aamc.org/metricsproject)), initiated to evaluate the cost and impact of the HHS financial conflict of interest regulations one year prior to implementation and several years following.<sup>28</sup> We would be more than happy to assist the FDA and HHS with the retrospective assessment of these regulatory changes, including providing guidance on how assessments could be useful to the academic research community.

▪ ***Related Harmonization Efforts***

We note the additional steps FDA is taking outside of this rulemaking process to bring its human subject protection regulations closer in uniformity with the revised Common Rule, including the proposed rule, *Institutional Review Boards; Cooperative Research*, on which the AAMC has also provided comments.<sup>29</sup> Additionally, although protections for children are not the subject of this proposed rule (*FDA regulations at 21 C.F.R. Part 50, Subpart D*), FDA recently issued draft guidance summarizing the ethical framework for including children in clinical investigations.<sup>30</sup> We commend FDA for these activities and encourage additional opportunities for public forum on the ethical considerations for protecting children and other vulnerable subjects in clinical trials.

▪ ***Clinical Trial Diversity***

We recognize clinical diversity and patient engagement are not a key focus of this proposed rule but appreciate FDA’s statement in the related press release that it hopes this comment opportunity will “invite broader participation in clinical research,” helping the agency to “advance [its] efforts to ensure that clinical trials reflect the diversity of patient populations and that these patient populations feel engaged by the clinical research community.”<sup>31</sup> This is an issue of great importance to the AAMC and AAMC Center for Health Justice<sup>32</sup> which was also expressed in recent comments on FDA’s draft *Race and Ethnicity Diversity Plan* and FDA’s related plans to improve the diversity of subjects enrolled in clinical trials.<sup>33</sup>

It is a critical and opportune time for FDA to address the underrepresentation of racial and ethnic populations in clinical trials given the Administration’s current efforts to advance racial justice and equal opportunity across the Federal Government under Executive Order 13985 (*Advancing Racial Equity and Support for Underserved Communities through the Federal Government*) and HHS’

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<sup>27</sup> AAMC Comments on Common Rule NPRM, Supra Note 4.

<sup>28</sup> AAMC Conflict of Interest Metrics Project: Measuring the Impact of the Public Health Service Regulations on Conflicts of Interest, <https://www.aamc.org/what-we-do/mission-areas/medical-research/conflicts-of-interest/metrics-project>

<sup>29</sup> 87 Fed. Reg. 58752, to be codified at 21 C.F.R. Part 56.

<sup>30</sup> U.S. Food and Drug Administration, Ethical Considerations for Clinical Investigations of Medical Products Involving Children: Draft Guidance (September 2022), <https://www.fda.gov/media/161740/download> (Accessed Dec. 20, 2022).

<sup>31</sup> FDA Press Release, Supra Note 5.

<sup>32</sup> For more information about the *AAMC Center for Health Justice* visit, <https://www.aamchealthjustice.org>.

<sup>33</sup> AAMC Comments to FDA on *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials* (Do. No. FDA-2021-D-0789, June 13, 2022), <https://www.aamc.org/media/61296/download?attachment>. Also see: AAMC Comments to FDA on Patient Focused Drug Development Draft Guidance (Do. No. FDA-2018-N-2455, September 27, 2022) <https://www.aamc.org/media/63181/download?attachment>.

related *Equity Action Plan*.<sup>34</sup> Through these efforts the FDA could help inform HHS’ interest in “increasing [the agency’s] understanding of root causes of inequities and ongoing evaluation of our efforts.”<sup>35</sup>

The AAMC appreciates the opportunity to comment on this proposed rule. We also commend to the FDA the responses from individual medical schools and teaching hospitals who offer perspectives from the vantage point of having implemented the revisions to the Common Rule through policy and practice. If we can assist FDA by providing additional information about our comments or bridging connections with our constituent community in furtherance of these harmonization efforts, please do not hesitate to contact me or my colleagues Daria Grayer (dgrayer@aamc.org) or Heather Pierce (hpierce@aamc.org).

Sincerely,

A handwritten signature in blue ink that reads "Ross E. McKinney, Jr., MD". The signature is written in a cursive style with a large initial "R" and "M".

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

cc: David J. Skorton, MD, President and Chief Executive Officer

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<sup>34</sup> HHS Equity Action Plan, <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf> (last visited Dec. 20, 2022).

<sup>35</sup> *Id.*