

April 29, 2024

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

*Submitted via Regulations.gov*

**Re: Collection of Race and Ethnicity Data in Clinical Trial and Clinical Studies for FDA-Regulated Medical Products (FDA-2016-D-3561)**

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, 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, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 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 participation in the AAMC by U.S. and international academic health centers.

The goal of the Center for Health Justice (Center), founded in 2021, is for all communities to have an equal opportunity to thrive — a goal that reaches well beyond medical care. Achieving health equity means addressing the common roots of health, social, and economic injustices and implementing policies and practices that are explicitly oriented toward equal opportunity. The Center partners with public health and community-based organizations, government and health care entities, the private sector, community leaders, and community members to build a case for health justice through research, analysis, and expertise. For more information, visit [www.aamchealthjustice.org](http://www.aamchealthjustice.org).

**General Comments**

The AAMC and the Center appreciate the opportunity to comment on the FDA's recommendations on the standardized collection and reporting of race and ethnicity data from clinical trials and clinical studies for FDA-regulated products. We have long supported the FDA's efforts to enhance diversity in clinical trials through our participation in public meetings and by providing comments on proposed guidance and initiatives. Related to this draft guidance, the AAMC provided feedback on the FDA's October 2016 draft guidance, *Collection of Race and Ethnicity Data in Clinical Trials*,<sup>1</sup> which will be superseded by the current draft guidance if finalized. More recently, in June 2022, we responded to the agency's plan to improve enrollment of underrepresented racial and ethnic groups in clinical trials through the development of a *Race and Ethnicity Diversity Plan*.<sup>2</sup> In our letter, we expressed concerns for the FDA's

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<sup>1</sup> AAMC Submits Letter to OMB on Presenting Federal Data on Race and Ethnicity (Oct. 2016) <https://www.aamc.org/advocacy-policy/washington-highlights/aamc-submits-letter-omb-presenting-federal-data-race-and-ethnicity>.

<sup>2</sup> AAMC Submits Comments on FDA Efforts to Increase Diversity in Clinical Trials (June 2022) <https://www.aamc.org/advocacy-policy/washington-highlights/aamc-submits-comments-fda-efforts-increase-diversity-clinical-trials>.

reliance on the Office of Management and Budget's (OMB) outdated definition of race and ethnicity, noting:

“[T]he OMB’s guiding principles have not been updated since the initial 1977 standards and subsequent 1997 revision. Reliance on the OMB’s antiquated terminology related to race and ethnicity in the context of drug/device product performance, increases the potential for bias and discrimination. It also undermines the intended goals of this proposed guidance and ultimately the broader goals outlined in the HHS Equity Action Plan. We recommend consideration of the recommendations issued by the White House Interagency Data Working Group, as well as coordination with the OMB’s current efforts to develop updated guidance to promote an “improved understanding” of racial and ethnic classification categories.”<sup>3</sup>

The AAMC commends the initiative the FDA has taken to develop a plan for the standardized use of race and ethnicity data in accordance with the *OMB’s Statistical Policy Directive No. 15* (SPD 15). Not only does this underscore the agency’s commitment to promoting diversity, but it is consistent with the broader objectives of the Administration to advance racial justice and equal opportunity (as outlined in Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through Federal Government*).<sup>4</sup> The AAMC submitted recommendations to the OMB in response to the proposed revisions and we are pleased that nearly all of the core revisions to SPD 15 align with the recommendations set forth in our letter. Given the majority of the recommendations in the FDA’s draft guidance reflect the now outdated version of SPD 15, our comments to the FDA are intended to:

- Highlight key recommendations in the FDA’s draft guidance that are consistent with or depart from the revised SPD 15.
- Express support for the next steps the FDA will take to finalize this draft guidance, as well as develop an *Agency Action Plan on Race and Ethnicity Data* (“Agency Action Plan”) pursuant to the updated SPD 15.

### **Collection of Race and Ethnicity Data**

In the comments below, we address the elements of SPD 15 in the FDA’s draft guidance, identifying areas where significant divergence exists due to the finalized updates to the standards.

- **Two Question Format and Self Reporting (Sect. III, Subsection A & B)**

The approach to collecting race and ethnicity information has transitioned from two separate questions to a single question format, enabling respondents to select one or more categories for race and ethnicity. The OMB’s adoption of the combined format is intended to allow respondents to select as many race and/or ethnicity options to better reflect self-identification. Consequently, the FDA’s recommendation for a two question format should now align with this shift, including the language for respondents to “select all that apply and enter additional details” in the write in spaces beneath each minimum category (refer to OMB Fig. 1 *Race and Ethnicity Question with Minimum Categories, Multiple Detailed*).<sup>5</sup> We recognize that the FDA has proposed the option to “Mark one or more” or “Select one or more” but note the OMB’s preferred language included in the revised SPD 15: “Select all that apply.”

Related, the FDA emphasizes that when the collection of self-reported information is not feasible, information may be obtained from “a first degree relative or other knowledgeable representative”

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<sup>3</sup> Supra Note 2.

<sup>4</sup> AAMC Submits Letter to OMB on Advancing Equity across the Federal Government, <https://www.aamc.org/advocacy-policy/washington-highlights/aamc-submits-letter-omb-advancing-equity-across-federal-government>.

<sup>5</sup> 89 FR 22195.

(lines 144-146). Notably, the updated SPD 15 endorses the use of proxy reporting, despite the prevailing support in public comments prohibiting the collection of race and ethnicity data through proxies or representatives. Specifically, SPD 15 states:

“Wherever possible, race and/or ethnicity data should be collected through self-report, where the respondents directly provide their own race and/or ethnicity. In cases where self-report is not possible, data may be collected by proxy reporting, where a person knowledgeable of another’s race and/or ethnicity responds on their behalf; by record matching, where existing records on an individual that contain their race and/or ethnicity are used to supply the information; or by observer identification, where an observer uses their best judgement of the most appropriate race and/or ethnicity categories in which to report an individual.”

In AAMC’s letter to OMB, we emphasized the need for the development of supplementary guidance on the “proxy collection” of race and ethnicity in circumstances where self-identification is impracticable. Building on the FDA’s recommendation concerning proxy reporting, we believe the proxy recommendation in this draft guidance would also benefit from further discussion. To ensure coherence, we suggest that any supplementary guidance are included in the Agency’s Action Plan pursuant to SPD 15’s requirements.

- **Race and Ethnicity Minimum Categories (Sect. III Subsection C & D)**  
The updated SPD 15 introduces a new "Middle Eastern and North African" (MENA) reporting category which is now distinct from the white category. During the OMB’s public feedback sessions regarding the proposed revisions to SPD 15, this proposition received significant attention with advocates strongly endorsing the inclusion of MENA as a separate category. In the AAMC’s comments, we urged OMB incorporate MENA into the minimum reporting categories noting that, "the single largest proportion of write-in responses to the AAMC’s open-ended self-identity questions for matriculating students have reflected Middle Eastern or North African backgrounds." Notably, the FDA’s draft guidance does not include MENA as a minimum category which is a major addition to the revised standards.
- **Collection of Detailed Race and Ethnicity Data (Sect. III. Subsection E)**  
The collection of detailed data beyond the minimum categories is now required (in most situations) and intended to increase consistency and comparability of data across the federal government. According to the draft guidance, the FDA should consult the 2011 HHS *Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary, Language, and Disability Status* if “additional granularity or more-detailed characterizations of race or ethnicity are collected” (lines 196-200). While this may serve as an appropriate reference, the FDA should acknowledge the revised SPD 15’s directive for agencies to submit a formal proposal if additional detailed data exceeding the minimum categories will be collected. Consequently, it would be prudent for the FDA to assess how the OMB’s expectations regarding data collection beyond the minimum categories align with or diverge from HHS’ 2011 implementation guidance.
- **Updated Terminology**  
It is also important to note that the updated SPD 15 introduces several changes to definitions and terminology to eliminate outdated and offensive terms. In Section III of the draft guidance (line 143) we are pleased to see that the FDA uses the term “multi-racial identity” which aligns with the revised terms in SPD 15 given the removal of the term “two or more races.” However, on line 226, the FDA uses “Other Pacific Islander” which contradicts the removal of the word “other” from the “Native Hawaiian and Other Pacific Islander” category.

### **Implementation and Coordination**

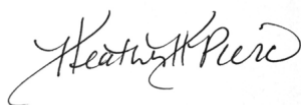
As previously discussed, we are encouraged by the OMB’s revisions to SPD 15 which are intended “to [...] keep[...] pace with changes in the population and evolving needs and uses for data.”<sup>6</sup> While the updated standards were released in the middle of the FDA’s request for comment on this draft guidance, we appreciate the agency’s proactive response to the proposed revisions and their potential impact on clinical trials and studies. However, since this current draft guidance *does not* reflect the revised standards, we strongly recommend a close review of the changes so they are directly applicable to the purpose and goals of this guidance.

Further, as the FDA moves towards finalizing this draft guidance and concurrently develops an Agency Action Plan in accordance with SPD 15, we recommend robust intra-agency collaboration, ensuring that the updates to SPD 15 are harmonized with ongoing agency initiatives. For instance, the FDA’s *Race and Ethnicity Diversity Plan*, as recommended in the 2022 Request for Information (yet to be finalized), should be closely aligned with these efforts. We also emphasize the importance of cross agency coordination, including communication with the newly established OMB *Interagency Committee on Race and Ethnicity Statistical Standards*. This will help foster information exchange and enhance coherence and uniformity across other agencies implementing SPD 15.

Finally, we would also like to highlight the OMB’s intention to pursue future research as detailed in the revised SPD 15 (*Topics for Future Research*, pg. 22191) and encourage the FDA to consider those topics as it relates to the collection of race and ethnicity data in clinical trials, but also in the development of the Agency Action Plan. In addition to the research topics in the revised SPD 15, we also suggest the FDA consider the collection of other demographic data and information for groups that are not currently represented in SPD 15 such as sexual orientation and gender identity data, religion, country of origin, primary language, disability status, and social risk factors.

We value the opportunity to provide feedback on this important endeavor, particularly at a time when there is unprecedented attention on advancing health equity and justice. The AAMC and the Center have developed extensive relationships across various sectors, including organizations and community leaders who are enthusiastic about supporting the FDA’s implementation of SPD 15. For questions about these comments or if there is an interest in engaging with our multi-sector community, please contact either of us or our colleague Daria Grayer, MA, JD, Director of Policy and Regulations ([dgrayer@aamc.org](mailto:dgrayer@aamc.org)).

Sincerely,



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

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<sup>6</sup> Initial Proposals for Updating OMB’s Race and Ethnicity Statistical Standards, 88 Federal Register 5377 (Jan. 27, 2023).