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Services Food and Drug Administration
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[Submitted Online]

RE: FDA-2016-D-3561: Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products

The Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT) has carefully reviewed the draft guidance for industry and we, the undersigned, appreciate the opportunity to comment on the proposed guidance to further influence the robust regulation concerning the collection of race and ethnicity data in clinical trials and clinical studies for medical products for the betterment of patient outcomes.

Suggestions for Revision

1) On page 4 line 94-97, refrain from suggesting "[racial] differences in the pharmacokinetics, efficacy, or safety of medical products" might be explained by genetics.
2) On page 5, line 146-147**,** refrain from recommending that study leaders not assign race to participants. Instead, recommend that if race is assigned, assignment follows the best practices established by the social sciences.

Recommendations

1) Add a "Middle Eastern North African" choice to the close-ended racial self-classification question.
2) Sponsors should:
    a) Specify the dimension (e.g. racial self-classification) and modality (e.g. one survey question) they used to ascertain research participant race and ethnicity;
    b) Explicitly connect the racial dimension and modality of ascertainment to the primary outcome in an explanatory model. For example, "we ascertained self-reported race through a single survey question offered to participants to better understand how it might influence heart rate variability";
    c) Explicitly state what, if anything, race is a proxy for **(**e.g. likelihood of negative discriminatory exposure).

These revisions and recommendations follow the newest guidance on the collection of race and ethnicity data from the Office of Management and Budget (OMB) (Office of Management and Budget 2024), the newest guidance from the National Academies of Sciences, Engineering and Medicine (NASEM) (National Academies of Sciences and Medicine 2023), as well as scholarly

research on the dimensions of race from experts in sociology, public health and medicine. (Roth 2010, 2016; Williams 1994; Jones et al. 2008)

1) Recommendation #1: On page 4 line 94-97, refrain from suggesting "[racial] differences in the pharmacokinetics, efficacy, or safety of medical products" might be explained by genetics.

Guidance released in March 2024 from the National Academies of Sciences, Engineering, and Medicine (NASEM) suggests avoiding the use of race and ethnicity as a proxy for genetic ancestry groups because race does not approximate genetic ancestry well. They write, "[a]lthough perhaps useful for some analyses, the concept of genetically differentiated, discrete populations that are static in place and time does not apply to humans." (National Academies of Sciences and Medicine 2023)

However, on page 4 lines 94-97, the current FDA guidance explicitly suggests that observed racial differences in the pharmacokinetics, efficacy, or safety of medical products might be mediated by genetic differences that correspond to race in humans. Although this statement is used to justify the collection of race and ethnicity data, it implies a claim of racial genetic determinism. As such, it conflicts with the recently released NASEM guidance.

Many experts agree that racial and ethnic descriptors correspond more with socially constructed national and continental borders than individual genetic variation, and that there is more genetic variation within each racially and ethnically defined population than there is between racially and ethnically defined populations. For example, the angiotensin-converting enzyme has two common alleles: one with an ALU insertion and one without an ALU insertion. The insertion allele (I) ranges from approximately 0.10–0.52 in Africa; 0.20–0.85 in Western Asia; 0.25–0.80 in Eastern Asia; 0.15–0.54 in Europe; 0.40–0.85 in North America; 0.30–0.90 in South America; and 0.45–1.00 in Oceania. (Brutsaert and Parra 2006; Valdez et al. 2013)

Moreover, the citation used in the FDA guidance does not corroborate its claim of racial genetic determinism. For example, the article cited by the guidance claims that "[t]he pharmacogenetic differences reported [in the article, for CYP 2D6] are based on interracial difference in germline genetic polymorphisms." (Ramamoorthy et al. 2015) To support this claim, it cites another article, which states:

> "It may, therefore, be difficult to predict the likely prevalence of the [CYP 2D6 Ultrametabolizer] phenotype accurately among African Americans for example, as estimates of this phenotype in African populations vary from 4.9% in African-Americans to 29% in Ethiopians, and data on what proportion of African-Americans is of Ethiopian descent are lacking. Wide ranges in the prevalence of both the UM and PM phenotypes have also been reported in individuals of European descent (0.8%–10% and 1.5%–10%)." (Yasuda, Zhang, and Huang 2008)

Articles referenced to support claims about the different prevalence of the CYP2D6 ultra-metabolizer phenotype among African Americans compared to other groups extrapolate from a sample of 258 African Americans living in Los Angeles County in the early 90s. Of note, the article did not state how each participant's race was ascertained. (London et al. 1997)

This sample of 258 African Americans living in Los Angeles in the early 1990s is likely not representative of the entire African American population, self-identified or otherwise. However, the article uses this data to draw conclusions associating differences in CYP2D6 metabolism to the entire African American population. Drawing a conclusion of genetic determinism about African Americans with such a small sample without demonstrating representativeness is a case of reverse ecological fallacy--when observations about an group of individuals with a characteristic are then assumed to apply to all or many individuals with that characteristic. Much stronger evidence is needed to make such an association credible, let alone causal, as racial genetic determinism would suggest.

For these reasons, the finalized guidance should omit any reference to a genetic mediation of different responses to interventions by race. Claims of racial genetic determinism are extraordinarily large, and so should be corroborated by an extraordinarily large evidence base. As of this writing, no such evidence is available: a 2024 study of 294 genetic researchers found that genetic databases commonly used in research contained samples primarily of European ancestral populations and lacked samples of non-European ancestral origin. (Jaffe et al. 2024) If references are not removed, more rigorous studies of the question should be cited to prevent undue and unproven suggestion of racial genetic determinism. To be clear, this is not to say that there couldn't be biological outcomes that differ by race. In other words, racial *biological* differences do not necessarily reflect racial *genetic* differences, and are often mediated by social factors. (Gravlee 2009)

2) Recommendation #2: On page 5, line 146-147**,** refrain from recommending that study leaders not assign race to participants. Instead, recommend that if race is assigned, assignment follows the best practices established by the social sciences.

OMB guidance updated in March 2024 suggests that other dimensions of race such as ascribed race—the race observers believe a person to be—might be well-suited if implemented well to answer important scientific questions about issues such as health effects of racial discrimination. (Office of Management and Budget 2024) Additionally, The European Commission's Subgroup on Equality Data acknowledges ascribed race as "an important element of the discrimination experiences of Afro-Europeans and European Muslims" and thus a worthy consideration for some research questions. (Commission 2021) In some cases, ascribed or observed race might be the most relevant dimension of race to real world situations pertinent to the phenomenon under study (e.g. interpersonal racial discrimination), and thus the most appropriate racial dimension to ascertain. Racial dimensions are explained below, with a case example thereafter.

Race has multiple dimensions, and which dimension(s) researchers choose to implement in their study influences the racial and ethnic inequities they find. (Roth 2016) Harvard Professor David Williams, a sociologist of race and health, observed in 1994 how infant birth and death certificates would over or underestimate infant mortality by race depending on whether race was observed or reported by parents. (Williams 1994)

University of Pennsylvania Professor Wendy Roth, another sociologist of race, has advanced this work by arguing that the dimension of race ascertained by researchers should correspond to the outcome being studied. (Roth 2016) She developed a typology associating dimensions of race with categories of research outcomes, which has been adapted in **Table 1**.

Self-reported race (racial self-classification)—the dimension preferred in many cases by revised OMB guidance—is the race a person chooses among a pre-determined set of choices on an official document or survey. The preference for racial self-classification is informed by a legitimate desire to protect participants right to self-determine. (Office of Management and Budget 1997) Self-determination is important to protect, considering our nation's history of distributing rights and privileges based on observed race. For example, before 1970, the US government would have one census worker observe and then record race to each individual. (Medina 2023) Implementing observed race for official government business such as the census ignores individuals right to self-determination, not least because the government is a steward of such rights. It is also not socially scientifically sound. Because race is a social construction (Searle 2006), there is interobserver variance regarding the race assigned to the same individual. (Herman 2010) Having one person observe and then record race for each person does not account for this variance.

However, race should not only be measured in situations where self-determination is possible. In fact, because self-determination is a form of power, situations where self-determination is not possible might be where the study of racism is most needed. Racial discrimination is one such example. Discrimination is often most harmful and most serious when imposed on the powerful against the powerless (e.g. police interactions). In situations where there is such a power imbalance, those who suffer discrimination often do not get the opportunity to self-determine their race. If rights reflect power, the ability for a participant to exercise their right of self-determination is a proxy for their power in the interaction. To ignore situations where self-determination is not possible is to ignore some of the most potentially racist phenomena.

Our current implementation of self-classified race is a great example of limiting a person's power to self-determine. Self-classified race is often implemented as a close-ended question. As a close ended question, it is a necessarily limited set of choices, which constrains some participants whose identities do not correspond with any of the choices offered for self-classification. In other words, many participants can't self-classify themselves as they would in an open-ended question. Limiting respondent choices through close-ended questions compromises self-determination, albeit to limit the number of possible race and ethnicity responses and improve the robustness of statistical analysis. To account for this compromise,

researchers have taken to asking participants, “What is your Census race?” when attempting to elicit a participant’s racial self-classification through close-ended questions.

Table 1: Abbreviated Table Listing Some Dimensions of Race			
Dimension of Race	Description	Typical Method of Ascertainment	Outcomes it may be appropriate to study
Racial Identity	Subjective self-identification, not limited by pre-set options	Open ended self-identification question	Attitudes, social networks, assimilation, residential decision-making
Racial Self-Classification	The race a person chooses on an official form or survey with constrained options (e.g. The Census)	Closed-ended survey question	Demographic change; vital statistics, disease and illness rates
Observed or Ascribed Race	The race others believe you to be	Interviewer Classification	Discrimination, socioeconomic disparities, health care/service provision
Reflected Race	The race you believe others assume you to be	"What race do most people think you are?"	Self-identification processes, perceived discrimination
Adapted from Roth WD. The multiple dimensions of race. Ethnic and Racial Studies 2016; 39(8): 1310-38.			

Having to ask “What is your Census race?” speaks not only to the aforementioned compromise of self-determination, but also to how close-ended questions for racial self-classification do not capture a part of how race and ethnicity operate in our social world. Professor Roth offers this example:

> “For example, Salvador, a restaurant worker in New York, identifies his race as Puerto Rican. Phenotypically, he is dark-skinned with indigenous features, leading some Americans to view him as Black. He believes that Americans view him as Hispanic, based on his accent and name. Yet on the census, Salvador checks White for his race because no listed option fits his identity and in Puerto Rico his mixed racial ancestry allowed him to consider himself closer to White than to Black.” (Roth 2010)

In the example, Salvador ethnoracially self-identifies as Puerto Rican—an American Territory—but the census choices presented to him do not offer him that choice, so he self-classifies as White based on his Puerto Rican acculturation. He is seen by other Americans as Black,

however, and presents as having dark skin and "indigenous" features. In other words, Salvador's race depends on who you ask (Salvador versus other observers), and where you ask the question (Puerto Rico vs. New York). Like most social constructed processes—including research and scientific publication (Young and Ryan 2020)—social context influences race's meaning and value. (Searle 2006)

Such context is missed with close-ended racial self-classification, and is important to capture in order to intervene on racial health inequity. Indeed, Omi and Winant, two sociologists whose Racial Formation in the United States popularized race as a social construction in sociology, define race as ""a concept that signifies and symbolizes social conflicts and interests by referring to different types of human bodies." (Omi and Winant 2014) How individuals present themselves to others, and how others respond to that presentation are important parts of their racial formation, and impacts racial health outcomes. For example, one NPR/Harvard study found that over half of African Americans report discrimination at work and discrimination by police, and about one-third report discrimination by police **(Figure 1)**. (National Public Radio and Health 2018) Racial discrimination in social interactions does not require those discriminated against to self-report their race. Rather, race is assigned by those discriminating and imposed upon those discriminated against based on self-presentation, not self-report. This exemplifies the power imbalance mentioned earlier. Interpersonal discrimination is operationalized through observed or assigned race.

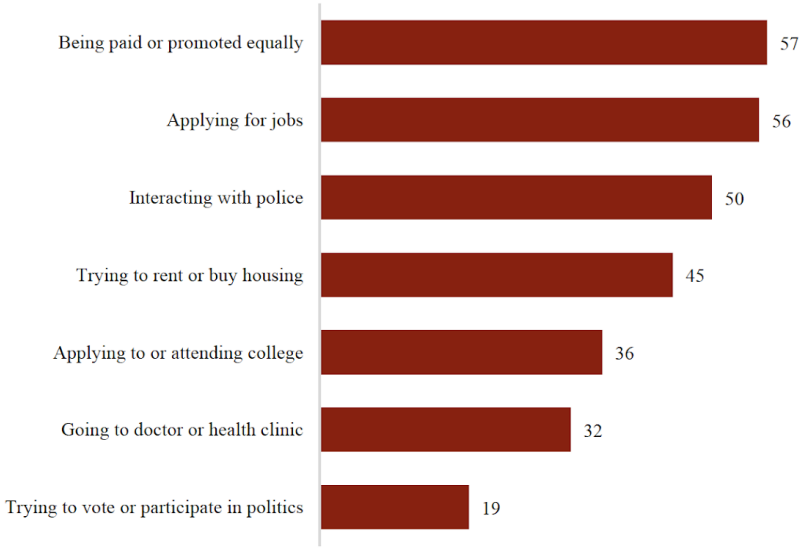


Figure 1: Percent of African American Saying They Have Ever Been Personally Discriminated Against In Each Situation Because They Are Black

Racial discrimination makes people sick across the lifespan. A study of 634 diverse caregiver-child dyads found early childhood experiences of primary caregiver discrimination (ages 3–5) predicted adolescent disruptive behaviors. (Savell et al. 2019) A study of 391 African American women found persistent exposure to discrimination predicted inflammation which, in turn, predicted chronic disease risk. (Simons et al. 2021) Additionally, a longitudinal cohort study of 322 participants from 2009 to 2021 found racial discrimination predisposes Black young adults

to Metabolic syndrome, which also predisposes people to chronic disease via sleep problems and inflammation. (Heard-Garris et al. 2024) As such, the health effects of racial discrimination are a worthy point of intervention to improve health inequities.

So a device or other tool that sought to reduce discrimination induced inflammation in racial minorities might be presented for FDA approval. The most sound dimension with which to ascertain race would be ascribed or observed race, since this dimension is also the basis upon which other people racially discriminate. However, due to the FDA categorical prohibition on assigning race at issue, researchers would be forced to used racial self-classification or some other .

Using self-reported race to study discrimination mediated via observed race would likely bias results toward the null. In several studies, Latinx and Native American individuals were often assigned or observed as White. (Arias, Heron, and Hakes 2016; Jim et al. 2014; Arias 2008) They would be included in the sample and counted as non-white. Professor Camara Phyllis Jones, former President of the American Public Health Association, has found that, as a group, those whose self-reported race was non-white but whose assigned race was White had better health—and likely less unhealthy inflammation-- than those whose self-reported race and observed race are both non-White. (Jones et al. 2008) They also are less likely to suffer discrimination on the basis of observed race, the mechanism on which the device or product would intervene, because they appear White. As such, categorizing them as non-white participants in a study of discrimination on the basis of observed race not only would attenuate the observed effect of discrimination on non-white appearing participants, it would also ignore the mechanism of the discrimination under study. For this reason, observed race is a better racial dimension with which to study discrimination mediated via observed race.

As interventions for racial health inequity mature, so should the standards used to evaluate them. For this reason, the finalized guidance should not categorically recommend against study teams assigning race to participants. Instead, they should recommend that if study teams decide to assign race to participants, that they that should explain why, and present their protocol. Protocol should, at minimum: 1) ensure participants consent to such assignment; 2) ensure assignment is performed by at least three observers with diverse backgrounds, to mitigate bias (Herman 2010); and 3) that said protocol explicitly adjudicates rating discordance.

Additionally, guidance should ask sponsors to elaborate on 1) the racial dimension(s) and method(s) of ascertainment used in the study; 2) how they hypothesize that the specific racial dimensions relate to the outcomes studied; and 3) what factor, if any, race is a proxy for in their overall explanatory model.

Recommendations

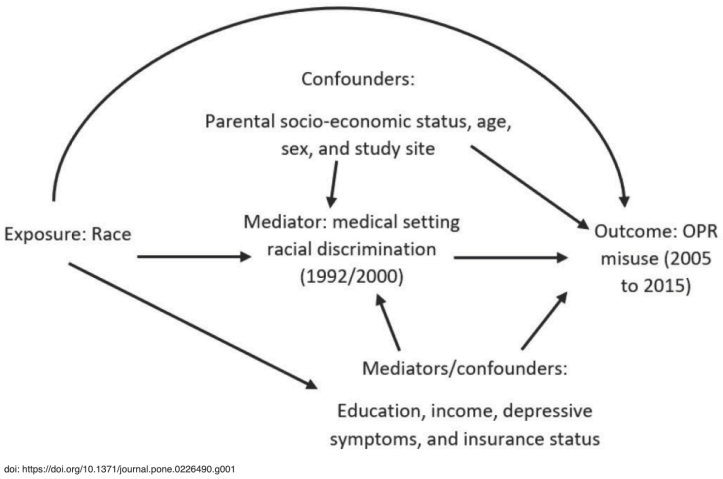
1) Add a “Middle Eastern North African” choice to the close-ended racial self-classification question.

OMB has added this choice has been added to the close-ended racial self-classification question (Office of Management and Budget 2024) as a result of the expertise and advocacy of clinical researchers. (Kader and Chebli 2022) Middle Eastern or North African people were previously categorized as White. Yet people who identify as Middle Eastern or North African have different health outcomes than people who identify as White. For example, compared to other groups of women, women with Arabic names had poorer birth outcomes after September 11th than before September 11th. (Lauderdale 2006)

2) Sponsors should:
    a) specify the dimension (e.g. racial self-classification) and modality (e.g. one survey question) they used to ascertain research participant race and ethnicity;
    b) explicitly connect the racial dimension and modality of ascertainment to the primary outcome in an explanatory model. For example, "we ascertained self-reported race through a single survey question offered to participants to better understand how it might influence heart rate variability";
    c) explicitly state what, if anything, race is a proxy for **(**e.g. likelihood of negative discriminatory exposure).

This recommendation is informed by **Table 1**. It would allow FDA regulators to ensure that the dimension of race was ascertained using an appropriate, OMB compliant instrument. Furthermore, it would provide regulators with more information on the data gathered by sponsors, which would enable follow-up questions and inter-study comparisons regarding racial representativeness that would be of interest to clinical trialists more broadly.

Recommending that sponsors also provide an explanatory model that includes the racial dimension ascertained would enable FDA regulators and other scientists to ensure that the model was internally valid (i.e. used the right dimension in relation to the outcome). As Lett et. al. have explained, sponsors could provide direct acyclic models, where explanatory factors are mapped in relation to outcomes under study. (Lett et al. 2022) For example, Swift et al use a direct acyclic graph (**Figure 2**) to illustrate their hypothesis: that there was a relationship between race, racial discrimination in medical care settings, and opioid pain relieve prescription mediated by several factors. (Swift et al. 2019)



doi: https://doi.org/10.1371/journal.pone.0226490.g001

Figure 2: Direct Acyclic Graph for Proposed Relationship between Race, Discrimination in a Medical Care Setting, and Opioid Pain Reliever Use

Implementing this recommendation would not only ensure that race was conceptualized soundly, but also would facilitate a more explicit evaluation of the hypothesis informing the intervention under review—and whether the hypothesis matches the intervention. If there was internal invalidity, evaluators would then be able to determine whether people were racially under or overcounted and adjust conclusions accordingly.

Race is often used as a proxy for some other outcome. Recommending sponsors explicitly state what it proxies for in their model would allow the FDA to determine whether there was a validated tool or better proxy for the outcome. For example, using race to directly proxy for perceived discrimination—as opposed to risk stratify for likelihood of exposure to discrimination, as in the example above—may not be better than using the everyday discrimination scale created and validated by Professor David Williams. (Lawrence et al. 2022) Explicitly stating the component for which race is a proxy would allow for fairer evaluation of the model in terms of its ethics and its efficacy.

Thank you for the opportunity to comment on this draft guidance.

Sincerely,

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