The Food and Drug Administration (FDA) has issued guidance regarding race and ethnicity as factors in the design of clinical trials, including regarding participant selection and data reporting. Historically, many clinical trials have not enrolled proportionate racial and ethnic subgroups reflective of disease distribution. Exclusion of participants based on common assumptions about the characteristics and circumstances of certain groups is likely to hinder discovery of important safety information about a drug or device in individuals who will receive the agent after approval.

Terminology

When incorporating race and ethnicity factors and data in research, FDA recommends use of the categories standardized in 1997 by the federal government's Office of Management and Budget. These categories are not scientifically or anthropologically based, but intended to reflect current sociocultural constructs and preferences.

FDA recommends that individuals self-report racial and ethnic identity and be given the option to designate multiracial identity. Race and ethnicity should not be assigned by the study team.

The guidance recommends various race and ethnicity categories, along with basic geographical criteria for each. For example, potential participants may identify as either "Hispanic or Latino" or "not Hispanic or Latino"; and racial identity options should, at minimum, include the following:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

The term "nonwhite" is unacceptable for use in the presentation of federal government data and should be avoided in research materials and publication.

More granular race-specific data—for instance, Ashkenazi Jewish or Han Chinese—may be important in instances in which certain medical conditions are more prevalent among particular groups.

Study design

To achieve an unbiased picture of investigational treatment effect in the general population, study designs should utilize a strategy to enroll populations diverse in racial and ethnic identity. Such a strategy may include:

- ensuring that study sites include geographic locations with more diverse populations by choosing neighborhoods where diverse populations receive their health care, such as
    - community clinics
    - nursing homes
    - pediatric hospitals

    - minority healthcare provider groups
    - urban hospitals
- alternative communication strategies for recruitment, informed consent, and research-related materials, such as
    - involvement of community-based organizations and places of worship
    - reading materials
        - in multiple languages with appropriate cultural references
        - tailored to low literacy skill
        - in electronic versions
        - via social media
    - accommodations for the visually and hearing-impaired
- where appropriate, development or revision of eligibility criteria to permit enrollment of a diverse study population
- holding recruitment events often, including during evening and weekends.
- flexibility in study visits, such as evenings and weekends, and, where practical, provision of child or elder care services
- consideration as to whether the comparatively restrictive exclusion criteria of phase 2 studies can be eliminated or modified for phase 3 trials
- financial reimbursement for expenses associated with participation, as well as monetary or other incentives in exchange for participation

Researchers should also consider cultural competency training for staff involved in screening and enrollment activities.

See FDA guidance, or contact the IRB, for more information about inclusive and appropriately representative study populations.

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