

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution:502
(A-24)

Introduced by: Medical Student Section

Subject: Tribally-Directed Precision Medicine Research

Referred to: Reference Committee E

1 Whereas, an estimated 80% of data used in precision medicine is from people with European
2 ancestry, limiting generalizability of research and possibly exacerbating health inequities¹⁻⁶; and
3
4 Whereas, effects of ongoing cultural genocide and colonization increase chronic disease burden
5 and reduce quality of care for American Indian and Alaska Native (AI/AN) persons^{3,7-11}; and
6
7 Whereas, a 2021 study found that AI/AN persons are underrepresented at only 0.3% of
8 research participants while comprising 3% of the US population, while non-Hispanic whites were
9 overrepresented at 82% while comprising 59% of the US population^{2,4,6,9,12}; and
10
11 Whereas, a National Institutes of Health (NIH) report on AI/AN engagement in the All of Us
12 Research Program noted a need for comanagement of precision medicine research with AI/AN
13 communities and consideration of the distinct ethical, legal, and social contexts when engaging
14 AI/AN communities in research, including their status as political entities¹³⁻¹⁶; and
15
16 Whereas, AI/AN researchers have developed specific models to recruit AI/AN persons for
17 clinical trials that account for the complex geopolitical climates of sovereign governments that
18 extend far beyond considerations of race and ethnicity, such as the principles for engaging in
19 ethical research with Indigenous people by Claw et al. and the Circle of Trust^{9,14,17-19}; and
20
21 Whereas, the Indian Health Service does not have the resources or facilities to support
22 precision medicine research without institutional partnerships²⁰; and
23
24 Whereas, a 2022 White House Office of Science and Technology Policy memorandum
25 recognized the value of Indigenous knowledge in scientific advances and created a working
26 group to include Indigenous perspectives in federal decisions and grantmaking²¹; therefore be it
27
28 RESOLVED, that our American Medical Association support clinical funding supplements to the
29 National Institutes of Health, the U.S. Food and Drug Administration, and the Indian Health
30 Service to promote greater participation of the Indian Health Service, Tribal, and Urban Indian
31 Health Programs in clinical research.

Fiscal Note: Minimal - less than \$1,000

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RELEVANT AMA Policy

H-460.884 Indigenous Data Sovereignty

Our AMA: (1) recognizes that American Indian and Alaska Native (AI/AN) Tribes and Villages are sovereign governments that should be consulted before the conduct of research specific to their members, lands, and properties; (2) supports that AI/AN Tribes and Villages' Institutional Review Boards (IRBs) and research departments retain the right to oversee and regulate the collection, ownership, and management of research data with the consent of their members, and that individual members of AI/AN Tribes and Villages retain their autonomy and privacy regarding research data shared with researchers, AI/AN Tribes and Villages, and governments, consistent with existing protections under 45 CFR 46; and (3) encourages: (a) the use and regular review of data-sharing agreements for all studies between academic medical centers and AI/AN Tribes and Villages be mutually agreed upon and aligned with AI/AN Tribes' and Villages' preferences, and (b) the National Institutes of Health and other stakeholders to provide flexible funding to AI/AN Tribes and Villages for research efforts, including the creation and maintenance of IRBs. [Res. 003, I-22]

H-460.911 Increasing Minority, Female, and other Underrepresented Group Participation in Clinical Research

1. Our AMA advocates that: a. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations. b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and c. Resources be provided to community level agencies that work with those minorities, females, and other underrepresented groups who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Black Individuals/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans. 2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities, females, and other underrepresented groups in clinical trials: a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs; b. Increased outreach to all physicians to encourage recruitment of patients from underrepresented groups in clinical trials; c. Continued education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety, and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate recruitment of underrepresented groups and methods for increasing trial accessibility for patients; d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and e. Fiscal support for minority, female, and other underrepresented groups recruitment efforts and increasing trial accessibility. 3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist. [BOT Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18; Modified: Res. 016, I-22]

D-460.976 Genomic and Molecular-based Personalized Health Care

Our AMA will: (1) continue to recognize the need for possible adaptation of the US health care system to prospectively prevent the development of disease by ethically using genomics, proteomics, metabolomics, imaging and other advanced diagnostics, along with standardized informatics tools to develop individual risk assessments and personal health plans; (2) support studies aimed at determining the viability of prospective care models and measures that will assist in creating a stronger focus on prospective care in the US health care system; (3) support research and discussion regarding the multidimensional ethical issues related to prospective care models, such as genetic testing; (4) maintain a visible presence in genetics and molecular medicine, including web-based resources and the development of educational materials, to assist in educating physicians about relevant clinical practice issues related to genomics as they develop; and (5) promote the appropriate use of pharmacogenomics in drug development and clinical trials. [CSAPH Rep. 4, A-06; Reaffirmed: CSAPH Rep. 4, A-10; Reaffirmed: CSAPH Rep. 01, A-20]