NIH POLICY ON REPORTING RACE AND ETHNICITY DATA: SUBJECTS IN CLINICAL RESEARCH

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(11/06/06 - See updated list of NIH contacts (MS Word) for this policy)

NOTICE: NOT-OD-01-053

National Institutes of Health

POLICY: The NIH has adopted the 1997 Office of Management and Budget (OMB) revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant applications, contract and intramural proposals and for all active research grants, cooperative agreements, contract and intramural projects. The minimum standards are described in the 1997 OMB Directive 15, http://www.whitehouse.gov/omb/fedreg/directive_15.html.

SUMMARY: This document provides additional guidance and instruction for using the revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity found in the PHS 398 (rev. 5/01) and PHS 2590 (rev.5/01) instructions and forms https://grants.nih.gov/grants/forms.htm. Comparable information will be provided in research and development contract solicitations and awards for intramural projects.
This document should be used in conjunction with the instructions in the PHS 398 and PHS 2590 instructions and forms.

The 1997 OMB revised minimum standards include two ethnic categories (Hispanic or Latino, and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. Using self-reporting or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Collection of this information and use of these categories is required for research that meets the NIH definition of clinical research.

EFFECTIVE DATE: This policy applies to all new applications and proposals, annual progress reports, competing continuation applications, competing supplement applications for research grants, contracts, and intramural projects as of January 10, 2002.

I. Revised Minimum Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

The following are the ethnic and racial definitions for the minimum standard categories (1997 OMB Directive 15).

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the "number selecting more than one race"; and, (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

II. Guidance on Reporting Ethnicity/Race and Sex/Gender in Clinical Research

NIH requires all grants, contracts, and intramural projects conducting clinical research to address the Inclusion of Women and Minorities (see https://grants.nih.gov/grants/funding/women_min/women_min.htm). NIH defines clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

New Applications (type 1), Competing Continuations (type 2), Requests for Proposals, and Intramural Projects

Submitting Applications or Proposals Involving the Collection of New/Additional Data in Clinical Research:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. This information must be reported using the newly revised categories and according to the new format provided in the Targeted/Planned Enrollment table https://grants.nih.gov/grants/funding/phs398/enrollment.pdf

Submitting Applications or Proposals Using Existing Data in Clinical Research with No Plans for Collecting New/Additional Data:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. Under these circumstances, investigators are not required to re-contact subjects solely to comply with the newly revised categories. If the existing data on ethnicity and race allows accurate correspondence with the new categories, the investigator can use the format in the Targeted/Planned Enrollment table. However, if the existing data do not allow accurate correspondence with the new categories, information may be reported using the former categories and according to the format in the 4/98 Version of the Inclusion Table https://grants.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf

Annual Progress Reports (type 5) and Competing Supplement Applications

In Annual Progress Reports and Competing Supplement Applications, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date (as well as any proposed additions to the Targeted/Planned enrollment in the case of Competing Supplement Applications) and to present the distribution by ethnic/racial categories and sex/gender.

If Data Collection is Ongoing, Such that New Subjects Will be Enrolled and/or Additional Data Will be Collected from Human Subjects:

Investigators may choose to report ethnicity/race and sex/gender sample composition using EITHER the format in the former 4/98 Version of the Inclusion Table OR the new Inclusion Enrollment Report https://grants.nih.gov/grants/funding/phs398/enrollmentreport.pdf [Note: If investigators with on-going data collection choose to report information using the new Inclusion Enrollment Report, they must continue to use this format for the remaining years of the project.]

If Data Collection is Complete, Such that No New/Additional Subject Contact is Planned:

Investigators may EITHER continue to report using the former categories and according to the 4/98 Version of the Inclusion Table, OR, if data allow accurate correspondence with the new categories, use the format in the new Inclusion Enrollment Report.

III. Frequently Asked Questions

1. What categories should I use in my application to estimate race and ethnicity, given the new OMB standards?

Investigators should use the categories described in the PHS 398 instructions and listed in the table “Targeted/Planned Enrollment Table” for New Applications. First, the investigator should report the anticipated total number of males and females to be enrolled by Ethnicity (Hispanic or Latino, Not Hispanic or Latino). Then, the investigator should report the anticipated total number of males and females by Racial Categories (American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White). The total number of subjects in the Ethnic Category section of the table should equal the total number of subjects in the Racial Categories section. Investigators do not need to estimate the anticipated number of individuals reporting multiple racial categories (either total number reporting multiple categories or number reporting specific combinations) for New Applications. However, the investigator must follow the OMB guidelines, which include allowing respondents to select multiple race categories, once data collection commences.

2. What if my new application involves analyzing secondary data in which the race and ethnicity categories do not comply with the new OMB guidelines?

If an investigator is using secondary data sets that do not conform to the new OMB guidelines and does not plan to collect any new/additional data from the subjects, this should be noted in the New Application. In this circumstance, the investigator should complete the “Targeted/Planned Enrollment Table” for a New Application and the “Inclusion Enrollment Report” for Continuation Applications, Competing Supplement Applications, and Annual Grant Progress Reports if the data allow. However, if the existing data do not allow accurate correspondence with the new categories, the investigator should report the information using the prior categories and use the 4/98 Version of the Inclusion Table.

3. There are many ways of tabulating the multiple race and ethnicity responses, particularly since the race and ethnicity categories are not mutually exclusive. Do the numbers I report have to “add up”?

The numbers in several parts of the two tables must be the same. In both the “Targeted/Planned Enrollment Table” for a New Application and the “Inclusion Enrollment Report ” for Continuation Applications, Competing Supplement Applications, and Annual Progress Reports, the sum in “Ethnic Category: Total of All Subjects” must equal the sum in “Racial Categories: Total of All Subjects.” In addition, the “Racial Categories: Total Hispanics or Latinos” in Part B of the “Inclusion Enrollment Report Table” must equal the Total Hispanic or Latino number reported in Part A of the “Inclusion Enrollment Report.” Footnotes in the tables clearly identify which numbers must be the same.

4. Can I use the Targeted/Planned Enrollment Table or the Enrollment Inclusion Report to collect data from individuals?

Neither the Targeted/Planned Enrollment Tablet nor the Enrollment Inclusion Report should be used for collecting data from individuals. These tables are only to be used for reporting aggregate data.

To collect data from an individual respondent, investigators should use respondent self-report or self-identification and use two separate questions. The first question should be about ethnicity, followed by a question that provides the option of selecting one or more racial designations. An example of a format for collecting information from an individual can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page in the PHS 398 (rev. 5/01) https://grants.nih.gov/grants/funding/phs398/personal.pdf

5. Can I ask more detailed questions about ethnicity and race than these guidelines indicate?

The revised OMB guidelines provide minimal standards for data collection. Indeed, researchers are encouraged to explore collecting additional types of information on race and ethnicity that will provide additional insights into the relationships between race and ethnicity and health. For example, after asking the ethnicity and then the race questions, researchers may opt to ask study participants who choose multiple categories to identify the group that they identify with primarily. Further questions identifying membership in subpopulations within the ethnic and racial categories provided by OMB may also be considered. The scientific question being addressed in the study should guide investigators' decisions regarding collection of any additional information on ethnicity or race. Information on subpopulations may be reported by listing the information in an attachment to the required table.

6. I have already begun data collection and my categories do not comply with the new OMB standards. Do I need to change my questions on race and ethnicity in the middle of the study?

If data collection has already begun, we do not expect investigators to change their questions on race and ethnicity prior to the completion of the study. For Annual Progress Reports, in this circumstance, investigators should note that the research project was initiated prior to the implementation of the new reporting guidelines. If the data do not accurately correspond with the new categories, the investigator may continue to use the format in the 4/98 Version of the Inclusion Table.

7. I began data collection prior to the new standards, but my race and ethnicity questions comply with the new standards. I submitted my original estimates of the study composition using the old standards. How should I present the data in the progress report?

If you began your data collection prior to the implementation of the new standards but your questions on race and ethnicity comply with the new standards, the choice is left up to the investigator as to how to present the data for Annual Progress Reports. We suggest completion of the new Inclusion Enrollment Report.

8. How should I report race and ethnicity data when my research involves a foreign population?

Investigators are encouraged to design their data collection instruments in ways that allow respondent self-identification of their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables, investigators should asterisk and footnote the table indicating that data includes foreign participants. If the aggregated data only includes foreign participants, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both domestic and foreign participants, we suggest the investigator complete two separate tables - one for domestic data and one for foreign data, with an asterisk and footnote accompanying the table with foreign data.

9. How do the 1997 OMB revised standards differ from the previous standards?

OMB issued the previous standards for maintaining, collecting, and presenting data on race and ethnicity in 1977. The minimum acceptable categories were: American Indian or Alaska Native; Asian or Pacific Islander; Black, not of Hispanic origin; Hispanic; White, not of Hispanic origin.

The 1997 OMB revised standards now include two ethnic categories (Hispanic or Latino or Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). When using self-reporting or self-identification to collect data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Additional Information and NIH Contacts

Additional information on NIH policy regarding the Inclusion of Women and Minorities in Clinical Research can be found at the website https://grants.nih.gov/grants/funding/women_min/women_min.htm

The following extramural staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs:

Dr. Miriam Kelty
National Institute on Aging
Gateway Building
7201 Wisconsin Avenue, Room 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322
Email: keltyM@nia.nih.gov

Dr. Eleanor Hanna
National Institute on Alcohol Abuse and Alcoholism
Willco Building
6000 Executive Boulevard, Suite 514
Rockville, MD 20892
Telephone: (301) 594-6231
Email: ehanna1@mail.nih.gov

Dr. John McGowan
National Institute of Allergy and Infectious Diseases
6700 B Rockledge
6700 Rockledge Drive
Bethesda, MD 20817
Telephone: (301) 496-7291
Email: jm80c@nih.gov

Dr. Julia Freeman
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building
Building 45, Room 5AS19F
Bethesda, MD 20892
Telephone: (301) 594-4543
Email: freemanj@ep.niams.nih.gov

Dr. Joan T. Harmon
National Institute of Biomedical Imaging and Bioengineering
Room 697
6707 Democracy Boulevard
Bethesda, MD 20892
Telephone: (301) 594-8813
Email: joan_harmon@nih.gov

Dr. Marvin Kalt
National Cancer Institute
Executive Plaza North
6116 Executive Boulevard, Suite 8001
Bethesda, MD 20892
Telephone: (301) 496-5147
Email: kaltm@dea.nci.nih.gov

Dr. Susan Streufert
National Institute of Child Health and Human Development
6100 Executive Boulevard
Building 61EB, Room 4A05
Bethesda, MD 20892
Telephone: (301) 435-6856
Email: streufes@mail.nih.gov

Dr. Julie Gulya
National Institute on Deafness and Other Communication Disorders

Executive Plaza South
6120 Executive Boulevard, Room 400D-7
Rockville, MD 20892
Telephone: (301) 435-4085
Email: gulyaj@ms.nidcd.nih.gov

Dr. Norman S. Braveman
National Institute on Dental and Craniofacial Research
Natcher Building
Building 45, Rm 4AN24C
Bethesda, MD 20892
Telephone: (301) 594-2089
Email: BravemanN@de45.nidr.nih.gov

Dr. Robert Hammond
National Institute of Diabetes and Digestive and Kidney Diseases
2 Democracy Boulevard, Room 715
Bethesda, MD 20892
Telephone: (301) 594-8834
Email: hammondr@extra.niddk.nih.gov

Dr. Teresa Levitin
National Institute on Drug Abuse
Neuroscience Building
6001 Executive Boulevard, Room 3158
Bethesda, MD 20852
Telephone: (301) 443-2755
Email: tlevitin@nida.nih.gov

Dr. Anne P. Sassaman
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-30
Research Triangle Park, NC 27709
Telephone: (919) 541-7723
Email: sassaman@niehs.nih.gov

Dr. Lore Anne McNicol
National Eye Institute
Executive Plaza South
6120 Executive Boulevard, Room 350
Rockville, MD 20892
Telephone: (301) 496-5301
Email: loreanne.mcnicol@nei.nih.gov

Dr. Alison Cole
National Institute of General Medical Sciences
Natcher Building
Building 45, Room 2AS49K
Bethesda, MD 20892
Telephone: (301) 594-1826
Email colea@nigms.nih.gov

Ms. Sharry Palagi
National Heart, Lung and Blood Institute
Building 31
31 Center Drive, Room 5A-07
Bethesda, MD 20892
Telephone: (301) 402-3424
Email: palagis@nih.gov

Dr. Mark Guyer
National Human Genome Research Institute
Building 31
31 Center Drive, Room B2B07
Bethesda, MD 20892
Telephone: (301) 496-7531
Email: guyerm@exchange.nih.gov

Dr. Richard Nakamura
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8235
Bethesda, MD 20852
Telephone: (301) 443-3675
Email: rnakamur@mail.nih.gov

Dr. Meredith Temple
National Institute of Neurological Disorders and Stroke
Neuroscience Building
6001 Executive Boulevard, Room 2227
Bethesda, MD 20892- 9525

Telephone: (301) 496-1447
Email: templem@ninds.nih.gov

Dr. Carole Hudgings
National Institute of Nursing Research
Natcher Building
45 Center Drive, Rm 3AN-12
Bethesda, MD 20892
Telephone: (301) 594-5976
Email: carole_hudgings@nih.gov

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
Building 31
31 Center Drive, Room 5B-58
Telephone: (301) 402-1030
Email: GoertzC@od.nih.gov

Dr. Eric Bailey
National Center on Minority Health and Health Disparities
2 Democracy Boulevard, Suite 800
Bethesda, MD 20817
Telephone: (301) 402-1366
Email: baileye@od.nih.gov

Dr. Geoffrey Cheung
National Center for Research Resources
Rockledge Centre I
6705 Rockledge Dr, Rm 6118
Bethesda, MD 20817
Telephone: (301) 435-0768
Email: cheungg@ncrr.ncrr.nih.gov

Dr. Kenneth Bridbord
Fogarty International Center
Building 31
31 Center Drive, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-2516
Email: bridbordk@ficod.fic.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Office of Extramural Research (OER)

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Department of Health and Human Services (HHS)

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