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FCMR-CD

Updated 2 July 2020

SUBJECT: The CDMRP Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

I. Executive Summary

Outlined below is the CDMRP Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research. This document includes:

- Background information regarding legislative requirements, existing policies and processes,
- Details regarding policy requirements and application,
- Roles and responsibilities of impacted parties, which include program staff, applicants, organizational Institutional Review Boards (IRBs), and review panels, and
- Resources and references for defining terminology and locating additional information.

Incremental implementation of this policy is anticipated. This policy will be incorporated into CDMRP funding opportunity announcements beginning in FY21. All awards made prior to 1 October 2020 are exempt from this requirement.

II. Legislative Background

The Department of Defense (DoD) was directed by the United States Senate Appropriations Subcommittee on Defense to develop a plan to ensure the appropriate representation of women and minorities in its extramural research in Congressional report 115-290, page 213, which accompanied H.R. 6157, the Department of Defense Appropriations Act of 2019. The report stated that CDMRP shall work in coordination with the National Institutes of Health (NIH) to develop a plan that provides for: “(1) representation of women and minorities in each clinical trial, as well as the data on specific challenges researchers face in seeking to include women and minorities in their studies; (2) examination of biological variables, including the appropriate analysis of differential outcomes by sex, in clinical research; (3) practice of making clinical findings, subgroup analyses, and data publicly available, as appropriate and applicable; and (4) requirements (including, but not limited to, programmatic controls) and updated guidelines to ensure the appropriate representation of women in clinical research. Outcomes should also be analyzed for potential sex differences.” This policy is a result of the directive and closely mirrors [NIH's policy](#).

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III. Federal Inclusion Policies for Clinical Research

Per Federal and DoD regulations¹, all DoD-supported research must comply with the Federal Policy for the Protection of Human Subjects, known as the “[Common Rule](#),” a set of Federal regulations for ethical conduct of research involving human subjects. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Human subject research conducted or supported by each Federal department/agency is governed by the regulations of that department/agency.

Historically, clinical research in the United States has largely been based on studies conducted in white, male populations, preventing female and minority populations from fully benefitting from clinical advances that may not have accounted for genetic and biomedical differences between sexes, races, and ethnicities. To address this disparity and improve the representation of women and minority participants in clinical research, the NIH Revitalization Act of 1993, PL 103-43, was signed into law on June 10, 1993, and directed the NIH to establish guidelines for inclusion of women and minorities in clinical research. In response, the NIH released “The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research” in 1994. This comprehensive policy, which was updated in 2000 and 2001, requires that all NIH-funded clinical research include women and members of minority groups unless there is a clear and compelling justification for excluding them. Another recent update in November 2017 provides additional guidelines regarding the reporting of analyses of sex/gender, racial, and ethnic differences in Phase III clinical trials.

The U.S. Army Medical Research and Development Command’s (USAMRDC) Office of Research Protections (ORP) ensures that USAMRDC-conducted, -contracted, -sponsored, -supported or -managed research and investigations involving human subjects, human anatomical substances, or animals are conducted in accordance with Federal, DoD, Army, USAMRDC, and international regulatory requirements. This includes CDMRP-managed awards.

IV. Current CDMRP Processes for Clinical Research

Clinical research, including interventional clinical trials, observational clinical studies, and research with human biospecimen samples or other medical information/datasets, is important for translating healthcare solutions from the bench to the bedside. All CDMRP-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by ORP’s subordinate Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local IRB, Ethics Committee (EC), or equivalent review.

¹ Title 45 Code of Federal Regulations part 46 and DoD Instruction 3216.02

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Some CDMRP programs are specifically focused on diseases affecting women and/or minorities. The Breast Cancer and Ovarian Cancer Research Programs both offer clinical research-focused funding opportunities for female participants. The Prostate Cancer Research Program has been supporting research on the disproportionate incidence and mortality of prostate cancer in minority men since its inception in FY97. Disease disparities in kidney cancer, of which there is a higher incidence in African American and Native American populations, is an area of emphasis of the Kidney Cancer Research Program's strategic plan and funding opportunities. The Peer Reviewed Medical Research Program and the Lupus Research Program solicit for and support research in diseases/conditions that disproportionately or exclusively affect women and/or minorities, including lupus, heart disease, endometriosis, rheumatoid arthritis, and Rett's syndrome.

CDMRP funding opportunity announcements have included language encouraging inclusion of women and minorities in clinical trials since 2009. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subject research.

CDMRP requires clinical research applications to outline specific components related to the proposed human subject research, such as details of the clinical strategy, appropriate study variables/endpoints, recruitment plan or the acquisition of human biospecimen samples, and inclusion/exclusion criteria. Clinical trial applications require an intervention plan (including study procedures and a clinical monitoring plan), detailed description of human subject recruitment and safety procedures that specifically address the target populations, anticipated enrollment counts at each study site, any potential barriers to accrual, and a data management plan. Importantly, the human subject recruitment and safety procedures description must include a justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, ethnicity, race, and/or sex/gender. Within the inclusion/exclusion criteria for any proposed clinical study, the inclusion of women and minorities must be described and an appropriate justification must be included if women and/or minorities will be excluded.

Clinical trial and clinical research applications undergo a rigorous technical review that evaluates against specific criteria. Guidelines are provided in each funding opportunity that instruct applicants on the information needed to support this thorough review. Additional information regarding the CDMRP program cycle is available on the [CDMRP website](#).

V. CDMRP's Policy

It is the policy of CDMRP that women and individuals from minority groups be included in all CDMRP-funded clinical research studies, unless there is a clear, justifiable rationale that it is inappropriate with respect to the health of the subjects or the purpose of the research.

Inclusion: The inclusion of women and individuals from minority groups and their subpopulations must be addressed across the lifespan of CDMRP-funded research. This requirement extends to all clinical research, including interventional clinical trials, observational clinical studies, and studies involving human biospecimens or datasets. Inclusion on the basis of sex/gender, race, and ethnicity should be guided by the disease and scientific aims of the study.

Exclusion: It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

VI. Clinical Research Application Requirements

In addition to CDMRP's current requirements in funding opportunity announcements for clinical trial applications, all clinical research applications are required to include a strategy for the inclusion of women and minorities appropriate to objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects (Figure 1). Plans for the examination and analyses of biological variables and subpopulation data are required and will be evaluated as part of the application. Consistent with the 21st Century Cures Act, PL 114-255 and the NIH policy, analyses are required to be uploaded to clinicaltrials.gov for Phase III clinical trials only.

Figure 1. Summary of CDMRP Requirements for Clinical Research Applications

<p>Regulatory Strategy</p> <ul style="list-style-type: none">• IRB/EC approval• HRPO approval <p>Project Narrative</p> <ul style="list-style-type: none">• Research Strategy describing study population and detailed plan for recruitment.• Describe the methods that will be used to recruit.• Define each arm/study group of the proposed trial or clinical research study. <p>Human Subjects/Sample Acquisition</p> <ul style="list-style-type: none">• Describe the study population (e.g., age ranges, gender, ethnic groups, and pertinent demographics).
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- Describe criteria for inclusion/exclusion and provide detailed justification for exclusions.
- Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be found in [Appendix 1](#).
- Describe methods used for recruitment/accrual.
- Describe how subject-to-group assignments will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures).
- Inclusion of women and minorities in study – consistent with the Belmont Report and Congressional legislation, special attention is given to inclusion of women and/or minorities. Provide justification if women and/or minorities will be excluded from the study.
- Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group.
- For Phase III clinical trials only, describe plans for the valid design and analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study and describe whether or not clinically important sex/gender and race/ethnicity differences are expected in the intervention effect based on existing evidence.

Peer Review Criteria

- How well the inclusion, exclusion and randomization criteria meet the needs of the proposed clinical effort.
- How well the sample population represents the target patient population that might benefit from the research outcome.
- How well the applicant addresses the proposed plan for the inclusion of women and minorities for appropriate representation or justifies the limitation or absence.
- How well the applicant addresses the proposed exclusion of women and minorities on the basis that a requirement for inclusion is inappropriate with respect to the health of the subject or the purpose of the research.
- For Phase III trials only:
 - How well plans for the valid design and analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study are described.
 - How well the application addresses whether or not clinically important sex/gender and race/ethnicity differences are expected in the intervention effect based on existing evidence.

During application submission, applicants are required to provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report (IER) format is a one-page fillable PDF form (see Appendices [1](#) and [2](#)). Throughout the life of the award, PIs shall provide an actual enrollment table(s) (see [Appendix 1](#) for suggested format) at the time of each Annual and Final Technical Progress Report submission, and report on challenges associated with including women and minorities in their studies. CDMRP staff will monitor and track the inclusion of women and individuals from minority groups when reviewing technical reports.

VII. Phase III Clinical Trial Requirements

When a Phase III clinical trial is proposed, plans for the valid design and analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study must be included in the research application. Evidence of whether or not clinically important sex/gender and race/ethnicity differences are expected in the intervention effect will be required. Considerations for existing evidence are described in more detail in Section IIB of the [NIH policy](#). Phase III clinical trials include statistically significant numbers of human subjects to allow for analyses down to the gender and minority level. As opposed to earlier phases of clinical investigation establishing safety and dosing regimens, the aim of Phase III investigations is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. Therefore, requiring plans for the valid design and analysis of group differences on the basis of sex/gender, race, and/or ethnicity and requiring entities conducting applicable clinical trials to submit results of valid analyses and outcomes by sex/gender, race, and ethnicity in [clinicaltrials.gov](#) is appropriate only at this phase. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting Phase III clinical trials. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical progress report, a justification and plan ensuring completion and reporting of the analyses is required.

VIII. Exceptions

Applicant requests for exceptions to this policy will be submitted to the CDMRP Program Manager. The CDMRP Director must approve any exceptions. In cases where it may be inappropriate to require a project to conform to these guidelines, for reasons other than the health of the subjects, the purpose of the research, or costs, the Program Manager may recommend exclusion of the project. The CDMRP Director will consider the exclusion of such projects on a case-by-case basis.

IX. Roles and Responsibilities

This policy applies to all applications for CDMRP-supported clinical research. Certain individuals and groups have special roles and responsibilities with regard to its implementation.

- 1. Principal Investigators and Organizations:** The CDMRP requires that applications address this policy after assessing the theoretical and/or scientific linkages between sex/gender, race/ethnicity, and their topic of study. The CDMRP requires that applicants provide the required information on inclusion of women and minorities and their subpopulations in clinical research projects, and any required justifications for exceptions to the policy.

- 2. Organizational Institutional Review Boards:** It is the responsibility of the IRBs to address the ethical issues as described in Section IX (1) for Principal Investigators. As the IRBs implement the Common Rule, they must ensure the equitable selection of subjects.²
- 3. Peer Review Panels:** In addition to current CDMRP review practices, the CDMRP requires that peer reviewers evaluate:

 - The proposed plan for the inclusion of women and minorities for appropriate representation or the proposed justification when representation is limited or absent.
 - The proposed exclusion of women and minorities on the basis that a requirement for inclusion is inappropriate with respect to the health of the subject.
 - The proposed exclusion of women and minorities on the basis that a requirement for inclusion is inappropriate with respect to the purpose of the research.
 - Plans for the analysis of group differences on the basis of sex/gender, race, and/or ethnicity in applications proposing Phase III clinical trials.
- 4. Programmatic Panels:** As is currently done, the CDMRP requires that programmatic panels consider the technical merit of the application, to encompass inclusion of women and minorities and the justification relative to the objectives of the study, as evaluated by the peer reviewers, in making funding recommendations.
- 5. CDMRP Staff:** CDMRP staff shall provide PIs and organizational representatives with relevant resources, such as a written policy, frequently asked questions (FAQs), forms and guidance to submit with their applications and progress reports. CDMRP staff will monitor and track the inclusion of women and individuals from minority groups in funded clinical trials and clinical research projects.
- 6. CDMRP Director:** The CDMRP Director may approve, on a case-by-case basis, the exclusion of projects. In cases where it may be inappropriate to require a project to conform to these guidelines, for reasons other than subject health, research purpose, or cost, the Program Manager may recommend exclusion of the project.

² Section XX.111 (3) Criteria for IRB approval of research

X. Definitions

1. **Clinical Research.** This policy uses the NIH [definition](#) of clinical research:
 - a) 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, and (d) development of new technologies.
 - b) Epidemiologic and behavioral studies.
 - c) Outcomes research and health services research.

2. **Clinical Trial.** This policy uses the Common Rule [definition](#) of clinical trials and the NIH [definition](#) of Phase III clinical trials:
 - a) Clinical trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
 - b) Phase III clinical trial: Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

3. **Racial and Ethnic Categories.** In order to maintain, collect, and present data on race and ethnicity, [OMB directive No. 15](#) is used to define minimum standards. The standards have five categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for data on ethnicity: “Hispanic or Latino” and “Not Hispanic or Latino”. For additional information, see [Appendix 3](#).

XI. Additional Resources and References

Additional information and guidance is available from CDMRP and NIH, as follows. Where there are differences between CDMRP and NIH guidance, investigators should defer to CDMRP’s guidance.

1. CDMRP Frequently Asked Questions (FAQs)
2. [NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research](#)

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3. Suggested IER format ([PHS Inclusion Enrollment Report, OMB No. 0925-0001](#)) and additional [guidance for form completion](#)
4. [NIH Application Guide Instructions for Completing Plans on the Inclusion of Women, Minorities, and Children](#)
5. [Food and Drug Administration Guidance for IRBs and Clinical Investigators on the Evaluation of Gender Differences in Clinical Investigations](#)

XII. CDMRP Contacts for Questions or Additional Information

For questions or further information about this policy, please contact:

eBRAP Helpdesk

Email: Help@eBRAP.org

Phone: 301-682-5507

Mail:

ATTN: MCMR-CD

1077 Patchel Street

Fort Detrick, MD 21702

CDMRP Public Affairs

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Director

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Appendix 2. Guidance for Using the Suggested IER format

[Instructions for Completing PHS 398 Inclusion Enrollment Report](#) from the Office of Information and Regulatory Affairs (Reginfo.gov)

NOTE: These report formats should NOT be used for collecting data from study participants. To ensure proper performance, please save frequently.

See below for the form description and please refer to Part II (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan) for additional guidance on how and when to use the PHS 398 Inclusion Enrollment report form.

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PHS Inclusion Enrollment Report

OMB Number: 0925-0001 and 0925-0002

This report format should not be used for collecting data from study participants

*Study Title:

*Delayed onset study? Yes No

If study is not delayed onset, the following selections are required:

Enrollment Type Planned Cumulative (Actual)

Using an Existing Dataset or Resource Yes No

Participants Location Domestic Foreign

Clinical Trial Yes No NIH-Defined Phase III Clinical Trial? Yes No Trial Phase? -- Select Phase--

- Select Phase--
- Phase 0
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4

Comments:

Ethnic Categories										
Racial Categories	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian or Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

DELETE REPORT

NEXT REPORT

To ensure proper performance, please save frequently

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. The title should be the same as submitted on the original Planned Enrollment form for this study. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.

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Field Name	Instructions
Delayed onset study?	Select whether the study is considered delayed onset. This generally means that a study has not been developed and cannot be described in terms of human subjects' protections and inclusion. This does NOT apply to a study that can be described but will not start immediately. Additional guidance on whether a study meets the criteria to be considered delayed onset can be found in Section 2, Scenario D of the Part II (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan) . If the study is delayed onset, select YES. If the study is not delayed onset, select NO. This is a required field.
Enrollment Type	Select whether the table reflects Planned Enrollment of individuals to be recruited into the study or Cumulative (e.g., actual) Enrollment for 1) participants already recruited into the study or 2) studies using an existing dataset or resource. This is a required field.
Using an existing dataset or resource?	Select whether this study involves use of an existing dataset or resource. This generally means that investigators are utilizing data from a previous study or data bank. Do NOT answer Yes for individuals previously recruited specifically for this study. For additional guidance on what is considered an existing dataset refer to Part II, Section 4.2 (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan) and this FAQ . This is a required field.
Domestic/Foreign	Select whether the participants described in the inclusion enrollment report are based at a US or non-US site. At a minimum, participants at US and non-US sites must be reported separately even if for the same study. For additional guidance on what is considered an existing dataset refer to Part II (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan) and this FAQ . This is a required field.
Clinical Trial	Select whether the study these participants are involved in is considered a clinical trial. This is a required field.
Agency-Defined Phase III Clinical Trial	Select whether the study is an agency-defined Phase III clinical trial. This is a required field.
Clinical Trial Phase	If this study is considered a clinical trial , select what Phase is most appropriate. The choices are the same as those available in Clinicaltrials.gov . This is a required field.

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Field Name	Instructions
Comments	Enter information you wish to provide about this Cumulative Inclusion Enrollment Report. This includes but is not limited to information if distinctive subpopulations are relevant to the scientific hypotheses being studied. Maximum 500 characters.
American Indian/Alaska Native	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
Asian	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
Black or African American	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and of unknown/not reported

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Field Name	Instructions
	ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
White	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
More than One Race	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
Unknown or Not Reported	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino; all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino, and all racial categories for females, males, and individuals of unknown/not reported sex/gender who are of unknown/not reported ethnicity. The total fields at the right are auto-calculated to total all individuals in a given racial category.

Appendix 3.

Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

This classification provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal reporting purposes. The categories in this classification are social- political constructs and should not be interpreted as being scientific or anthropological in nature. They are not to be used as determinants of eligibility for participation in any Federal program. The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies.

The standards have five categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for data on ethnicity: "Hispanic or Latino," and "Not Hispanic or Latino."

1. Categories and Definitions

The minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting are defined as follows:

-- **American Indian or Alaska Native.** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation 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.

-- **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."

-- **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 be used in addition to "Hispanic or Latino."

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

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

Respondents shall be offered the option of selecting one or more racial designations. Recommended forms for the instruction accompanying the multiple response question are "Mark one or more" and "Select one or more."

2. Data Formats

The standards provide two formats that may be used for data on race and ethnicity. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. In situations where self-reporting is not practicable or feasible, the combined format may be used.

In no case shall the provisions of the standards be construed to limit the collection of data to the categories described above. The collection of greater detail is encouraged; however, any collection that uses more detail shall be organized in such a way that the additional categories can be aggregated into these minimum categories for data on race and ethnicity.

With respect to tabulation, the procedures used by Federal agencies shall result in the production of as much detailed information on race and ethnicity as possible. However, Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

a. Two-question format

To provide flexibility and ensure data quality, separate questions shall be used wherever feasible for reporting race and ethnicity. When race and ethnicity are collected separately, ethnicity shall be collected first. If race and ethnicity are collected separately, the minimum designations are:

Race:

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

Ethnicity:

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-- Hispanic or Latino

-- Not Hispanic or Latino

When data on race and ethnicity are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino.

When aggregate data are presented, data producers shall provide the number of respondents who marked (or selected) only one category, separately for each of the five racial categories. In addition to these numbers, data producers are strongly encouraged to provide the detailed distributions, including all possible combinations, of multiple responses to the race question. If data on multiple responses are collapsed, at a minimum the total number of respondents reporting "more than one race" shall be made available.

b. Combined format

The combined format may be used, if necessary, for observer-collected data on race and ethnicity. Both race (including multiple responses) and ethnicity shall be collected when appropriate and feasible, although the selection of one category in the combined format is acceptable. If a combined format is used, there are six minimum categories:

-- American Indian or Alaska Native

-- Asian

-- Black or African American

-- Hispanic or Latino

-- Native Hawaiian or Other Pacific Islander

-- White

When aggregate data are presented, data producers shall provide the number of respondents who marked (or selected) only one category, separately for each of the six categories. In addition to these numbers, data producers are strongly encouraged to provide the detailed distributions, including all possible combinations, of multiple responses. In cases where data on multiple responses are collapsed, the total number of respondents reporting "Hispanic or Latino and one or more races" and the total number of respondents reporting "more than one race" (regardless of ethnicity) shall be provided.

3. Use of the Standards for Record Keeping and Reporting

The minimum standard categories shall be used for reporting as follows:

a. Statistical reporting

These standards shall be used at a minimum for all federally sponsored statistical data collections that include data on race and/or ethnicity, except when the collection involves a sample of such size that the data on the smaller categories would be unreliable, or when the collection effort focuses on a specific racial or ethnic group. Any other variation will have to be specifically authorized by the Office of Management and Budget (OMB) through the information collection clearance process. In those cases where the data collection is not subject to the information collection clearance process, a direct request for a variance shall be made to OMB.

b. General program administrative and grant reporting

These standards shall be used for all Federal administrative reporting or record keeping requirements that include data on race and ethnicity. Agencies that cannot follow these standards must request a variance from OMB. Variances will be considered if the agency can demonstrate that it is not reasonable for the primary reporter to determine racial or ethnic background in terms of the specified categories, that determination of racial or ethnic background is not critical to the administration of the program in question, or that the specific program is directed to only one or a limited number of racial or ethnic groups.

c. Civil rights and other compliance reporting

These standards shall be used by all Federal agencies in either the separate or combined format for civil rights or other compliance reporting from the public and private sectors and all levels of government. Any variation requiring less detailed data or data which cannot be aggregated into the basic categories must be specifically approved by OMB for executive agencies. More detailed reporting which can be aggregated to the basic categories may be used at the agencies' discretion.

4. Presentation of Data on Race and Ethnicity

Displays of statistical, administrative, and compliance data on race and ethnicity shall use the categories listed above. The term "nonwhite" is not acceptable for use in the presentation of Federal Government data. It shall not be used in any publication or in the text of any report.

In cases where the standard categories are considered inappropriate for presentation of data on particular programs or for particular regional areas, the

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sponsoring agency may use:

- a. The designations "Black or African American and Other Races" or "All Other Races" as collective descriptions of minority races when the most summary distinction between the majority and minority races is appropriate;
- b. The designations "White," "Black or African American," and "All Other Races" when the distinction among the majority race, the principal minority race, and other races is appropriate; or
- c. The designation of a particular minority race or races, and the inclusion of "Whites" with "All Other Races" when such a collective description is appropriate.

In displaying detailed information that represents a combination of race and ethnicity, the description of the data being displayed shall clearly indicate that both bases of classification are being used. When the primary focus of a report is on two or more specific identifiable groups in the population, one or more of which is racial or ethnic, it is acceptable to display data for each of the particular groups separately and to describe data relating to the remainder of the population by an appropriate collective description.

5. Effective Date

The provisions of these standards are effective immediately for all **new** and **revised** record keeping or reporting requirements that include racial and/or ethnic information. All **existing** record keeping or reporting requirements shall be made consistent with these standards at the time they are submitted for extension, or not later than January 1, 2003.