Frequently Asked Questions for the Congressionally Directed Medical Research Program's (CDMRP) Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research[1]

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I. General CDMRP Directive Questions

A. What is the purpose of the CDMRP directive on the inclusion of women and minorities as participants in research?

In 2019, 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.

The overarching goal of this directive is to ensure the appropriate inclusion of women and minorities in all clinical research supported by CDMRP. CDMRP-supported clinical research should address/include all population(s) at risk for the disease or condition under study and ensure that examination of biological variables, including sex, race and ethnicity, are incorporated into the study design.

Full details on the directive are available on the eBRAP website under the Funding Opportunities & Forms tab, in the Resources and Reference Material section. There are additional requirements for studies meeting the definition for a Phase III clinical trial. These requirements are addressed under FAQ Section II.

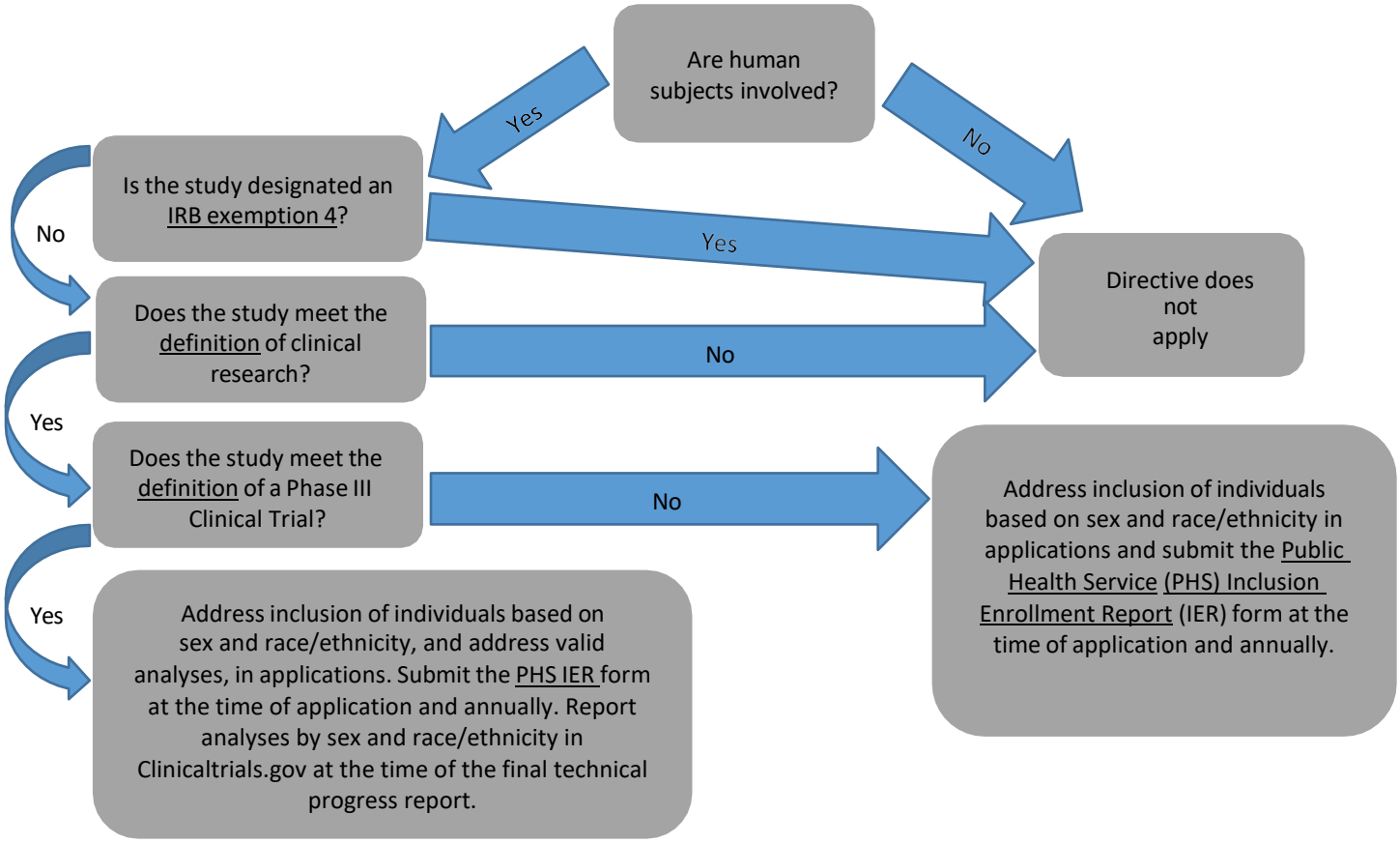
[1] Adapted with permission from the NIH Inclusion Policy Officer. Last updated March 2025.

B. Which studies are subject to the directive?

All projects funded by CDMRP that meet the CDMRP's definition for clinical research are subject to the CDMRP directive. This includes CDMRP-funded studies supported by grants, cooperative agreements, R&D contracts, and Other Transaction Agreements. Use the following decision tree to help determine whether a given study is subject to the directive.

Because of how human subjects research is defined, there may be studies using information from humans that is not considered human subjects research. Although these studies are not subject to the CDMRP directive, this does not mean that an understanding of the demographics (e.g., sex, race, ethnicity, age, etc.) is not important. CDMRP encourages applicants to address this information, as appropriate, for the scientific question(s) under study.

Decision Tree for Reporting of Inclusion Based on Sex and Race/Ethnicity



C. What is the definition of CDMRP clinical research?

CDMRP follows the same definition of clinical research that is used by the NIH, which is defined 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, and (d) development of new technologies;
(2) Epidemiologic and behavioral studies; and
(3) Outcomes research and health services research.
Note: Studies that meet the requirements for Institutional Review Board (IRB) review Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available. More information on Exemption 4 can be found here.

D. How is research that is Exempt from IRB (Institutional Review Board) review considered under the CDMRP directive?

Human subjects research that meets the criteria for IRB Exemption 4 is not considered "clinical research" as defined by CDMRP; therefore, the CDMRP directive on inclusion of women and minorities does not apply to research that is determined to meet the criteria for Exemption 4. Research meeting other IRB exemptions generally do meet the CDMRP/NIH definition for clinical research. Investigators can review the list of the 45 CFR 46.101 (b) exemption categories, including Exemption 4, here.

E. Does the CDMRP directive apply to studies involving human cadavers?

No. The Medical Research and Development Command Human Research Protection Office does not consider research use of human cadavers to be clinical research requiring enrollment reporting under Public Law 103-160.

F. Is cost an acceptable justification for not including certain groups in clinical research studies or trials?

No. The cost associated with ensuring that the clinical research study population composition is appropriate in regards to sex, racial, and/or ethnicity distribution is not an acceptable justification for excluding a particular group(s).

G. What is the "target population" for a given study?

The number of subjects in the trial or study that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question. Target population considerations must include distribution by sex, race, and ethnicity based on the prevalence of the disease or outcome of interest in the population and study characteristics.

H. When is someone considered a "participant" whose enrollment should be reported to CDMRP?

Any individual who is considered to be a human subject for a study as defined by 45 CFR 46 is considered a participant whose enrollment should be reported to CDMRP. An individual is considered to be a human subject once the individual is enrolled or entered into the study, including situations where data is collected about an individual through a proxy, such as the collection of data about infants from mothers. This definition includes all subjects who are eligible to contribute data to the scientific aims of the study, including individuals who subsequently dropout. Subjects who are screened for participation but are not eligible would not be considered as participants. This definition is limited to studies that fall under the CDMRP/NIH definition of clinical research.

I. Are clinical research subjects required to provide information about their sex, race, and ethnicity?

Whenever possible, collection of information on sex, race, and ethnicity should be self-reported by the individual research participant. The data collection instrument should include the option to not identify sex, race, and/or ethnicity, in which case, these participants would be reported to CDMRP as "unknown/not reported."

J. Which studies are required to conduct valid analyses by sex and race/ethnicity?

Valid analyses are required only for CDMRP/NIH-defined Phase III clinical trials.

A Phase III clinical trial is defined as a 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 standards or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

K. Can I design a clinical research study that limits inclusion to a specific sex, racial, and/or ethnic group?

When proposing any study meeting the CDMRP/NIH definition of clinical research you should address plans for inclusion in the context of the study population, considering such factors as who is at risk for the disease or condition under study. If you propose to limit your sample within a given study population, additional justification should be provided in the context of the scientific goals of the study and why this is an appropriate sample. Some factors that can be considered as part of the justification include the nature of the scientific question, a requirement for data provided by the cohort, or addressing a gap in knowledge. For example a clinical research study that limits inclusion to a specific sex would be a prostate cancer study that only has male subjects.

L. What do I do if my study sample is from a geographic area with a limited population?

When proposing any study meeting the CDMRP/NIH definition of clinical research you should address plans for inclusion in the context of the study population, considering such factors as who is at risk for the disease or condition under study. If you are in a geographic area with a limited population, additional justification should be provided in the context of the scientific goals of the study and why this is still an appropriate sample. Cost to recruit certain groups is not an acceptable justification for limiting the inclusion of those groups. If you are aware of similar research completed or underway employing populations complementary to those available proposed in your study, you can present this as a rationale for limited representation. Alternatively, if the appropriate sample cannot be achieved in your geographic area, you should also address the feasibility of making collaborative or other arrangements to include the appropriate populations in your sample, e.g., seeking collaborators in other geographic areas where there is access to the other populations.

II. Questions Regarding CDMRP/NIH-defined Phase III Clinical Trials

A. Are there additional requirements for CDMRP/NIH-defined Phase III clinical trials?

In addition to addressing inclusion for any CDMRP/NIH-defined clinical research study, investigators conducting CDMRP/NIH-defined Phase III clinical trials must also address requirements for valid analysis of sex, racial, and ethnic differences in their original application and, if awarded, in their annual/final technical progress reports.

Additional requirements include subgroup analyses reporting in Clinicaltrials.gov. Instructions regarding Clinicaltrials.gov registration and reporting can be found here.

B. At what stage of study development should investigators consider sex, race, and ethnicity for a CDMRP/NIH-defined Phase III clinical trial and develop plans for valid analyses?

Applicants are expected to consider the potential for clinically important differences in sex, race, and ethnicity when planning a CDMRP/NIH-defined Phase III clinical trial and address plans for conducting valid analyses in the original application. Applicants are expected to review existing evidence of significant difference in intervention effect by sex and race/ethnicity prior to submitting an application. Following a review of existing evidence, applications should resonate with one of the three situations below:

1. Prior Studies Support the Existence of Significant Differences

If the data from prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on sex, racial/ethnic, and relevant subpopulation comparisons, the primary question(s) to be addressed by the proposed CDMRP/NIH- defined Phase III clinical trial and the design of that trial must

specifically accommodate these expected differences.

Example: If males and females are thought to respond differently to intervention X, then the CDMRP/NIH-defined Phase III clinical trial must be designed to answer two separate primary questions, one for the effect of intervention X on males and the other for the effect of intervention X on females, with adequate sample size for each question.

2. Prior Studies Support No Significant Differences

If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect based on sex, race, ethnicity, and/or relevant subpopulation comparisons, then analyses by sex, race, and/or ethnicity are not required. However, the inclusion and analysis of sex and/or racial/ethnic subgroups is still strongly encouraged.

Example: If evidence from prior studies demonstrates, to the satisfaction of the scientific community, that there are no differences in the effect of intervention Y among racial and ethnic groups, then analysis of the trial's primary question by race and ethnicity is encouraged, but not required.

3. Prior Studies Neither Support nor Negate Significant Differences

If the data from prior studies neither strongly support nor strongly negate the existence of significant differences of clinical or public health importance in intervention effect based on sex, racial/ethnic, and relevant subpopulation comparisons, then the CDMRP/NIH-defined Phase III clinical trial will be required to include sufficient and appropriate entry of participants by sex, race, and/or ethnicity, so that valid analysis of the intervention effects can be performed. However, the trial will not be required to provide high statistical power for these comparisons.

Example: If insufficient evidence exists to determine if males and females respond differently to intervention Z, then the study must be designed in a way to provide the results of the effect of intervention Z separately for males and females. The study is encouraged, but not required, to ensure an adequate sample size to provide high statistical power.

C. How should valid analysis be conducted?

To conduct a valid analysis, many investigators present primary outcomes stratified by sex and race/ethnicity. CDMRP recognizes that many studies will not have sufficient statistical power to definitively answer whether there are clinically significant differences in how well the intervention works among sex and racial/ethnic groups. However, even when these analyses are not powered, they may still have value in informing future studies. For example, the data may be used in meta-analysis of related clinical trials that further explore potential differences in responses to specific treatments by sex and race/ethnicity. CDMRP

expects that investigators will consider how data from valid analyses may inform future studies when designing their study, including its use in subsequent meta-analysis.

D. What constitutes "prior evidence" of differences in outcome by sex or race/ethnicity?

Prior evidence may come from a variety of sources, including but not limited to: data from basic research and earlier phase studies, clinical observations, metabolic studies, genetic studies, pharmacology studies or observational, natural history and epidemiology studies.

III. Questions on Inclusion Information When Submitting CDMRP Applications/Proposals

A. What inclusion-related information do I need to submit in my competing application/proposal if conducting CDMRP/NIH-defined clinical research?

When submitting a new application/proposal to CDMRP that includes CDMRP/NIH-defined clinical research studies, investigators should address plans for inclusion on the basis of sex, race, and ethnicity as well as provide planned inclusion enrollment numbers using the Public Health Service (PHS) Inclusion Enrollment Report (IER), OMB No. 0925-0770, available here. At a minimum, the plan for inclusion should describe the proposed sample distributions by sex, race, and ethnicity. Applicants should justify the proposed sample in the context of the scientific goals of the proposed study.

B. How do I address inclusion if I do not have definite plans to conduct human subjects research, such as in the case of delayed onset studies?

The Federal Protection of Human Subjects regulations, 45 CFR 46, recognize that certain research applications may be submitted to a sponsoring agency with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement cannot be described in the application (45 CRF 46.118). Applicants should refer to the specific funding opportunity announcement to which they are applying for additional details.

IV. Working with Existing Datasets and/or Resources

A. Does the directive apply to research using existing datasets or other types of existing resources involving human subjects?

If the study is considered human subjects' research and meets the CDMRP/NIH definition of clinical research, then it is subject to the CDMRP directive. Please note this directive applies to awards made on or after 1 October 2020.

B. For the purposes of the CDMRP directive, what is an existing dataset/resource?

An existing dataset may consist of different types of data including but not limited to survey

data, demographic information, health information, genomic information, etc. Also included would be data (to be) derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the CDMRP/NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

C. Is it acceptable to use existing datasets or resources that are limited to specific sex, racial, and/or ethnic groups?

Yes. You can propose a study or analyses of an existing dataset where the cohort is limited in sex, racial, and/or ethnic participation. However, you should justify why this dataset is useful in the proposed scientific context, particularly if the dataset does not reflect the population of the disease or condition under study. Some factors that can be considered as part of the justification include the nature of the scientific question, a requirement for data provided by the cohort, or addressing a gap in knowledge.

D. If I am using an existing dataset or resource, how do I use the PHS Inclusion Enrollment Report (IER) in my application/proposal?

If you are conducting research with an existing cohort or dataset, you would respond "yes" to the existing dataset question using the PHS IER form, which can be found here, and complete only the Cumulative (Actual) Inclusion Enrollment table (page 3 of the PDF).

E. If I am working with an existing dataset or resource, do I provide the sex, race, and ethnicity information for the entire dataset?

You should provide the sex, race, and ethnicity information for the data points you will use from the existing dataset or resource. You would provide information for the entire dataset or resource if you were analyzing data from all individuals in that dataset or resource. If your project is limited to analyzing data from only a subset of subjects in the existing dataset or resource, then you would complete the IER form using data only from the subset of subjects included in your analysis. For example, if you want to analyze data from 2000 individuals in a large population-based survey that includes 10 million individuals, you would provide the sex, race, and ethnicity information for the 2000 individuals you plan to analyze. If you were analyzing information about all 10 million participants, you would provide the sex, race, and ethnicity information for all 10 million.

F. What do I do if my proposed study involves both an existing dataset/resource AND recruitment of new participants?

If you are proposing a study that will include both an existing dataset and recruitment of new participants, you should provide separate IER forms for the existing dataset and the

participants to be prospectively recruited.

G. What do I do if my proposed study involves multiple, different existing datasets or resources? How do I address inclusion and use the PHS Inclusion Enrollment Report (IER)?

If you are proposing a study that will include multiple existing datasets/resources, you may submit the datasets/resources on separate IER forms or consolidate onto one IER. For existing datasets/resources, complete the Cumulative (Actual) Enrollment table within the IER. The decision to use multiple IERs or one consolidated IER should be considered in the context of the scientific goals of the study and whether there is value in providing separate forms to illustrate the breakdown of sex, race, and ethnicity information for each dataset/resource. Also, please be sure to check the funding opportunity announcement to which you are applying in case there is additional guidance on this issue. Post- award, please check with your CDMRP Science Officer to determine the best approach for submitting the annual/final IER.

V. Monitoring Inclusion in Multi-site Studies

A. In studies or trials involving multiple sites, is each study site required to address inclusion separately?

Possibly. When multi-site clinical research studies (or trials) are proposed, the appropriate distribution by sex, race, and ethnicity should consider the recruitment across the different sites. Principal Investigators (PIs) should work with the CDMRP Science Officer to determine whether it is most useful to provide inclusion data individually by site or by overall study.

VI. Monitoring Inclusion When Working with non-U.S. Participants

A. Does the CDMRP directive apply to studies conducted outside of the US that are supported by CDMRP?

Yes, the CDMRP directive applies to CDMRP-funded studies conducted outside of the United States.

B. Since I'm working with non-US participants, how do I collect and report information on sex, race, and ethnicity?

When feasible, self-report of sex, race, and ethnicity is the preferred method. However, working with non-US participants can present a unique challenge to the collection and reporting of racial and ethnic information. The racial and ethnic standards used for reporting to CDMRP are set by the Office of Management and Budget (OMB) and are defined for the US population. It is not expected that investigators would use the OMB categories for race and ethnicity in data collection instruments designed for use in other countries. Investigators

should design culturally appropriate data collection instruments that allow a participant to self-identify with their racial and ethnic affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use the OMB-defined categories for reporting sex, race, and ethnicity to CDMRP. Since the OMB categories reference world-based geographic origin, this should facilitate the "translation" of the information for reporting purposes to CDMRP. More information on the OMB categories and their definitions can be found in section VIII and are defined in the CDMRP directive.

C. What if I'm conducting a study with sites within the US and outside the US?

It is important for reporting purposes to CDMRP that US and non-US participants be distinguishable. At a minimum, investigators must provide separate planned and cumulative inclusion enrollment reports for US and non-US participants even if part of the same study. Further breakout of enrollment reports by site, country, etc. is permissible.

VII. How Inclusion is Considered in the CDMRP Peer and Programmatic Review Processes for Applicants

A. How is inclusion by sex, race, and ethnicity in clinical research considered in peer and programmatic review?

Peer reviewers will be asked to evaluate the plans for the inclusion by sex, race, and ethnicity in the application. When making funding recommendations, programmatic reviewers will 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. Applicants should review the specific language in the General Application Instructions (GAI) and funding opportunity announcement to which they are submitting for additional guidance.

B. Does the peer review consider additional factors about sex, race, and ethnicity when the application includes a CDMRP/NIH-defined Phase III clinical trial(s)?

Yes. In addition to reviewing plans for inclusion by sex, race, and ethnicity when a CDMRP/NIH-defined Phase III clinical trial is proposed, the reviewers will evaluate the study design and plans addressing valid analysis.

C. What happens if, during peer review, my plan for inclusion is unfavorably reviewed?

Criterion weaknesses identified during peer review will be outlined in the summary statement. If concerns regarding an applicant's plan for inclusion arise during peer review and the application is recommended for funding, the applicant will need to work with the Grant Officer/Grant Specialist at the US Army Medical Research Acquisition Activity (USAMRAA) and the Science Officer at CDMRP during award negotiations to ensure the concerns are addressed prior to award. If the application is not recommended for funding,

the applicant should carefully consider the summary statement concerns in subsequent submissions.

VIII. How to Collect and Report Sex, Race, and Ethnicity in Awarded CDMRP Projects

1. Overview of Racial and Ethnic Standards

A. Who determined the race and ethnicity standards for the categories used in reporting participants?

The racial and ethnic standards are set by the Office of Management and Budget (OMB). The racial and ethnic categories are defined in terms of geographic origins.

B. Where are the race and ethnicity standards and categories described?

The OMB categories and their definitions were updated in 2024 and are available at https://spd15revision.gov/content/spd15revision/en/2024-spd15/categories-definitions.html.[1]

2. Collection of Sex, Race, and Ethnicity Information from Research Participants

A. Who decides a participant's sex, race, and ethnicity?

Typically, the research participant should be provided the opportunity to self-select and report the sex, racial, and ethnic categories with which they identify. Also, data collection must allow for participants to not provide these data, in which case they will be reported to CDMRP as "unknown/not reported."

There may be situations where self-report of race and ethnicity is not feasible because the participant is incapable of providing the information. In these situations, investigators should determine what is the most reasonable approach, such as obtaining the information from other sources (e.g., medical records, family members, etc.), or whether it is more appropriate to indicate "unknown/not reported."

B. How is racial and ethnic information collected from a research participant?

Investigators should design demographic data collection approaches that allow individuals to self-select their race and ethnicity. As discussed above, individuals have the right not to select any category(s), in which case they will be reported to CDMRP as "unknown/not reported."

[1] Note that the current version of the PHS IER form reflects the 1997 OMB standards. An updated PHS IER form is anticipated in the future, reflecting these new categories. The guidance provided below pertains to the current PHS IER form and will be updated when a new PHS IER form is approved.

C. How should race and ethnicity data be collected for individuals who identify with more than one race?

In structuring an appropriate demographic data collection, participants should be offered the choice to select as many racial categories as they deem appropriate. When the investigator reports to CDMRP, these individuals will be aggregated under the "more than one race" category.

D. What if my study involves analyzing an existing dataset in which the race and ethnicity categories do not comply with the 2024 OMB standards?

If an investigator is using previously collected data sets that do not conform to the current (2024) OMB standards and does not plan to collect any new/additional data from the subjects, this should be noted in the inclusion section of the application and/or in the comments section of the Planned Enrollment Report. When preparing to report on cumulative (actual) enrollment to CDMRP, investigators should report the information they have and use the unknown/not reported category, when necessary. Investigators should not assume an individual's racial or ethnic category. For new data collections, investigators will need to use the OMB-defined categories for reporting sex, race, and ethnicity to CDMRP.

E. Can the PHS IER form be used to collect data from research participants?

The PHS IER form should NOT be used to collect data from research participants. This form is only to be used by the PI to report the enrollment of individuals by sex, race, and ethnicity for a given study(s).

Investigators should develop an instrument for collecting this information that is appropriate for the research setting and that meets the scientific needs of the study. Also, investigators should think carefully about the way the information is asked of participants to ensure they obtain the information needed for their study and for reporting on the forms. Investigators may want to frame the demographic questions differently depending on the scientific goals of the study and what information is needed for that purpose.

F. Can more detailed questions than indicated by the OMB guidelines be asked about ethnicity and race?

The scientific question being addressed in the study should guide investigators' decisions regarding collection of any additional information on ethnicity or race. Researchers are encouraged to consider collecting additional information on race and ethnicity that will provide insights into the relationships between race and ethnicity and health. The 2024 OMB guidelines provide minimum standards for data collection and should be used when reporting race and ethnicity to CDMRP.

3. How to Report Sex, Race, and Ethnicity Information to CDMRP

A. When is information on sex, race, and ethnicity reported to CDMRP?

In general, when conducting CDMRP-funded clinical research, investigators are expected to provide information on sex, race and ethnicity in all technical progress reports (annual, final or other). More details on the directive are available on the eBRAP website under the Funding Opportunities & Forms tab, in the Resources and Reference Material section.

When submitting a new application to CDMRP, investigators should address plans for inclusion on the basis of sex, race, and ethnicity in their research studies and create an IER form as described in the funding opportunity announcement.

B. What form is used to report sex, race, and ethnicity?

The PHS Inclusion Enrollment Report, OMB No. 0925-0770 is a fillable PDF document that must be used for completing information on sex, race, and ethnicity. The form can be found on the eBRAP website under Funding Opportunities and Forms.

C. How should race and ethnicity data be reported for research participants who identify with more than one race?

In structuring an appropriate demographic data collection, participants should be offered the choice to select more than one racial category, as appropriate. When the investigator reports to CDMRP, individuals who selected multiple racial categories should be aggregated under the "more than one race" category.

D. What do I do if there are subjects who did not identify their sex, race, and/or ethnicity?

Participants always have the right to not identify with any category, in which case they will be reported to CDMRP as "unknown/not reported."

4. General Reporting Information

A. How do I provide inclusion enrollment updates to CDMRP for funded awards?

The fillable IER form can be found on the eBRAP website under Funding Opportunities and Forms. This version of the form should be used by all CDMRP applicants and funded investigators. The form must be uploaded as a functional PDF via eBRAP at the time of annual and final technical report submission.

B. Who is required to provide individual-level data?

PIs on all applicable awards made after 30 September 2020 are required to comply with the CDMRP directive.

IX. Inclusion - Award Closeout and Inclusion

A. How is inclusion handled during the award closeout process?

As outlined in the CDMRP directive, an updated IER form should be submitted at the time of the final technical progress report. For applicable Phase III clinical trials, results of analyses of sex and race/ethnicity will be reported in clinicaltrials.gov at the time of final report submission. For information about submitting results to Clinicaltrials.gov, see https://clinicaltrials.gov/ct2/manage-recs/how-report. If final analyses from an applicable Phase III clinical trial are not available at the time of the final technical report, a justification and plan for ensuring completion and reporting of the analyses will need to be submitted to USAMRAA and the CDMRP Science Officer.

B. Are there any inclusion requirements after award closeout?

Possibly, for applicable Phase III clinical trials. If final analyses of sex and race/ethnicity are not available at the time of the final technical report, they should be reported to clinicaltrials.gov after award closeout, in accordance with the plan agreed upon with USAMRAA.

X. Additional Information

A. Where do I go to get more information about the CDMRP Directive on Inclusion of Women and Minorities as Subjects in Clinical Research?

The complete CDMRP directive can be found here. For additional information post-award, reference your assistance agreement/contract for any specific terms and conditions related to this directive and reach out to the CDMRP Science Officer with any questions. During application submission, additional questions should be directed to the eBRAP Help Desk.

B. Where can I find information on the recruitment and retention of women and minorities in clinical research?

The NIH and NCI provide a number of resources regarding the recruitment and retention of women and racial and ethnic minorities, which may be useful:

NIH Outreach Toolkit- Provided by the NIH Office of Research on Women's Health (ORWH). This toolkit provides recruitment case studies and other important information regarding the recruitment and retention of women in research.

AccrualNet- This resource provided by the National Cancer Institute (NCI) includes literature, tools, and educational/training materials for recruiting and retaining clinical trial participants, including underserved populations and racial and ethnic minorities.

The National Institute on Aging (NIA) Health Professionals Information website- NIA's website provides materials to assist healthcare professionals in communicating with older

adults, including considerations for diverse populations. See also this featured research story. This link opens a new window or tab. on minority recruitment.

Points to Consider about Recruitment- Provided by the National Institute of Mental Health (NIMH), this resource outlines important considerations for the recruitment and retention of research participants, including women and racial and ethnic minorities.

C. Additional Resources

eBRAP Help Desk- Help@eBRAP.org, 301-682-5507

CDMRP Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research

Public Health Service Inclusion Enrollment Report (IER)

CDMRP Directive on Sex as a Biological Variable (SABV) in Research