

MIC-DROP Study: Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era
(PS22-004) Data Use Agreement Plan

This plan describes the anticipated use and release by CDC of the dataset(s) named below. All CDC data use plans are required to be in compliance with the CDC/ATSDR Policy on releasing and sharing data, available at: [CDC OD OCOO Strategic Business Initiatives Unit \(SBI\) - Policy on Public Health Research and Nonresearch Data Management and Access - All Documents \(sharepoint.com\)](#). This plan is modifiable and does not represent a legal contract between CDC and any other entity.

Dataset Name: MIC-DROP Study (PS22-004), Cooperative Agreement #U01PS005244 awarded to Emory University

Data in this dataset were collected by Emory University (Principal Investigator), University of Michigan, and San Diego State University supported by PS22-004, “Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era.” This Notice of Funding Opportunity (NOFO) was designed to collect quantitative and qualitative data from a cohort of sexually active gay, bisexual, and other men who have sex with men (MSM). This includes a quarterly survey of HIV prevention (e.g., PrEP) behavior over the 2-year study period (n=1275), with 3 waves of qualitative research (n=30 individual interviews each wave) and 3 waves of focus groups (n=30-50 MSM each wave) to further assess prevention challenges, needs, and messaging development and testing to enhance PrEP and other prevention product use.

Custodial Unit/Contact Information:

NCHHSTP/DHP/HRB: Gordon Mansergh, PhD, Project Officer (gcm2@cdc.gov)

Study/Program Description:

In this transformational era of HIV prevention products, public health researchers and practitioners need to understand the use of multiple primary prevention methods by MSM over time. This includes awareness, uptake, adherence, persistence, and maintenance of new methods, appropriate combinations of prevention methods (such as PrEP and condom use), and conditions that impact transitions among prevention products over time. Prevention messaging will continue to evolve as new prevention methods are promoted and MSM have increasingly more complex choices to make.

The purpose of this cooperative agreement study is multifold:

1. Enroll a 2-year cohort (n=1275) of HIV-negative MSM across the three sites (n=425 per site, in Atlanta, Detroit, and San Diego) with ~60% of sample taking PrEP and 40% not taking PrEP at baseline assessment. Quantitative assessments are conducted quarterly (total eight assessment waves) that address: awareness, knowledge, beliefs, and perceptions of various HIV/STD prevention products; substance using behavior; and development and testing of prevention messages. The sample includes ~30% Black/African American and ~30% Hispanic/Latino MSM. All study materials and assessments are offered in both English and Spanish language.

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2. HIV and STD testing are completed every six months starting at baseline for the full sample.
3. The study includes three qualitative assessments (n=30 in-depth interviews and n=30-50 MSM in focus groups each qualitative assessment). Assessments are staggered approximately every six months during the study period and address: PrEP use, PrEP adherence, condom use, and HIV sexual risk behaviors and substance using behavior; awareness, knowledge, beliefs, and perceptions of various HIV prevention products; testing of brief HIV prevention messages for prevention products.

Memoranda of Understanding (MOU) Pertaining to Datasets: Persons who request data are required to provide an approved copy of the Publication Guidelines Concept Proposal and signed copy of the Data Sharing Agreement before data will be transferred. The agreement must be signed by all individuals who will have access to the data or participate in preparing materials for publication before engaging in research activities with these data.

Data Source(s): All data collected and provided to CDC under MIC-DROP Study (PS22-004), Cooperative Agreement #U01PS005244.

Population Represented by Datasets: Sexually active gay, bisexual, and other men who have sex with men enrolled in Atlanta, Detroit, and San Diego.

Type of Data: Quarterly survey data, in-depth interview and focus group data, and HIV and STD test results every six months over the 2-year cohort study. All data shared with and by CDC will be stripped of participant names and contact information.

Process for Omitting Identifying Information: Prior to transferring data to CDC, the MIC-DROP (PS22-004) cooperative agreement awardee, Emory University, will electronically delete all directly identifiable information including study participant names and contact information (addresses, phone numbers, and email addresses), from all data. Therefore, data provided by CDC for public release will not contain participant names or contact information. All quotations used in publications from qualitative data where the research population contains 40 or fewer participants can only be identified using gender identity, age category (not specific age), and race/ethnicity (if more than one race is provided, use 'multi-race'). For example, quotes will follow this format:

"Lorem ipsum dolor sit amet, duo ei dicta theophrastus intellegebat. Est meliore liberavisse cu. An duo populo laboramus, eam iusto appareat no. Eum probatus evertitur in. Ad ius feugiat consetetur, eu liber maiorum mea. Nec an alia iriure."
Hispanic/Latina Transgender Woman, 18-24 years old.

Data Quality Protocol: The funding recipient, Emory University, will conduct data cleaning on all data sets prior to delivery to the CDC. This process will ensure that all direct identifiers are deleted from the

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data. All data will be coded with an identification number. The document that links participant name and identification number will be maintained by Emory University, using security measure described in the project protocol. The linking document will never be shared with CDC or other entities seeking to use project data through this agreement.

Data Retention/Disposal Plan: All data will be retained by the Emory University Research Team until analyses are complete and for up to 25 years following study closure, in line with Emory University IRB guidelines. Study closure date will be determined by 1) final reporting to the research sponsor; 2) final financial close-out of a sponsored research award; 3) final publication of research results; or 4) cessation of an academic or research project, regardless of whether its results are published. At that time, users must delete all data stored on their servers. The de-identified public access dataset will be hosted by CDC receives will be stored on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

Data Analysis Plan:

Applicants requesting access to specific datasets will submit a plan for analysis of the data. The data analysis plan will include a description of the topic(s), expectations or hypotheses that will be assessed based on analysis of the requested dataset, and a description of planned steps for analyzing and presenting the results of the planned data analysis.

Dataset Release Type*: (**BOLD all that apply**) 1) public-access 2) **restricted access** / *special-use data sharing agreement, 3) no public access

*Special-use data sharing agreement:

- Proposed activities involving the use of the data are reviewed and approved by CDC
- The special use dataset will be generated from a subset of the MIC-DROP public-access dataset hosted by CDC, with specific data elements to be determined with each individual request

Dataset Release Site: ___ CDC/NCHHSTP/DHAP/HRB _____

Dataset Release Timeline: The grantee, Emory University, will submit project data to CDC after the data have been cleaned of directly identifying information. CDC project staff, the awardee, and its project partners will collaboratively review all data and analyze data relative to dissemination topics agreed to by all project partners. It is anticipated that the restricted use dataset will be available approximately September 2029, after CDC, the awardee, and its partners have agreed that all key study analyses have been completed and cleared by CDC for publication.

Data Elements to be Released: The awardee will share with CDC all qualitative and quantitative data collected for this research project in addition to codebooks and data dictionaries. All data will be coded. All data will be stripped of directly identifying information. Data elements that may be shared

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via restricted access/special use data sharing agreement will include qualitative responses from client and provider participants and structured survey instruments and responses from client participants. All data will be stripped of directly identifying information.

Dataset Release Format: Focus group and in-depth interview data will be available in text format. Data from survey assessments will be provided in a SAS or SPSS format.

Data Release Outside of CDC: Data collected and stored by CDC will not contain names, contact information, or other identifiable information. Persons from outside of CDC who request data are required to provide an approved copy of the Publication Guidelines Concept Proposal and signed copy of the Data Sharing Agreement before data will be transferred. The agreement must be signed by all individuals who will have access to the data or participate in preparing materials for publication before engaging in research activities with these data. Persons requesting data will submit a plan for analysis of the data requested from CDC. The data analysis plan will include a description of the topic(s), expectations or hypotheses that will be assessed based on analysis of the requested dataset, and a description of planned steps for analyzing and presenting the results of the planned data analysis.

It is anticipated that the restricted use dataset will be available approximately September 2029, after CDC, the awardee, and its partners have agreed that all key study analyses have been completed and cleared by CDC for publication. The de-identified public access dataset will be hosted by CDC and will be stored on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

Last Revised: March 21, 2023

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Data Sharing Agreement for CDC PS22-004 (MIC-DROP Study) Datasets

This data sharing agreement ensures that CDC's guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity are adhered to. This agreement is subject to change. All changes will be retroactive, and applicants provided with a summary notice of changes made. A signed data sharing agreement is a contract between CDC and the signatory data users.

Dataset Contract Number and Name:

Applicants Who Will Have Access to Data:

List all persons (name, job title, research role, affiliation, email, phone) approved to have access to data and identify the principal person responsible for the analysis and maintenance/security of the data.

Period of Approval to Use Data: From [Date]:_____ To [Date]:_____

Restrictions on Use of Data:

I will not use these data except for qualitative and/or statistical analysis and reporting as described in the attached Publication Agreement product proposal.

Any effort to determine the identity of any individual, group or organization whose data appears in the dataset is prohibited. I will not link these data files with individually identifiable data from other data files.

Maintaining Confidentiality and Requirements if Individual Identity Discovered:

It is of utmost importance that the identity of data subjects cannot be disclosed. All direct identifiers, as well as characteristics that might lead to identification, are omitted from the dataset. If an individual identity is discovered, I will make no use of the identity and will immediately advise Dr. Gordon Mansergh (gcm2@cdc.gov), and no one else, of this discovery.

Requirement to Include CDC Disclaimer in Publications:

All written and oral presentations of results of analyses will include the following disclaimer: "The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the US Centers for Disease Control and Prevention."

Requirement / Request for Copies of Draft and Final Publications:

Copies of draft oral and written presentations will be submitted to the CDC program office at least 2 weeks prior to presentation or submission to a publisher so that CDC and program partners can be

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informed. CDC and partners may submit comments within this 2-week window. CDC reserves the right to refuse publication.

CDC will be notified upon final publication of a product and provided with a copy and citation information.

Penalties for Violating Agreement:

I understand that if I violate this agreement, penalties may apply in accordance with CDC policies and Federal law.

Compliance with this agreement will be monitored through pre-publication review of presentation products and/or verification of dataset destruction.

Signature of Data User:

Date: _____

All approved users must sign and date application

Signature of CIO/Division/Branch Oversight Official:

Date: _____

Signature of approving official