



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 8/17/23

Title: Medical Monitoring Project
Project Id: 0900f3eb821eb56a
Accession #: NCHHSTP-COT-8/4/23-d7f20
Project Contact: Linda Beer
Organization: NCHHSTP/DHP/BCSB/COT
Status: Pending Regulatory Clearance
Intended Use: Project Determination
Estimated Start Date: 06/01/2024
Estimated Completion Date: 05/31/2027
CDC/ATSDR HRPO/IRB Protocol #:
OMB Control #: OMB #0920-0740

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	8/17/23	Dodson_Janella R. (jhd7) CIO HSC
PRA: PRA Applies		8/17/23	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

Description & Funding

Description

Priority: Standard
Date Needed: 08/29/2023
Determination Start Date: 08/17/23

Description: This request is to add an active, ongoing non-research, surveillance system with a current Project Determination into STARS for the first time. The Medical Monitoring Project (MMP) is an annual surveillance system that conducts behavioral interviews and medical record abstraction with a representative sample of persons with diagnosed HIV (MMP; OMB # 0920-0740, exp. 5/31/2024). MMP has a two-stage sampling design in which, during the first stage, 16 states#including 6 separately funded jurisdictions within those states#and Puerto Rico were sampled from all U.S. states, the District of Columbia, and Puerto Rico. During the second stage, annual simple random samples of persons with diagnosed HIV aged 18 years and older are drawn for each participating state /territory from the National HIV Surveillance System. Data collection instruments are developed by CDC staff and data are collected by state and local health departments. Participants may complete the 40-minute interview by telephone or in person. MMP has previously received a Project Determination, but it has not been entered into STARS. This survey does not involve human subjects research because it is a surveillance activity. It will require OMB approval; an OMB PRA ICR has been submitted to the DHP PRA Coordinator for review.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No
IMS Activation Name: Not selected
Primary Priority of the Project: Not selected
Secondary Priority(s) of the Project: Not selected
Task Force Associated with the Response: Not selected
CIO Emergency Response Name: Not selected
Epi-Aid Name: Not selected
Lab-Aid Name: Not selected
Assessment of Chemical Exposure Name: Not selected

Goals/Purpose MMP's goals are to facilitate understanding of health-related behaviors, experiences, and needs of people with diagnosed HIV across the U.S. and in specific jurisdictions.

Objective: The objectives of the project are, among persons with diagnosed HIV, to 1) provide locally and nationally representative estimates of risk behaviors and clinical outcomes; 2) describe health-related behaviors; 3) determine accessibility and use of prevention, care, and support services; 4) increase knowledge of the care and treatment provided; and 5) examine variations of factors by respondent characteristics.

Does your project measure health disparities among populations/groups experiencing social, economic, Yes

geographic, and/or environmental disadvantages?:

Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?: Yes

Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?: No

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: Other - Adults with diagnosed HIV

Tags/Keywords: HIV ; Antiretroviral Therapy, Highly Active ; Healthcare Disparities ; Social Determinants of Health ; Men who have sex with men (MSM)

CDC's Role: Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided

Method Categories: Individual Interview (Quantitative); Record Review; Survey

Methods:

Detailed information on MMP's methods can be found in the attached Project Description. Since 2015, MMP's population of inference has been all adults with diagnosed HIV reported to the National HIV Surveillance System (NHSS), a census of U.S. persons with diagnosed HIV. MMP employs a 2-stage sample design that results in annual cross-sectional probability samples of adults with diagnosed HIV in the United States. During the first stage of sampling, geographic primary sampling units (PSUs) were selected using probability proportional to size (PPS) sampling based on AIDS prevalence at the end of 2002. Seventeen PSUs have comprised the first stage sample since 2009. During the second stage of sampling, participants are annually sampled directly from NHSS. Persons eligible for sampling are: adults (>18 years old) who meet the HIV case definition, have been reported to the NHSS and reside in one of the PSUs (which include 23 participating project areas: Puerto Rico, 16 sampled states, and 6 separately funded cities within the sampled states). MMP data are weighted based on probabilities of selection, adjusted for nonresponse using information on all sampled persons from NHSS (Appendix C), and post-stratified to NHSS population totals by age, sex, and race/ethnicity. The design allows for national and state or local estimates of characteristics and behaviors that will be generalizable to adults with diagnosed HIV in the U.S. and participating jurisdictions. Sampled patients will continue to be recruited to participate in either telephone or in-person interviews, and persons who have received medical care for HIV will have their medical records abstracted. Most often, MMP project area staff contact and recruit sampled persons, although in some cases HIV care facilities may assist in recruitment. Project area and facility staff will continue to use the same model recruitment letters and telephone, text, and email scripts as in previous cycles (see Appendices D1, D2, D3, and D4). Sampled persons may be interviewed wherever they currently reside, as long as they are confirmed to have been living in an MMP project area on the date of sampling. Sampled persons will be offered \$50 in cash or equivalent (such as a gift card) as a token of appreciation for participation. Informed consent will be obtained from all participants; the consent form can be found in Appendix H.

MMP's data collection continues to have two primary components: an interview and medical record abstraction. Data from interviews provide information on the current behaviors that may facilitate HIV transmission and conditions or circumstances that facilitate or impede receipt of HIV medical care and adherence to antiretroviral therapy; patients' seeking of, access to, and use of HIV-related prevention services; utilization of HIV-related medical services; and adherence to antiretroviral medication regimens (Appendix A). The interview averages 40-minutes in length and is completed over the telephone or in-person according to the sampled person's preference. Data from medical record abstraction provide information on insurance status, clinical conditions that result from HIV-infected persons' disease or the medications they take, as well as the HIV care and support services they receive

Collection of Info, Data or Biospecimen:

and the quality of these services (Appendix B). MMP interview and medical record abstraction data are collected via a web-based data collection tool called Voxco, which has undergone Security Assessment and Authorization (SA&A) by CDC and meets all Federal Information Systems Management Act (FISMA), OMB, HHS, and CDC IT Security requirements which ensure the confidentiality, integrity, and availability of data on federal information systems. Demographic and HIV-related laboratory information associated with sampled participants will continue to be extracted from CDC's existing HIV case surveillance database, NHSS. Data extracted from NHSS consist of very basic demographic and clinical data and are used to assess non-response bias (Appendix C). These datasets also contain the NHSS coded identifier. This link to NHSS data allows MMP and NHSS data to be combined at CDC for proper weighting of MMP data and other analytic purposes such as monitoring of ongoing care and treatment of MMP respondents through CD4+ T-lymphocyte counts and viral load test results reported prospectively to NHSS. MMP and interview and medical record data do not contain any personally identifiable information. Previously collected date of birth will continue to be extracted from NHSS. Date of birth has been found in certain cycles to be a predictor of non-response for MMP and is sometimes used to adjust for non-response bias.

Expected Use of Findings/Results and their impact:

With its national scope and unique design, MMP allows CDC to monitor national progress toward ensuring high quality care for all people with diagnosed HIV. Specifically, at the national level, MMP data are used for tracking national trends in HIV-related morbidity and service access and utilization, for focusing and prioritizing national initiatives to improve the provision of treatment and prevention resources, and for benchmarking and evaluating progress toward national prevention and treatment initiatives. CDC is responsible for issuing policies and recommendations for HIV-related medical and prevention services, and MMP provides an evidence base for these activities, as well as a means to monitor the uptake and impact of the guidelines. At the local health jurisdiction level, MMP data are used for HIV prevention program planning purposes, including the development of local epidemiologic profiles and responding to data requests from the Health Resources and Services Administration (HRSA) and other agencies that manage resources for HIV prevention, care, and treatment. MMP provides information to evaluate local care and prevention services for persons receiving HIV medical care. This information is used to improve local care and prevention services for people with diagnosed HIV in these jurisdictions. Many of the results from MMP are useful at the local level; other results are more meaningful after the data from all project areas have been aggregated. Each project area has responsibility for the release of local estimates. CDC has primary responsibility for aggregated estimates from the project areas and disseminates this information. These data are distributed to the providers, researchers, policymakers, and other interested persons through presentations at local, national, and international conferences, publications in peer-reviewed journals, and presentations at forums such as continuing medical education courses and seminars. Furthermore, CDC regularly publishes surveillance reports based on the data collected annually.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Medical Monitoring Project (MMP)	CDC-RFA-PS20-2005	2020	5	705000.00

HSC Review

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB? No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated No Selection

Comprehension tool is provided No Selection

Short form is provided No Selection

Translation planned or performed No Selection

Certified translation / translator No Selection

Translation and back-translation to/from target language(s) No Selection

Other method No Selection

Clinical Trial

Involves human participants No Selection

Assigned to an intervention No Selection

Evaluate the effect of the intervention No Selection

Evaluation of a health related biomedical or behavioral outcome No Selection

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Institutions yet to be added

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Angela Blackwell	11/30 /2025				Project Officer	ifa1@cdc.gov	404-498-4354	CLINICAL OUTCOMES TEAM
Catherine Espinosa	07/10 /2026	08/14/2023	08/16/2026		Project Officer	xwn7@cdc.gov	573-864-3223	CLINICAL OUTCOMES TEAM
Jason Crow	07/25 /2026				Project Officer	emf4@cdc.gov	404-639-6395	CLINICAL OUTCOMES TEAM
JEN FENG LU	07/27 /2026				Statistician	ogj7@cdc.gov	410-259-8474	BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH
Jennifer Fagan	07/07 /2026		11/09/2025		Project Officer	chx5@cdc.gov	404-639-8396	CLINICAL OUTCOMES TEAM
Jennifer Taussig	07/14 /2026				Project Officer	jft0@cdc.gov	404-718-3323	CLINICAL OUTCOMES TEAM
John Weiser	08/08 /2026				Project Officer	eqn9@cdc.gov	404-639-8405	CLINICAL OUTCOMES TEAM
Linda Beer	07/28 /2026				Project Officer	gur0@cdc.gov	404-639-5268	CLINICAL OUTCOMES TEAM
Mabel Padilla	03/28 /2026		05/17/2025		Project Officer	ymj0@cdc.gov	404-639-8013	CLINICAL OUTCOMES TEAM
Mohua Basu	06/04		06/08/2025		Project	rax6@cdc.gov	404-718-	CLINICAL OUTCOMES TEAM

Yunfeng (Tracy) Tie	06/27 /2026				Project Officer	hzu3@cdc. gov	404- 718- 5781	CLINICAL OUTCOMES TEAM
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Data

DMP

Proposed Data Collection Start Date: 6/1/24

Proposed Data Collection End Date: 5/31/27

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Surveillance data collected under an Assurance of Confidentiality

Public Access Justification: N/A

How Access Will Be Provided for Data: Data will be available upon request from CDC and contingent on meeting the requirements of the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.

Plans for Archival and Long Term Preservation:

All MMP data are received for processing by ICF's Data Coordinating Center (DCC), a contractor who performs data management activities and weighting for MMP. Interview and medical record abstraction data for MMP are collected via the Voxco platform, which sits behind CDC's Secure Access Management System (SAMS). CDC, DCC, and MMP health department staff are granted access to specific MMP activities within SAMS based on their role in the project. DCC fully complies with all federal IT security standards, and MMP has an Authorization to Operate (ATO) which authorizes DCC operation until 7/1/2024. Physical site visits to the contractor's facility are conducted annually by MMP staff and the Contracting Officer's Representative for the DCC contact. Data transmitted to CDC are sent monthly by DCC via their secure DCC Data Portal, which sits behind CDC SAMS. All data deliverables are double encrypted and require recipient-specific PGP keys to decrypt and download the data files. Once downloaded, all MMP data are saved to restricted access data drives with user access managed using CDC's Multi-User Share Tool (MUST). To access MMP datasets, a user must complete annual data security and confidentiality training, complete and sign all required paperwork, request access to the specific restricted data drives, and be granted access by the team's data steward. At least twice per year, the team's data steward reviews the complete list of all persons with access to MMP data drives and revokes access for any persons who have departed the team, whose time duration for access has expired, or those who have not completed annual data security and confidentiality training. CDC MMP data management staff are the only staff with the ability to create and modify final MMP datasets and accompanying documentation such as data dictionaries, labels, formats, and format statements. All other MMP staff have read-only access to final MMP datasets and documentation. Files that contain data from the National HIV Surveillance System (NHSS) are archived or destroyed within 12 months of the end of the data collection cycle. MMP staff document all NHSS data files that are archived or destroyed and share this information with the Division of HIV Prevention's HIV Surveillance Branch at least two times per year. All NHSS and MMP data files at DCC are purged from the Data Portal and from SAS servers within 24 months of the end of the data collection cycle. Data destruction documentation listing all purged data files is shared with MMP staff on an annual basis.

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Beer_Linda (gur0) Project Contact	08/07/2023	MMP project description	Protocol	Medical Monitoring Project Project Description .docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App G.1 Adverse Events and Protocol Breach Guidance	Other-Adverse Events and Protocol Breach Guidance	App G.1 Adverse Events and Protocol Breach Guidance.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App B MMP MRA Data Structure 2024	Other-MRA Data Structure	App B MMP MRA Data Structure 2024.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App H MMP Model Consent	Other-MMP Model Consent	App H MMP Model Consent.doc
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App A MMP 2024 Questionnaire	Data Collection Form	App A MMP 2024 Questionnaire.pdf
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App G.2 Model Adverse Events and Protocol Breach Report Form	Other-Model Adverse Events and Protocol Breach Report Form	App G.2 Model Adverse Events and Protocol Breach Report Form.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App D.1 MMP Model Recruitment Letter	Other-MMP Model Recruitment Letter	App D.1 MMP Model Recruitment Letter.docx
Current	Beer_Linda (gur0)	08/07/2023	App C MMP NHSS Dataset	Other-MMP NHSS Dataset	App C MMP NHSS Dataset Elements.docx

	Project Contact		Elements	Elements	
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App I Agreement To Abide by Restrictions	Other-Agreement To Abide by Restrictions	App I Agreement To Abide by Restrictions.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App D.3 MMP Recruitment Script Facility	Other-MMP Recruitment Script Facility	App D.3 MMP Recruitment Script Facility.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App D.2 MMP Recruitment Script Project Staff	Other-MMP Recruitment Script Project Staff	App D.2 MMP Recruitment Script Project Staff.doc
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App E MMP Cross-Jurisdictional Agreement	Other-MMP Cross-Jurisdictional Agreement	App E MMP Cross-Jurisdictional Agreement.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App D.4 MMP Recruitment Script Text E-mail	Other-MMP Recruitment Script Text E-mail	App D.4 MMP Recruitment Script Text E-mail.docx
Current	Beer_Linda (gur0) Project Contact	08/07/2023	App F Assurance of Confidentiality	Other-Assurance of Confidentiality	App F Assurance of Confidentiality.docx



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