Attachment 6 Data Use 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: http://www.cdc.gov/od/foia/policies/sharing.htm. This plan is modifiable and does not represent a legal contract between CDC and any other entity.

Dataset Name: Qualitative Inquiry Methods to Understand Issues in HIV Prevention, Care, and Treatment in the United States (iQual) collected under IDIQ Task Order contracts:

Atlas Research LLC, Contract #_200-2013-57339
Research Support Services Contract #_200-2013-57341

Custodial Unit/Contact Information: NCHHSTP/DHAP/PRB – James W. Carey, PhD (jfc9@cdc.gov)

Study / Program Description: Thirty years into the HIV/AIDS epidemic, many advances have been made in HIV prevention, care, and treatment. Great strides have been made in the development of faster and more efficient HIV testing and screening technologies, and in medical treatments that allow HIV-positive persons to live long and productive lives. Yet despite these efforts, approximately 50,000 Americans are infected with HIV each year, and the overwhelming majority of these new infections remain among minority and vulnerable communities, such as racial and ethnic minorities, men who have sex with men (MSM), transgender persons, and youth (aged 13-29). This health disparity in the HIV epidemic is anchored in long-standing social issues, such as racism, discrimination, stigma, poverty, incarceration, and healthcare inequity. In July, 2010, President Barack Obama unveiled the first National HIV/AIDS Strategy (NHAS) for the United States, a coordinated national response to reduce the burden of HIV in the U.S. by 2015. The strategy outlined 3 major goals: (1) reduce the number of people who become infected with HIV; (2) increase access to care and improve health outcomes for people living with HIV; and (3) reduce HIV-related health disparities. The strategy emphasizes focusing efforts in communities where HIV is highly concentrated, and by addressing HIV in these communities, lowering the collective HIV risk of all Americans. The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) provides leadership in helping to control the HIV epidemic. To continue these efforts and in alignment with NHAS, DHAP requires the support of an indefinite delivery, indefinite quantity (IDIQ) contract to (1) conduct qualitative inquiry methods (via individual problem-specific Task Orders awarded to eligible IDIQ contractors) to help answer timely questions related to HIV prevention, and (2) to use the findings to strengthen existing and future HIV prevention efforts.

Using in-depth qualitative methods to understand the issues related to HIV prevention, care, and treatment aligns with NHAS Goal 2 [Increasing Access to Care and Improving Health Outcomes for People Living with HIV] by collecting qualitative data to support the following recommended step: the establishment of a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV (Step 1), and support people living with HIV with co-occurring health

conditions and those who have challenges meeting their basic needs (Step 3). These activities are also consistent with NHAS Goal 3 [Reducing HIV-related Disparities and Health Inequities] and supports the following recommend steps: reduce HIV-related mortality in communities at high risk for HIV infection (Step 1), and adopt community-level approaches to reduce HIV infection in high-risk communities (Step 2). These efforts are expected to address a wide array of HIV-related needs among various populations throughout the United States, including but not limited to: men who have sex with men (MSM); injection and non-injection drug users; persons living with HIV/AIDS (PLWH); incarcerated populations or ex-prisoners; commercial sex workers; male and female heterosexual groups at high risk for HIV infection; transgendered persons; and clinicians and HIV providers that serve persons at greatest need for HIV prevention, care, and treatment services. See individual Task Order protocols for specific study details.

Memoranda of Understanding (MOU) Pertaining to Datasets: Persons who request iQual data are required to provide an approved copy of the iQual Publication Guidelines Concept Proposal and signed copy of the iQual 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 Task Order Contracts.

1. Contract #:200-2013-57339-0001. HIV providers (Providers Study).
2. Contract #:200-2013-57341-0001. MSM living with HIV (Insights Study).
3. Contract #:200-2013-57339-0002. Local Area Effectiveness Projects for MSM (LEAP1 Study).
4. Contract #:200-2013-57341-0002. HIV-negative MSM in South (Pulse Study).
5. Contract #:200-2013-57341-0003. Local Area Effectiveness Projects for MSM (LEAP2 Study).
6. Contract #:200-2013-57339-0003. Transgender women and providers (T-Qual Study).
7. Contract #:200-2013-57341-0004. The Data to Care public health strategy: successes, challenges, and lessons learned in identifying, linking, and reengaging persons diagnosed with HIV to medical care (D2C Study).
8. Contract #:200-2013-57341-0005. MSM who refuse or are unsuccessful using PrEP (PrEP Study).
9. Contract #:200-2013-57341-0006. HIV prevention and treatment services among young men of color who have sex with men, and young transgender persons of color, living in the Deep South (Deep South Study).
10. Contract #:200-2013-57341-0007. Syringe service programs' user experiences with HIV/HCV/HBV prevention, testing and linkage to care and treatment (SSP Study).
11. Contract #:200-2013-57341-0008. Qualitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta (2PM)
12. Contract#:200-2013-57341-0009. Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States (2ADoPT)

Population Represented by Datasets: (See Task Order protocols for complete eligibility requirements.) Populations will include, but are not limited to: MSM; Race/ethnic minorities; Youth; Transgender persons; HIV Providers; Healthcare Providers; Persons living with HIV; Persons who inject drugs; HIV program staff; Local, State, and Federal government officials.

Type of Data: Focus groups, in-depth interviews, observational data, document reviews, brief structured surveys, structured assessments. All data shared by CDC will be stripped of all personally identifying information.

Process for Omitting Identifying Information: Personally identifiable information (PII) including names, addresses, phone numbers, email addresses, will be electronically deleted by Atlas Research Inc., and Research Support Services Inc., before data are transferred to CDC. Therefore, data provided by CDC for release will not contain PII.

All quotations by participants used in publications from qualitative data where the research population contains 40 or fewer participants can only be identified using gender, transmission group, 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 consectetuer, eu liber maiorum mea. Nec an alia iriure." Hispanic/Latino MSM, 18-24 years old.*

Data Quality Protocol: Atlas Research Inc., and Research Support Services Inc., will conduct data cleaning on all data sets prior to delivery to the CDC. This process will ensure that all PII (including indirect identification data) are deleted from the data.

Data Retention/Disposal Plan: All data will be retained until analysis is complete and for up to two years after publication. At that time, users must delete all data stored on their servers. CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, Prevention Research Branch.

Data Analysis Plan: All qualitative data will be coded with computer-assisted qualitative data analysis software. Codebooks will be developed and assessed for inter- and intra-coder reliability. Quantitative data will be analyzed in SAS or SPSS software. Data will be analyzed for outcome publications per agreement with original contract research staff and CDC. No public- or special-use data requests will be approved while CDC directed dissemination efforts are ongoing.

Dataset Release Type*: (**BOLD *all that apply***) 1) public-use dataset, 2) **special-use data sharing agreement,** 3) restricted release, 4) no release

Dataset Release Site: __ CDC/NCHHSTP/DHAP/PRB _____

Dataset Release Timeline: Data will be made available for release after the data have been cleaned of all PII and delivered to CDC custodian (James W. Carey). CDC staff will review each dataset from each of the Task Order activities and analyze and publish primary research questions before the data are made available for public use or restricted use. It is anticipated that the complete dataset will be available approximately June 2020, after CDC has conducted the analyses and prepared papers and other products related to primary findings for publication.

Data Elements to be Released: Interview/focus group guides and qualitative responses. Structured survey instruments and responses.

Dataset Release Format: Focus group and in-depth interview data from individual Task Orders will be available in text format. Data from structured surveys or assessments will be provided in a SAS, SPSS, or excel file format.

Date This Form Filled / Last Revised: _____ April 18, 2019/last revised April 18, 2019_____

Data Sharing Agreement for CDC iQual 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:

_____

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 iQual 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. James Carey, 404-639-1903, 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 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 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 Users:

_____Date:_____

All approved users must sign and date application

Signature of CIO/Division/Branch Oversight Official:

_____

_____ Date:_____

Signature of approving official