Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" HHS Online Customer Surveys (OMB Control Number: 0990-0379)

TITLE OF INFORMATION COLLECTION: Evaluation of Harm Reduction Practices and Policies Aimed at Reducing Infectious Disease Risks and Substance Use Disorders in Rural Communities

PURPOSE:

In 2019, the U.S. Department of Health and Human Services (HHS) launched the Ending the HIV Epidemic: A Plan for America (EHE). The goal of this initiative was to reduce new HIV infections by scaling up evidence-based prevention and treatment strategies. Within EHE, seven states were identified as having a substantial rural burden of new HIV diagnoses[i]. Moreover, many rural communities continue to face a great burden of HIV, STIs, and viral hepatitis cases, in addition to SUDs.

Implementing broad public health practices that mitigate an individual's risk of incurring additional harm is a critical step, as many behaviors compound the risk of other negative outcomes. Harm reduction is an important tool in reducing the burden of HIV, STIs, and viral hepatitis, in addition to addressing SUDs[ii]. While initially described in relation to reducing infection risks among people who inject drugs (due to sharing needles), harm reduction principles are also applicable to prevention strategies around HIV acquisition, such as the use of pre-exposure prophylaxis (PrEP) for individuals. Although proven effective, harm reduction strategies are not widely used or accepted, particularly in rural areas of the United States. ORHO, in partnership with other HHS operating divisions, supports harm reduction efforts across the Nation by sharing and promoting evidence-based strategies to help mitigate infectious diseases and SUDs that can be replicated in underserved communities.

The purpose of this project is to evaluate the public health implications for implementing harm reduction prevention strategies to reduce incidence of HIV, sexually transmitted infections (STIs), and viral hepatitis, and decrease the prevalence of substance use disorders (SUDs) in rural communities.

DESCRIPTION OF RESPONDENTS:

Persons who inject drugs (PWID), people who have experienced an overdose or are at high risk of overdose in rural areas, and Providers who work in harm reduction, risk mitigation, HIV, STI services, mental health, SUD treatment to provide a holistic view of challenges and opportunities. All respondents will live within rural communities throughout the U.S.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[X] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[ ] Other:_____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Corstella Johnson

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [X] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

We recognize and appreciate the time, expertise, and contributions of all focus group participants. Participants are regarded as essential consultants in the research process, and each will be compensated as a token of appreciation for their valuable input and engagement. The consultant fee is $125. Various payment methods, such as checks, gift cards, and digital platforms like CashApp, are being considered to facilitate a convenient and secure transaction process tailored to meet the preferences and necessities of the participants.

We also acknowledge that certain participants may encounter unique circumstances, such as temporary housing challenges, that might affect their ability to receive the compensation seamlessly. Necessary adjustments and special arrangements will be implemented to accommodate these specific situations, ensuring that each participant has equitable access to their compensation in a timely and secure manner.

Additionally, dissemination of the consultant payments will be facilitated by MayaTech's senior administrative coordinator, who will have limited access to restricted participant information.

BURDEN HOURS

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden hour**
Focus Group Participants -Individual	50	1.5	75
Totals	**50**		**75**

FEDERAL COST: The estimated annual cost to the Federal government is $140,882.00

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

We (OASH/Office of Regional Health Operations) will engage local partner organizations within the 10 HHS Regions that serve the populations of interest to facilitate recruitment. MayaTech (contractor) will draft an invitation for focus group participants. The invitation will provide a brief overview of the purpose of the discussion, overview of the format, time commitment, consultant fee, and confidentiality practices that will be employed to ensure no identifying information will be used during or after the focus groups. Each focus group participant will serve as a consultant—receiving an appropriate fee to encourage participation and show gratitude for their contributions to the discussion.

Recruitment will take place until all five focus groups are completed, working to capture a diverse participant selection in terms of geographic location and socio-demographic characteristics to encompass a broad spectrum of experiences and viewpoints. We will create informed consent documents that will describe the risks and benefits of focus group participation and how confidentiality will be maintained, contact information, and required clauses describing human research protections. Partner organizations will share the informed consent document with the potential focus group participants during recruitment. If participants have concerns, MayaTech will serve as the point of contact.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [X] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [ ] Other, Explain
2. Will interviewers or facilitators be used? [X] Yes [ ] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

[i] Center for Disease Control and Prevention: Ending the HIV Epidemic Initiative (2021). Accessed on 12/6/2022; https://www.cdc.gov/endhiv/about.html.

[ii] Substance Abuse and Mental Health Services Administration: Harm Reduction (2022. Accessed on 12/6/2022; https://www.samhsa.gov/find-help/harm-reduction.