REQUEST FOR NCHHSTP PROJECT DETERMINATION & APPROVAL

NCHHSTP ADS/ADLS Office on behalf of CDC (New, Continuation, or Amendment)

This form should be used to request NCHHSTP/OD/ADS or ADLS office review and approval on behalf of CDC of a new, continued, or amended project for those projects for which NCHHSTP staff/employees, branches, divisions, and center/OD/ADS or ADLS office are responsible.

Any NCHHSTP activity that meets the definition of a project (see the following section) and represents one of the four project categories must be approved by the respective NCHHSTP branch and division and by the NCHHSTP/OD/ADS or ADLS office. Approval by the NCHHSTP ADS or ADLS office (nchstphs@cdc.gov) of these projects indicates approval by CDC. This review and approval process complies with obligations for adherence of projects to federal regulations, state laws, ethics guidelines, CDC policies, and publication requirements.

For research that involves identifiable human subjects in which CDC/NCHHSTP is engaged, use CDC Human Research Protection Office forms and submit them to CDC Human Research Protection Office through the NCHHSTP ADS human subjects email box after approval at the branch and division levels.

RELEVANT INFORMATION

What is a project?

A project is defined as a time-limited activity that is funded for a specific period of time, an activity with specified funds for a limited time, or as a limited time responsibility by specific CDC employees or staff, including projects that might be ongoing or continuous for an extended period. A project has defined objectives, tasks (e.g., essential public health services), dedicated resources, and is funded for a specified time. NCHHSTP reviews and approves projects for the four project categories listed on this form. Every project officer, project team and staff, NCHHSTP branch, and NCHHSTP division or office is responsible for submitting this form for each project and for obtaining NCHHSTP OD/ADS or ADLS approval on behalf of CDC before project initiation, continuation, or amendment. Such programs as surveillance are approved and funded as specific projects for certain periods.

What is research?

The federal regulations and CDC/OD/ADS office define ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, regardless if these activities are conducted or supported under a program that is not considered research for other purposes. For example, demonstration and service programs sometimes include research activities.

What is a human subject?

A ***human subject*** is a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual or
2. identifiable private information.

What is an intervention?

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

What is private information?

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is occurring and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information identifies individuals (i.e., the identity of the person is or might be readily ascertained by the investigator or associated with the information) for the information to constitute research involving human subjects.

What does being "engaged" mean?

An institution becomes "***engaged***" in human subjects research when its employees or agents intervene or interact with living individuals for research purposes, or obtains individually identifiable private information for research purposes. An institution is automatically considered to be engaged in human subjects research whenever it receives funding or resources (e.g., a direct award) to support such research. In such cases, the awardee institution has the ultimate responsibility for protecting human subjects under the award.

What is surveillance?

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs."

What is program evaluation?

Program evaluation is the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, or inform or guide decisions about future program development. Program evaluation should not be confused with *treatment efficacy*, which measures how well a treatment achieves its goals and that can be considered research.

Sources (links)

- http://intranet.cdc.gov/od/oads/osi/hrpo/
- http://www.hhs.gov/ohrp/index.html

PROJECT REQUEST

Project Stage

Choose one by selecting a checkbox:

- **New:** Fill out entire form, even if a protocol is attached (approval is for work by CDC/NCHHSTP employees).

Continuation: For projects expected to continue beyond NCHHSTP approved date; include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).

Amendment: Include brief description of changes and attach relevant documentation and a copy of approved project (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: Project Engage:Engaging Gay "Community" Activism for Syphilis Prevention

NCHHSTP Project Number:

Division: DSTDP

Project Location/Country(ies):

New Orleans, LA and Washington, DC USA

Telephone: (404) 639-4488

CDC Project Officer or CDC Co-Leads:

Karen Kroeger and Monique Carry

Project Dates:

Start 01/15/2017

End 12/30/2017

Laboratory Branch Submission:

If applicable, select the checkbox:

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

I. **Activity is not human subject research.** The primary intent of the project is public health practice or a disease control activity.

A. Epidemic or endemic disease control activity; collected data directly relate to disease control. If this project is an Epi-AID; provide the Epi-AID number and documentation of the request for assistance, per division policy. Epi-AID no.

B. Routine disease surveillance activity; data will be used for disease control program or policy purposes.

C. Program evaluation activity; data will be used primarily for that purpose.

D. Post-marketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or device.

E. Laboratory proficiency testing.

II. Activity is not human subjects research. The primary intent is public health program activities.

A. Public health program activity (e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction or support; development of patient registries; needs assessments; and demonstration projects to assess organizational needs, management, and human resource requirements for implementation).

B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).

III. Activity is research but does NOT involve identifiable human subjects.

A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (i.e., not individual persons.)

B. Activity is research involving data or specimens from deceased persons.

C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1–4) below are required:

1. No one has contact with human subjects in this project; **and**
2. Data or specimens are or were collected for another purpose; **and**
3. No extra data or specimens are or were collected for this project; **and**
4. Identifying information was (one of the following boxes must be checked)
    a. not obtained;
    b. removed before this submission, or before CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects; or
    c. protected through an agreement (i.e., CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. A copy of the agreement must be attached.)

- **IV. Activity is research involving human subjects, but CDC involvement does not constitute "engagement in human subject research."** Select only one option by checking the box: A indicates the project has current funding; B or C indicates no current funding is applicable.
    - **A.** This project is funded under a grant, cooperative agreement, or contract award mechanism. **ALL** of the following 3 elements are required:
        - 1. CDC staff will not intervene or interact with living individuals for research purposes.
        - 2. CDC staff will not obtain individually identifiable private information.
        - 3. Supported institution(s) must have a Federalwide Assurance (FWA), and the project must be reviewed and approved by a registered IRB or an institutional office linked to the supported institution's FWA.*

Supported institution of primary investigator or co-Investigators/entity name:*

National Network of Public Health Institutes/Michigan Public Health Institute

Supported institution/entity FWA Number:* FWA00000277
FWA expiration date:* 02/21/2019
Expiration date of IRB approval:* 01/29/2018
***Attach copy of IRB approval letter(s) supporting project review and approval.**

B. CDC staff provide technical support that does not involve possession or analysis of data or interaction with participants from whom data are being collected (no current CDC funding).

C. CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (no current CDC funding).

Project Description

Participating project staff must complete all 18 elements of this section.

This is a required description from CDC employees or staff for review and approval of a project plan or proposal (or for changes) for projects conducted by CDC or in which CDC is involved. All 18 elements are required to standardize the review and approval process across NCHHSTP, document that all 18 elements have been addressed, expedite review and approval by the NCHHSTP ADS or ADLS office, and minimize CDC/OD/ADS office audit requests for additional information. A protocol may be attached to this form, but it does not eliminate the requirement to complete all 18 elements.

PROJECT TITLE: Project Engage:Engaging Gay "Community" Activism for Syphilis Prevention

Instructions: Use the following boxes to complete the 18 items. Each box will expand as you type, and you are not limited in the length of your answers. Formatting features and symbols also may be used.

1. CDC Principal Investigator(s) or Project Directors and branch/division/office affiliations:

Karen Kroeger, PhD
Monique Carry, PhD
Community Assessment and Engagement Team
Social and Behavioral Research and Evaluation Branch
Division of STD Prevention

2. CDC Project Officer(s) and each person's role and responsibilities and affiliations:

Randall H. Nielson
Umbrella Cooperative Agreement CDC-RFA-OT13-1302
Partnership Support Unit (PSU), Office for State, Tribal, Local & Territorial Support (OSTLTS)
Centers for Disease Control and Prevention (CDC)
Office: 770-488-1602
Cell: 404-274-8204
Fax: 770-488-1600

3. Other CDC project members, branches, divisions, and other participating institutions, partners, and staff:

CDC:
Damian Denson, PhD
Prevention Research Branch
Division of HIV/AIDS Prevention

National Network of Public Health Institutes:
1100 Poydras St., Suite 950
New Orleans, LA 70163

Aaron Alford, PhD, Principal Investigator
Brittany Bickford, MPH, Project Manager

4. Institution(s) or other entity(ies) funding the project:

CDC via OSTLTS Umbrella Cooperative Agreement CDC-RFA-OT13-1302

5. Project goals:

To explore 1) how Black/African-American men who have sex with men (MSM) define and perceive concepts of "community," "gay community," and "black gay community;" 2) the relevance and importance of self-defined concepts of community for engaging Black/African-American MSM in actions/interventions to improve sexual health, and specifically STD prevention efforts; and 3) insights and lessons learned by Black/African-American MSM who have been engaged in activism or collective action to improve the sexual health of MSM.

6. Project objectives:

To inform the development of strategies to prevent and reduce syphilis transmission and promote sexual health among Black/African American MSM

7. Public health (program or research) needs to be addressed:

Syphilis rates have increased dramatically in the United States since 2000, with most of the increases among MSM. In 2015, over 90% of primary and secondary syphilis cases occurred among men, with 81.7% of cases among males reporting a male sex partner (CDC 2015). Syphilis increases the risk of HIV transmission and acquisition; in 2015, nearly half of MSM with syphilis were HIV-positive. According to sentinel surveillance data, 33% of MSM syphilis cases were among Black MSM, a disproportionate burden of disease (CDC 2015).
Untreated syphilis can lead to serious sequelae, including neurosyphilis, which has increased in recent years. Cases of ocular syphilis, which can lead to permanent blindness, have been reported among MSM in recent months (CDC 2016). The reasons for syphilis increases among MSM are not entirely clear; however, sex without condoms, sero-sorting among HIV positive men, and the perception among some men that syphilis is relatively benign and easily cured, are factors. The increased availability and use of PrEP (pre-exposure prophylaxis), which protects against HIV transmission but not STDs, further increases the need for STD programs to devise new and effective strategies for engaging MSM in STD prevention efforts. Among Black/African American MSM, social isolation compounded by racism, homophobia, high prevalence of HIV and STD in sexual networks, and lack of access to health may also increase vulnerability to syphilis and other STDs (Maulsby 2014).

Findings from the interviews will help inform community engagement and mobilization efforts, and will be used to refine and tailor current outreach and communication strategies for reaching Black/African-American MSM. The project will build capacity of STD programs by helping to identify key partnerships needed to promote more inclusive involvement of Black/African-American MSM in integrating STD prevention into a broader sexual health framework. Findings are also likely to be helpful to DSTDP and its state health department partners as they develop a framework for encouraging and supporting services that target gay, bisexual, and other Black/African-American MSM in local areas.The findings from this project will help ensure the relevance of prevention efforts, including but not limited to influencing dissemination strategies and identifying appropriate content.

8. Population(s) or groups to be included:

Black/African American MSM in New Orleans and Washington DC

9. Project methods:

We will conduct in-depth qualitative phone interviews. We will follow a qualitative research design that includes purposive sampling. This focus will allow for responsiveness to the specific research objectives. Qualitative methods will allow participants to share their perceptions and opinions in their own words. This approach allows for the investigation of potential reasons and the mechanisms, beyond simple associations.

10. Selection, inclusion, or sampling of participants (persons or entities):

Sampling Strategy: We plan to recruit approximately 40 black/African American MSM to discuss the notion of community and its relevance to sexual health activism. The sample will be stratified by city (New Orleans and Washington, DC), age (18+) and individual identification as engaged in sexual health activism. In each city, we will target recruiting five MSM aged 18-25, five MSM aged 26-40, five MSM over the age of 40, and five key informants who have been identified as black/African American MSM sexual health activists, loosely defined as participating in a collective action or advocacy for improving sexual health for black/African American MSM. The following table shows the participant pool (N=40) stratification:

Age	New Orleans	Washington DC
18-25	5	5
26-40	5	5
>40	5	5

In addition we will recruit 5 black/African American MSM currently engaged in sexual health activism from each city (10 total) for a total desired participant pool of 40.
Eligible participants will be:
- 18 years or older
- Male
- Non-Hispanic, black/African American
- Had oral or anal sex with a male in the past 12 months
- Lives in the metropolitan statistical areas of Washington, DC or New Orleans, LA

11. Incentives to be provided to participants:

NNPHI staff will provide all forty participants a $40 Amazon electronic gift card code as a token of appreciation for completing the phone interview. The gift card is redeemable by accessing the internet and submitting the code.

At the end of each interview, interviewees will be provided a code that will allow them to access the gift card. Obtaining an email address will not be necessary as the code will be sufficient to allow them access to the funds.

12. Plans for data collection and analysis:

NNPHI will work with local partner the Institute for Public Health Innovation, IPHI, in Washington, DC and hire an intern with evaluation experience as well as significant experience working with MSM to facilitate recruitment in New Orleans, LA. We anticipate recruiting potential participants through a variety of community venues in both jurisdictions, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/hand cards) recruitment techniques. Examples of community venues to be used for both active and passive recruitment of participants will include local bars, clubs, university/college groups, house/ballroom communities, faith-based centers, community organizations and social events where black/African American MSM are known to congregate as well as virtual internet-based venues such as social media and/or sexual networking websites or mobile apps, if necessary. As all interviews will be conducted over the phone; verbal informed consent will be obtained for all potential interview participants. Prior to beginning the in-depth interview, NNPHI staff will read the consent form script and document verbal consent by assigning the consent form with the given participant name (Appendix F) for study record. This consent will address in more detail the potential benefits and address the potential risks of participation, such as a breach of privacy. As part of the verbal consent process, the interviewer will ask each participant if they have a clear understanding of the study, its purpose, risks, benefits, and right to withdraw from the study without consequence. Interviewees will be asked to provide their verbal consent twice: before the recording has begun and after to ensure consent is documented on record.

Members of CDC and NNPHI project teams will lead the quantitative and qualitative analysis. Analysis will include descriptive characteristics of the study participants based on the quantitative data collected in the first part of the interview. Descriptive statistics will be computed from results of the demographic survey. Additional descriptive analyses will be performed as appropriate for the demographic data set.
Qualitative data will be imported into NVivo 10, a software program used to aid qualitative analysis. The software will facilitate analysis by organizing, classifying, and sorting data into categories and frequencies. The initial phase of qualitative analysis will involve transcript review to identify categories, emergent themes, and to develop codes. CDC and NNPHI will work together to build an electronic codebook during this process. Open coding of larger segments of text will then commence. Axial coding will include assessment of possible relationships between code groups. Descriptive subcodes and categories will be developed; codes may be restructured throughout the entire comparative analysis process until it is determined that saturation is attained. The codebook will be refined as needed during this process. Members of the coding team will continually re-review, reconcile, and revise any discrepancies to ensure inter-coder consistency. Additional themes that are discovered through the process will also be analyzed and included in the findings.

13. Confidentiality protections:

Data will be reported in ways that protect the privacy of participants and comply with CDC's Data Sharing Policy. Incoming participants will be assigned a participant ID. A file will be created that links the ID and identifying information. This linking file will be the only record kept that includes both PII and the participant ID. Like the transcripts, the file will be stored on an external drive kept in a locked office, in a locked filing cabinet. Transcripts will be transferred between NNPHI using CDC's External SharePoint site for partners, and stored on password protected laptops. All analytic data will be completely de-identified; no individual names will be used in any reports. In order to increase the level of privacy, demographic summary data will be reported separately from any quotes used. No PII will be delivered to CDC as part of this project. As needed, the NNPHI and CDC project teams will implement other needed measures to ensure privacy (e.g., removing any components from quotes or anecdotes in interview notes that may re-identify a participant). Further, we will inform participants that data will be de-identified, however that there is a potential risk of breach of privacy and that, given the nature of interview data, they may be re-identifiable. NNPHI will also inform participants that we cannot ensure privacy but that our team is committed to taking steps to protect their privacy to the best of our ability. NNPHI staff will destroy any identifiable data and all recordings at the end of the study.

14. Other ethics concerns (e.g., incentives, risks, privacy, or security):

Participants will be asked some questions that may be sensitive or uncomfortable and may trigger unpleasant feelings. Additionally, it is possible privacy may be breached during recruitment, although recruitment support staff will be instructed to do everything they can ensure privacy during the recruitment process such as not administering the screening tool in a public area.

The following steps will be taken to minimize the risk of breach of privacy during recruitment:
NNPHI Roster of Potential Key Informants: An electronic roster of potential key informants will be maintained by NNPHI staff. Names of potential key informants will be identified through research partners as well as via internet searches of relevant organizations and groups. The roster will include names and phone numbers of potential participants, but will not include a study name. The roster of potential key informants will not be linked to the interview data.

15. Projected time frame for the project:

01/15/2017-12/30/2017

16. Plans for publication and dissemination of the project findings:

Results will be disseminated via a final report from NNHPI to CDC. All disseminated data will be de-identified and stripped of personal identifying information. Research findings may also be disseminated to the public in the form of manuscripts, abstracts, and presentations used for submission for oral presentations at such conferences as the National STD Prevention Conference, National HIV Prevention Conference, the American Public Health Association Conference, and/or for peer-reviewed publications.

17. Appendices — including informed consent documents, scripts, data collection instruments, focus group guides, fact sheets, or brochures:

Application for IRB review by Michigan Public Health Institute Office of Research Integrity and Compliance with approved appendices
Approval letter from MPHI ORIC

18. References (to indicate need and rationale for project):

References
1. Arnold EA and Bailey MM. (2009). Constructing Home and Family: How the Ballroom Community supports African-American GLBTQ Youth in the Face of HIV/AIDS. Journal of Gay and Lesbian Social Services 21, 171-188.
2. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2015. Atlanta: U.S. Department of Health and Human Services; 2016.
3. Goltz, B. (2015). We're Not in Oz Anymore": Shifting Generational Perspectives and Tensions of Gay Community, Identity, and Future, Journal of Homosexuality, 61:11, 1503-1528.
4. Holt, M. (2011). Gay men and ambivalence about 'gay community': from gay community attachment to personal communities, Culture, Health & Sexuality: An International Journal for Research, Intervention and Care, 13:8, 857-871.
5. Maulsby C, Millett G, Lindsey K, Kelley R, Johnson K, Montoya D, Holtgrave D. (2014). HIV Among Black Men Who Have Sex with Men in the United States: A review of the literature. AIDS Behavior 18:10-25
6. Ross, M. (2014). Gay Community Involvement: Its Interrelationships and Associations with Internet Use and HIV Risk Behaviors in Swedish Men Who Have Sex with Men, Journal of Homosexuality, 61:2, 323-333.
7. Rowe M. (2008). Sex, love, friendship, belonging and place: Is there a role for 'Gay Community' in HIV prevention today? Culture, Health & Sexuality: An International Journal for Research, Intervention and Care, 10:4, 329-344.
8. Wilson P, Valera P, Martos A, Wittlin N, Munoz-Laboy M, Parker R. (2016). Contributions of Qualitative Research in Informing HIV/AIDS Interventions Targeting Black MSM in the United States. The Journal of Sex Research. 53:6, 642-654

PROJECT APPROVAL

Choose one of the following options (Division or Center/OD Project)

DIVISION PROJECT

NCHHSTP BRANCH AND DIVISION ADS REVIEW AND APPROVAL (Sign electronically by clicking next to the X and following the prompts)

X Matthew S. Hogben -S

Digitally signed by Matthew S. Hogben -S
DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1001688154, cn=Matthew S. Hogben -S
Date: 2017.02.08 11:44:01 -05'00'

Branch Chief or Branch Science Officer

X Frederick Bloom -S

Digitally signed by Frederick Bloom -S
DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000343387, cn=Frederick Bloom -S
Date: 2017.02.13 14:52:14 -05'00'

Division ADS, Acting ADS, or Deputy ADS

CENTER/OD PROJECT

NCHHSTP OD OFFICE REVIEWS AND APPROVALS (Sign electronically by clicking next to the X and following the prompts)

X

Office Associate Director or Designee

X

NCHHSTP ADS or Designee

NCHHSTP ADS/DEPUTY ADS OR ADLS REVIEW AND APPROVAL

Project Title: Project Engage:Engaging Gay "Community" Activism for Syphilis Prevention

Date received in NCHHSTP ADS or ADLS office:

Date received by NCHHSTP Deputy ADS or ADLS:

Select the checkbox for each applicable comment for Nos. 1–5 or select the checkbox for No. 6 if all of the comments apply. Additional applicable comments may be added to No. 7. If additional information is required before approval can be granted, select No. 8.

1. This project is approved by NCHHSTP/CDC and CDC (per CDC policies and federal regulations) for CDC staff participation.
2. Participating partners and sites must obtain project review and approval, according to their institutional policies and procedures and according to local, national, and international regulations and laws, including 45 CFR 46 regulations and state laws. CDC project officers must maintain a current copy of local sites' approvals in project records.
3. CDC investigators and project officers need to adhere to the highest ethics standards of conduct and to respect and protect the privacy, confidentiality, autonomy, data, welfare, and rights of participants and integrity of the project. All applicable country, state, and federal laws and regulations must be followed.
4. Informed consent or script is needed as required by laws and regulations. Information conveyed in an informed consent or script process needs to address all applicable required elements of informed consent. Consent of employees in related projects about their institutions needs to include a statement that their voluntary participation or withdrawal would not affect their employment status or opportunities.
5. OMB Paperwork Reduction Act determination by the NCHHSTP OMB/PRA Coordinator might be needed for this project.
6. **All** previous comments apply.
7. **Other applicable comments:** Type your comment in the box. The space will expand as you type.

None from Deputy ADS

8. **More information is required before approval is granted:** Explain what additional information is requested by typing in the box. The space will expand as you type.

None requested from Deputy ADS

Date Information was requested:

Date Information was received:

Approval must be granted by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science (ADS), Acting ADS, or Deputy ADS, or for laboratory-associated projects, by the Associate Director for Laboratory Science (ADLS) or Acting ADLS.

Project Title: Project Engage:Engaging Gay "Community" Activism for Syphilis Prevention

X 

NCHHSTP ADS, Acting ADS, or Deputy ADS

X

NCHHSTP ADLS or Designee

Or