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 copy of approved project (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers

NCHHSTP Project Number: Click to add your answer. The space will expand as you type.

Division: DHAP

Telephone: 404-639-8297

Project Location/Country(ies): Multiple US Cities

Project Dates:
Start 4/30/2016
End 4/30/2019

CDC Project Officer or CDC Co-Leads: Euna M. August, PhD, MPH, MCHES

Laboratory Branch Submission:
If applicable, select the checkbox: ☐

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

D: Change Category:

☒ 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:*

Click to add your answer. The space will expand as you type.

Supported institution/entity FWA Number:* Click to add your FWA number.
FWA expiration date:* Click to add FWA expiration date.
Expiration date of IRB approval:* Click to add IRB expiration date.
***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: FORMATIVE RESEARCH TO DEVELOP HIV SOCIAL MARKETING CAMPAIGNS FOR HEALTHCARE PROVIDERS

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:

Euna M. August, PhD, MPH, MCHES, Prevention Communication Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

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

Euna M. August, PhD, MPH, MCHES will be working as the Team Lead of the Research and Evaluation Team and will participate in all aspects of CDC's evaluation efforts; provide oversight and ensures proper data collection and adherence to reporting guidelines by partner organizations. Elana Morris, MPH and Tiffiany Aholou, PhD will serve as the lead CDC evaluators for various projects and will coordinate CDC's evaluation efforts and will be responsible for leading the project activities and daily management of the project.

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

Prevention Communications Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention - Elana Morris, MPH; Ichhya Pant, MPH

RTI International - Jen Uhrig, PhD and Jennie Harris, MPH

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

Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention, Prevention Communication Branch

5. Project goals:

To deepen our understanding of providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their practices generally as well with populations that have been largely overlooked (e.g., transgender individuals); and how to develop new or enrich existing provider materials to make them more informative, appealing, and usable.

6. Project objectives:

There are two main objectives of this study. One is to gather information on providers' exlore how HIV screening and testing is handled in their practices. Exploratory research will be conducted focusing on three areas: 1) prevention with postives and retention in care, 2) transgender health, and 3) HIV testing and prevention and PrEP. In these interviews, we plan to explore such topics as barriers and facilitators to screening for behavioral risk factors, their knowledge of HIV Testing Recommendations, their Transgender Experiences, how they communicate with Patients (Positive and Negative Patients) about Risk Reduction, Knowledge and experiences with PrEP, ART Adherence and Retention in Care, Patient resources and the role of Influencers and Decision-Makers in their practices. These data will inform the development and refinement of CDC's campaigns.

The second objective of the study is to gather information on providers' reactions to core messages, concepts, and materials comprising HIV Prevention Campaigns. The proposed study will conduct qualitative research with health care providers to 1) examine concept, message, and material comprehension, clarity, word choice, reactions, personal relevance, credibility, practicality, and motivational appeal and 2) gather information on provider practice details, information needs re: HIV/AIDS, use of electronic media, patient resources, continuing medical education (CME) / continuing education (CE), and communication with patients.

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

The data collected will help CDC ensure HIV messages, concepts, and materials are understood as intended, culturally relevant, and acceptable. In addition, the results of this study will enhance future CDC HIV social marketing campaigns geared at providers, specifically the campaign materials that will be developed and refined based on the results of this study.

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

Physicians, physician assistants, and nurses who work in primary care, internal medicine, and infectious disease clinics.

9. Project methods:

The evaluation contractor will conduct one hour interviews with health care providers to initially exlore how HIV screening and testing is handled in their practices and, subsequently, examine concept, message, and material comprehension, clarity, word choice, reactions, personal relevance, credibility, practicality, and motivational appeal.

In addition, prior to the start of the qualitative interview, the contractor will conduct quantitative research through a brief online web survey to collect data on provider practice details, information needs re: HIV/AIDS, use of electronic media, patient resources, continuing medical education (CME) / continuing education (CE), and communication with patients.

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

This study will employ non-probability purposeful sampling to recruit up to 600 health care providers over a three year period residing in high HIV prevalent cities across the United States.

11. Incentives to be provided to participants:

Healthcare providers will be offered a token of appreciation for their participation. An amount of $100 will be offered initially. If there are challenges to recruiting providers, we will offer up to $350 for their participation in a one-hour in-depth interview.

12. Plans for data collection and analysis:

Participants will be recruited by a recruitment firm in each of the targeted cities. The recruitment firm will identify, screen, and recruit potential participants using their proprietary recruitment list/database. A health care provider screening instrument will be used to determine eligibility (Attachment 1). Individuals who meet the screening criteria and agree to participate will be invited to attend a one hour interview. Before the in-depth interview begins, the contractor will inform providers about their rights as a participant and will direct them to the electronic informed consent form for their review and acknowledgement (Attachment 2). Once participants indicate their consent to participate, they will proceed directly to a brief (15 minute) web-based, quantitative survey (Attachment 3). After participants complete the web-based survey, the contractor will conduct the in-depth interview using a semi-structured discussion guide. A subset of interviews will be exploratory and focused the areas of 1) prevention with postives and retention in care, 2) transgender health and 3) HIV testing and prevention and PreP (see Attachments 4a-c for the three exploratory guides). Additional interviews will be conducted to test campaign messages, concepts, and materials using semi-structured interview guides (Attachments 5, 6 and 7). Individuals will participate in the study only once. Individuals will not be contacted after their participation in the interview has concluded. All interviews will be audio recorded, and available for listening/viewing via telephone or video streaming. The contractor staff will analyze the data thematically and summarize the results in topline reports.

13. Confidentiality protections:

Neither CDC nor the contractor will have identifiers of participants recruited by professional recruiting firms. We will only have first names. The findings from the interviews will be reported in summary form so that the participants cannot be identified.

Each interview will be audio-recorded. Some interviews may be videostreamed depending up on the resources at the interviewing facility. Individuals observing the video-streaming will require password protected access to the streaming site. The contractor will retain a digital copy of the audio/video files which will be kept on password protected laptop computers and a share drive to which only the contractor team members have access. All audio/video files will be destroyed three years after completion of the project.

Hard copies of any document will be destroyed at the end of the project.

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

N/A

15. Projected time frame for the project:

4/30/2016 – 4/30/2019 (dependent on OMB approval)

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

The contractor will analyze data collected and present a written report(s) of all findings to the CDC Project Officer. The findings may also be published in peer-reviewed journal articles and/or presented at scientific conferences.

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

See attached documents:
Attachment 1. Provider Screener
Attachment 2. Informed Consent Form
Attachment 3. Web-based Survey
Attachments 4a-c. Exploratory Guides
Attachment 5. Message Testing Guide
Attachment 6. Concept Testing Guide
Attachment 7. Materials Testing Guide

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

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. Proceedings of the Survey Research Methods Section of the American Statistical Association.

Bureau of Labor Statistics (2013). May 2013 National Occupational Employment and Wage Estimates United States. U.S. Department of Labor. Retrieved July 14, 2014, from http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000.

CDC. (2015). HIV in the United States: At a Glance. http://www.cdc.gov/hiv/statistics/overview/ataglance.html Last updated on September 29, 2015.

Kreuter, M., Farrell, D., Olevitch, L, & Brenna, L. (2000). Tailoring health messages, customizing communication with computer technology. Mahway, NJ: Lawrence Erlbaum Associates.

Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. Journal of Official Statistics, 15, 231–250.

Minority Research Participants. Annual Review of Public Health.27:1-28.

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)

3/7/2016

X Jo Stryker

Branch Chief or Branch Science Officer
Signed by: Jo E. Stryker -S

X

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: Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers

Date received in NCHHSTP ADS or ADLS office: Click to add date ADS/ADLS office received.

Date received by NCHHSTP Deputy ADS or ADLS: Click to enter date ADS/ADLS Deputy received.

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.

all previous comments apply) Dr. Dodson

☐ 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.

Date Information was requested: Click to add date information requested

Date Information was received: Click to add date information 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: Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers

X _____

NCHHSTP ADS, Acting ADS, or Deputy ADS

X _____

NCHHSTP ADLS or Designee

Or