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: Assessment of the Association of Asian Pacific Community Health Organizations (AAPCHO) Providers' Kn

NCHHSTP Project Number:

Division: Division of Tuberculosis Elimination

Project Location/Country(ies):
United States

Telephone: (404) 639-6428

CDC Project Officer or CDC Co-Leads:
Amera Khan and Leeanna Allen

Project Dates:
Start 09/01/2017
End 12/30/2018

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. <u>Activity is not human subjects research.</u>** 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. <u>Activity is research but does NOT involve identifiable human subjects</u>.

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: **<u>ALL</u>** (1–4) below are required:

1. No one has contact with human subjects in this project; **<u>and</u>**
2. Data or specimens are or were collected for another purpose; **<u>and</u>**
3. No extra data or specimens are or were collected for <u>this</u> project; **<u>and</u>**
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. <u>Activity is research involving human subjects, but CDC involvement does not constitute "engagement in human subject research."</u> Select only one option by checking the box: A indicates the project has current funding; B or C indicates <u>no</u> current funding is applicable.

A. This project is funded under a grant, cooperative agreement, or contract award mechanism. **<u>ALL</u>** 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:*

Supported institution/entity FWA Number:*
FWA expiration date:*
Expiration date of IRB approval:*
***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: Assessment of the Association of Asian Pacific Community Health Organizations (AAPCHO) Providers' Kn

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:

Amera Khan and Leeanna Allen: Communications, Education, and Behavioral Studies Branch (CEBSB), Division of Tuberculosis Elimination (DTBE)

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

Amera Khan and Leeanna Allen will provide technical assistance to the Mayo Clinic Center for Tuberculosis (MCCT) and Association of Asian Pacific Community Health Organizations (AAPCHO), who plan to conduct an assessment of AAPCHO's health care providers' knowledge, attitudes, and practices regarding latent TB infection (LTBI) testing, diagnosis, treatment, guidance, and resources. Technical assistance activities will include input and review of assessment tools developed by MCCT and AAPCHO and overall assessment plan. MCCT and AAPCHO are responsible for the content.

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

The following partners organizations and staff are responsible for assessment tool development, implementation, data analysis, and presentation of findings.
AAPCHO: Rosy Chang Weir and Vivian Li
MCCT: Jennifer Curran

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

MCCT is funding AAPCHO to conduct this assessment. MCCT receives cooperative agreement funds from CDC to serve as TB Regional Training and Medical Consultation Center (RTMCC).

5. Project goals:

In order for the United States to progress towards TB elimination, efforts must be made to test and treat populations at high-risk for latent TB infection (LTBI) to prevent the development of TB disease. Non-U.S.-born Asian Americans are one group who are at an elevated risk of having LTBI. Subsequently, they are at risk for developing TB disease. One strategy to increase testing and treatment of this population is to engage community health care providers who serve them. As such, the goal of this project is to engage with community health care providers in the AAPCHO network to understand their current knowledge, attitudes, and practices (KAPs) regarding LTBI testing and treatment and to identify potential solutions to expand LTBI testing and treatment within this community.

6. Project objectives:

-To identify AAPCHO clinicians' KAPs regarding LTBI testing and treatment
-To identify potential solutions to expand LTBI testing and treatment among high-risk populations served by these community health centers

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

Promote LTBI testing and treatment among high-risk populations.

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

Clinicians who are part of the AAPCHO community health center network

9. Project methods:

AAPCHO will survey clinicians and conduct focus groups and/or key informant interviews in their network of community health centers. MCCT and AAPCHO are responsible for the content.

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

AAPCHO is responsible for selection of sites and participants. Inclusion criteria will be clinicians who serve in community health centers in the AAPCHO network.

11. Incentives to be provided to participants:

None.

12. Plans for data collection and analysis:

AAPCHO and MCCT will be responsible for data collection and analysis.

13. Confidentiality protections:

AAPCHO will ensure that individual respondent's identities will not be revealed in any presentation of the results of this assessment.

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

No other ethical concerns identified.

15. Projected time frame for the project:

September 2017 - December 2017 AAPCHO and MCCT activities
Time frame of CDC technical assistance through December 2018 includes one year follow up for potential presentation at TB conferences and meetings

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

AAPCHO and MCCT will develop a report that will be shared with CDC and other TB control partners. Dissemination activities will include a written report for distribution and presentations at TB conferences and meetings.

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

Attached is the statement of work AAPCHO developed by MCCT.

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

N/A

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 Maria F. Sessions -S — Digitally signed by Maria F. Sessions -S Date: 2017.08.31 08:44:56 -04'00'

Branch Chief or Branch Science Officer

X Carla Winston -S — Digitally signed by Carla Winston -S Date: 2017.08.31 11:14:51 -04'00'

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: Assessment of the Association of Asian Pacific Community Health Organizations (AAPCHO) Providers' Kn

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.

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:

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: Assessment of the Association of Asian Pacific Community Health Organizations (AAPCHO) Providers' Kn

X 9/20/17

NCHHSTP ADS, Acting ADS, or Deputy ADS

X

NCHHSTP ADLS or Designee

Or

Statement of Work
AAPCHO assessment of Health Care Provider's Knowledge, Attitudes, and Practices Regarding Latent TB Infection

AAPCHO Project Staff

Rosy Chang Weir, Director of Research
Vivian Li, Research Analyst

Description

The Association of Asian Pacific Community Health Organizations (AAPCHO) will work with the Mayo Clinic Center for Tuberculosis (MCCT) to conduct an assessment of AAPCHO's health care providers' knowledge, attitudes, and practices regarding latent TB infection (LTBI) testing, diagnosis, treatment, guidance, and resources. AAPCHO will seek technical assistance from MCCT, CDC, and other TB control partners for input and review of assessment plan and tools. AAPCHO is responsible for the final assessment tool development, implementation, data analysis, and presentation of findings.

Goal

AAPCHO will explore and assess needs around expanding latent TB infection testing and treatment at their clinics.

Deliverables

1. Select sites for assessment implementation (Sept. 15, 2017)
2. Develop provider assessment tools (online and paper) for online survey and (Sept. 20, 2017)
   focus group or key informant interviews
3. Acquire approvals as needed (Oct. 15, 2017)
4. Conduct assessments (Oct. 15- Nov. 15, 2017)
5. Analyze data and develop and present findings and recommendations (presentation and written report)
   (Dec. 31, 2017)