Request for Approval Under the Generic Clearance for Emergency Epidemic Investigation Data Collections (0920-1011)

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

Determine if your investigation is appropriate for this Generic mechanism: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the EEI Generic ICR mechanism. Complete the checklist below. If you select "yes" to all criteria in Column A, the EEI Generic IR mechanism can be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism cannot be used.*

Column A	**Column B**
CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organization). X Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes X No
The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death). X Yes ☐ No	The investigation is not urgent in nature. ☐ Yes X No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. X Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes X No
One or more CDC staff (including trainees and fellows) will be deployed to the field. X Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes X No
Data collection will be completed in 90 days or less. X Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes X No

Did you select "Yes" to ***all*** criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. → You may proceed with this form.

Did you select "Yes" to ***any*** criterion in Column B?

If yes, the EEI Generic ICR is not appropriate for your investigation. → Stop completing this form now.

GenIC # 2016016 - XXX **Date** 5/4/2016

Title of Investigation: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for [disease/problem] among [subpopulation]—[State], [Year]*

Undetermined transmission and risk factors for multidrug-resistant *Mycobacterium tuberculosis* among Tribal members — Arizona, 2016

Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:	Arizona
City/County (if applicable)	
Country	United States

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:	Arizona Department of Health Services
Name and Position Title:	Ken Komatsu, State Epidemiologist

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Description of Investigation

1. Problem to be Investigated: *Instruction: Provide a summary of the outbreak or event. The summary should include all the information you know at this time about the outbreak or event and the investigation that is planned. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event, including a justification of the need for an investigation and why this issue requires an urgent response; 2) the objectives of the investigation, including how the information collected will be used to inform prevention and control measures; and 3) a brief overview of the investigation planned, including study design, respondents, mode of data collection. In the description, indicate whether a data collection instrument is attached with the GenIC request (refer to as Appendix 1, etc) and what instruments will be developed in the field. (suggested length: 250-500 words).*

In September 2015, an elderly man, a member of a Tribe and residing on a reservation in Arizona, received an incidental diagnosis of tuberculosis (TB) disease during a pre-operative evaluation for cardiac surgery to treat coronary artery disease. Initially prescribed TB treatment, the regimen was changed in October 2015 when molecular testing for drug resistance detected mutations that confer resistance to the first-line drugs isoniazid and rifampin, consistent with multidrug-resistant (MDR) TB. The patient's *Mycobacterium tuberculosis* isolate's genotype was unique in the United States, so the index case's source was unclear. The ensuing investigation among the index patient's contacts (i.e., persons who shared air space with an infectious TB case) identified no additional cases, but one child received a diagnosis of latent TB infection, presumably from a recent infection with the MDR TB strain, suggesting at least limited transmission. Based on recommendations from clinical experts in the management of MDR TB, the child began treatment for infection to prevent development of MDR TB disease. The index patient responded well to MDR TB treatment, but died from complications of coronary artery disease in January 2016.

In April 2016, a second member of same Tribe residing on the same reservation, an adult woman who used illicit substances and had poorly controlled diabetes, presented to hospital A in diabetic ketoacidosis. While hospitalized, the woman twice underwent bronchoscopy, an invasive, aerosol-generating respiratory procedure, before TB disease was recognized. Multiple lung cavities were observed on computed tomography of the chest, suggesting infectious TB disease. Cultures performed on respiratory specimens obtained from the woman are pending, so no *M. tuberculosis* isolate is yet available for genotyping to confirm that the woman was infected with the same strain as the index patient. However, a clinical specimen obtained during bronchoscopy was submitted for molecular testing and revealed evidence for infection with an *M. tuberculosis* strain whose drug resistance pattern matched that of the index patient's isolate (i.e., resistance to isoniazid and rifampin). Once MDR TB disease was recognized, the woman was placed in respiratory isolation at hospital A and prescribed a treatment regimen based on recommendations from clinical experts in the management of MDR TB disease. Health-care providers discovered that the woman was related to the index patient, which along with the matching drug resistance patterns that suggested the cases were connected, raised concerns about the previously unrecognized contact between the two patients or the possibility of an unrecognized common source case.

The Arizona Department of Health Services, in collaboration with local county, Indian Health Service, and Tribal partners, requests CDC assistance in the form of an Epi-Aid to assist with the public health investigation.

The objectives of the investigation are to:

1) To identify cases and determine how cases are related to each other
2) To identify contacts and prioritize them based on disease risk for evaluation and treatment
3) To identify risk factors for infection

Data are ultimately collected to inform prevention and control measures.

This GenIC requests OMB approval for the following data collections: 1) Case Medical/Public Health Abstraction Form (Appendix 1); 2) Case Interview Form (Appendix 2); and 3) Contact Interview/Abstraction Form (Appendix 3).

2. Characteristics of Outbreak or Event (Check all that Apply):

- ☐ Undetermined agent
- ☐ Undetermined source
- ☐ Undetermined mode of transmission
- ☒ Undetermined risk factor

3. Respondents: *Instruction: Select all that apply. For each respondent type selected, provide a brief description. Be sure to include a description of control respondents, if applicable. Use as much space as necessary for each description.*

- ☒ General public (describe):
  Contacts who were exposed to an infectious case of MDR TB who need evaluation to exclude MDR TB disease (Appendix 3)
- ☒ Healthcare staff (describe):
  Contacts who were exposed to an infectious case of MDR TB who need evaluation to exclude MDR TB disease who may be healthcare staff (Appendix 3)
- ☐ Laboratory staff (describe):

☒ Patients (describe):

Patients who are ill with MDR TB disease meeting the outbreak case definition (Appendix 2)

☐ Restaurant staff (describe):

☒ Other (describe):

Federal staff will abstract case medical and public health records (Appendix 1)

4. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

Federal staff on the investigation team will abstract case medical/public health records (Appendix 1).

Cases will be identified through molecular and other public health surveillance data. All cases identified will be included (Appendix 2).

Contacts will be identified based on interviews with the cases or the case's proxy (Appendix 3). Contacts are persons who shared airspace with a patient with MDR TB during the estimated infectious period. Infectious periods for cases will be estimated based on symptom onset or timing of diagnostic studies whose results were consistent with TB disease.

5. Study Design: *Instruction: Select all that apply. For each study design planned, provide a brief description. Use as much space as necessary for the description.*

☒ Epidemiologic Study (indicate which type(s) below)

☒ Descriptive Study (describe):

Investigators will describe the demographic features of cases, determine the frequency of clinical and social risk factors for TB disease, and identify cases and contacts.

Investigators will characterize the frequency, duration, and intensity of exposure of contacts to infectious outbreak cases of MDR TB. Investigators will also describe the frequency of MDR TB disease and TB infection among contacts who have completed evaluations.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

☒ Survey Mode (indicate which mode(s) below):

☒ Face-to-face Interview (describe):

Investigators will conduct semi-structured, face-to-face interviews of cases or their proxies meeting the outbreak TB case definition (Appendix 2) and their contacts (Appendix 3) to estimate infectious periods, identify contacts exposed during the infectious period, and determine potential transmission sites.

☐ Telephone Interview (describe):

☐ Self-administered Paper-and-Pencil Questionnaire (describe):

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Investigators will conduct standardized reviews of medical and public health records for cases and contacts to estimate infectious periods, identify contacts exposed during the infectious period, identify risk factors for progression to TB disease after TB infection for contacts, and determine potential transmission sites (Appendices 1 and 3).

☐ Biological Specimen Sample

☐ Environmental Sample:

☐ Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

☒ Behaviors (describe):

Because certain behaviors are associated with TB risk (e.g., substance use), investigators will ask cases (Appendices 2 and 3) with infectious MDR TB and contacts (Appendix 3) about activities during the estimated infectious period, including use of substances (alcohol, injection drugs, non-injection drugs, other illicit drug use).

☒ Clinical information/symptoms (describe):

To estimate the infectious period, investigators will ask cases (or their proxies) about symptom onset (Appendix 2).

Investigators will ask contacts about the presence of TB symptoms as part of the evaluation to determine the scope of transmission (Appendix 3).

☐ Contact information (describe):

☒ Demographic information (describe):

To characterize the demographic features of cases (Appendices 1 and 2) and contacts (Appendix 3) and identify TB risk factors, investigators will ask cases and contacts about their age, gender, employment (to determine whether TB exposure was related to occupational work), country of birth, and incarceration history.

☒ Environmental factors (describe):

Because the TB transmission occurs more efficiently in enclosed spaces with poor ventilation usually over prolonged periods of exposure, investigators will inquire both cases (Appendix 2) and contacts (Appendix 3) about the setting, duration, and frequency in which exposures to infectious MDR TB cases occurred.

☒ Exposures (describe):

Cases (Appendix 2) and contacts (Appendix 3) will be asked whether (including where and when) they had previous exposure to TB disease. Because tests for TB infection sometimes are unable to distinguish between remote and recent infection, this information is needed to assess risk of infection with MDR TB or another form of TB that is drug-susceptible.

☒ Medical history (describe):

Cases (Appendix 2) and contacts (Appendix 3) will be asked about prior testing and treatment for both TB disease and TB infection. Prior treatment can increase the risk of having MDR TB.

☒ Risk factors (describe):

See above behaviors and medical history

☒ Specimen/lab information (describe):

Investigators will review the results of molecular testing for drug resistance performed on specimens, microscopic examination of serial sputum specimens for acid-fast bacilli, microbiologic tests performed on specimens to obtain an M. tuberculosis isolate, genotyping results for M. tuberculosis isolates. Collection of specimens from cases or contacts and testing performed specimens or isolates from those specimens would have been completed already by health department or other healthcare personnel involved in providing medical care to patients or contacts, as part of routine activities during TB case management and contact investigations. Investigators will only be involved in reviewing and abstracting this information from existing medical and public health records. Results from cases will be recorded on Appendix 1 and from contacts on Appendix 3.

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):

2 weeks

Research Determination: *Instruction: Indicate the research determination decision. If the decision is research, provide the research determination letter and IRB approval, if required.*

☐ Research ☒ Not Research

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name:	Krista Powell
Title:	Lead, Outbreak Investigations Team
Affiliation:	CDC, Division of TB Elimination

CDC Sponsoring Program and Primary Contact Person: *Instruction: Indicate the sponsoring CIO/Division/Branch for this investigation. Indicate the name, title, and contact information of the CDC Primary Contact Person for this investigation. Indicate the preferred method of contact during the OMB approval process. Note, contact person or a designee must be available during the OMB approval process in case questions arise.*

CIO/Division/Branch:	NCHHSTP/DTBE/SEOIB
Name:	Krista Powell
Title:	Lead, Outbreak Investigations Team

Certification: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, [insert name of CDC sponsoring program contact], certify the following to be true:

1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact Name:	Krista Powell
Date of Certification:	5/5/2016

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*

5/8/2016

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

EEI Information Collection Request Liaison:

Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
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