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). ☒ Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes ☒ 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). ☒ Yes ☐ No	The investigation is not urgent in nature. ☐ Yes ☒ No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. ☒ Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes ☒ No
One or more CDC staff (including trainees and fellows) will be deployed to the field. ☒ Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes ☒ No
Data collection will be completed in 90 days or less. ☒ Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes ☒ 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 # 2015012 - XXX **Date** 08/17/2015

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 risk factor and mode of transmission for HIV infection among persons injecting an opioid painkiller—Indiana, 2015

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

State:	Indiana
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:	Indiana Department of Health
Name and Position Title:	Pam Pontones, MA, 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).*

On January 23, 2015, the Indiana State Department of Health (ISDH) began investigating an HIV outbreak in a rural community in Scott County, Indiana. As of August 18, 2015, 175 individuals were diagnosed with HIV infection in a community of a population size 4,200 (www.in.gov/isdh). Over 90% of these cases reported injecting the prescription opioid oxymorphone, but sexual risk factors, including engaging in sex work, were reported as well. Therefore, the primary risk factor in this outbreak is still undetermined.

In response to the outbreak, standard HIV control and prevention interventions were rapidly implemented and persons at risk for HIV were identified through contact tracing and tested for HIV and HCV infections. Diagnoses of new infections have slowed, however, the risk for new infections has not been completely eliminated. Questions

critical to effective control remain, including but not limited to i) how are prescription-type opioids procured, prepared, shared, and injected; and, ii) what are the barriers to accessing care (e.g., antiretroviral treatment) and prevention services (e.g., syringe service programs, PrEP, HIV retesting).

This investigation will utilize qualitative methods to conduct in-depth interviews with persons who inject drugs (PWID), both HIV-infected and uninfected, to identify risk practices as well as access to and utilization of the emergency public health interventions implemented in Scott County.

The objectives of this investigation include:

1. Identify high-risk behaviors of PWID to understand drug use practices, sexual practices, and other potential pathways of HIV and HCV transmission in this outbreak

2. Understand the facilitators and barriers to accessing treatment and prevention programs

The findings from this investigation will directly contribute to control of the ongoing HIV outbreak in Scott County by collecting the necessary data i) to inform recommendations to reduce new HIV infections and ii) to increase demand for and uptake of prevention services. Findings will be summarized and disseminated in a timely manner to key public health response partners, including ISDH, Scott County Department of Health, and local health care providers.

We will conduct purposeful sampling of up to 30 PWID in Scott County; 15 HIV-positive and 15 HIV-negative participants. In-depth, face-to-face interviews using a semi-structured, open-ended interview guide (see Appendix 1) will be conducted to collect information about risk behaviors, utilization of preventive and health care services and any emerging topics not yet identified through the ongoing outbreak investigation efforts.

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):
  Persons who inject drugs and reside in Scott County, IN
- ☐ Healthcare staff (describe):
- ☐ Laboratory staff (describe):

☐ Patients (describe):

☐ Restaurant staff (describe):

☐ Other (describe):

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.*

Respondents will be selected from adult residents of Scott County, IN who have injected drugs at least once in the past 12 months, can complete an interview in English, and are able to provide informed consent. Respondents will be recruited i) from locations where PWID are likely to congregate (e.g., local medical clinic, the syringe exchange program, food bank, street intercepts in high-prevalence neighborhoods), and ii) through peer-to-peer referral by recruited participants.

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):

A qualitative study design will be utilized to collect in-depth information on key risk factors contributing to this rural HIV outbreak, to inform current public health interventions, including the syringe service program and treatment of HIV and substance use disorder.

☐ 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):

Face-to-face interviews using a semi-structured, open-ended interview

guide (see Appendix 1) will be conducted to collect information about risk behaviors, utilization of preventive and health care services and any emerging topics not yet identified through the ongoing outbreak investigation efforts.

- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

- ☐ Medical Record Abstraction (describe):
- ☐ 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):
  Data on risk behaviors that may have contributed to the rapid spread of HIV will include: current drugs used, drug preparation and drug injection practices, injection equipment sharing, and sexual risk behaviors. Information on preventive behaviors will also be collected, including access and utilization of HIV prevention and care services.
- ☒ Clinical information/symptoms (describe):
  Self-reported history of HIV testing and treatment, hepatitis C testing and treatment, and substance abuse treatment
- ☐ Contact information (describe):
- ☒ Demographic information (describe):
  Self-reported age, race/ethnicity, and residence
- ☐ Environmental factors (describe):
- ☐ Exposures (describe):
- ☐ Medical history (describe):
- ☒ Risk factors (describe):
  Behavioral risk factors described above

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
12 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

NOTE: This investigation received a determination of "research" to allow for local IRB review, but the primary purpose of the data collection is public health practice (identify prevention and control measures).

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

Name:	Dita Broz, PhD MPH
Title:	Epidemiologist
Affiliation:	CDC/NCHHSTP/DHAP/BCSB

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/DHAP/Epidemiology Branch
Name:	John Brooks, MD
Title:	Medical Officer

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:	John Brooks, MD
Date of Certification:	08/18/2015

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

08/24/2015

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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