

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

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]*

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

State:

City/County (if applicable)

Country

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

Agency:

Name and Position Title:

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 9, 2015, the CDC Poxvirus and Rabies Branch was contacted about a suspect case of human monkeypox (MPX) in Impfondo, Republic of Congo (ROC). The case was an eight year old male resident of Democratic Republic of Congo (DRC), who had traveled to an American missionary clinic in ROC for medical care. The patient developed a fever on 27 December 2014 and a subsequent rash on 1 January 2015. Photographs of the patient taken on January 9 depicted a typical MPX rash, including lesions on the palms of the hands and soles of the feet. Monkeypox virus DNA signatures were amplified from a crust and vesicular swab at the national laboratory in Kinshasa, DRC (INRB).

In humans, infection with MPX virus, an *Orthopoxvirus*, can lead to a smallpox-like illness with fatal outcomes. Severe sequelae such as blindness have also been reported. There are currently no drugs licensed for the treatment of MPX. The MPX virus is endemic in western and central Africa. The overwhelming majority of reports of human cases are from DRC. In 2009, interethnic conflict

forced the movement of refugees across the border from DRC into the Impfondo area of ROC. Further, given the porous nature of the border between the two countries, there is a great deal of movement between the two countries. Training and recognition of disease by healthcare workers has been key to the identification and reporting of MPX cases in this area. Community education for MPX in 2009 resulted in an increased number of reports of suspect illness in the Impfondo area; however, the exit of a local non-governmental organization that used to manage clinics for refugees has caused a recent change and void in healthcare personnel in the Impfondo area. There is concern that there are additional, undiagnosed cases of MPX.

An assessment of risk factors for and sources of transmission among community members in ROC is needed to develop effective prevention and control messages to prevent new cases. The ROC MOH has therefore requested urgent assistance from the CDC to investigate sources and risk factors of MPX introduction and transmission in ROC.

CDC will work with partners from the Republic of Congo Ministry of Health to halt the spread of a communicable zoonotic pathogen from an endemic area to a largely non-affected area by:

- 1) Identify the behavioral and environmental risk factors among populations in and around Impfondo, ROC (Appendix 1a and 1b),
- 2) Train local healthcare workers on clinical recognition, appropriate specimen collection, surveillance, patient care, and healthcare worker protection with regards to suspect monkeypox cases, and
- 3) Provide community educational outreach using film-based educational tools.

This request seeks OMB approval for the data collection instrument to be used to assess behavioral and environmental risk factors among community and healthcare workers (Appendix 1a – French version; Appendix 1b – English version).

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):

Information will be collected from households in and around Impfondo, ROC with a goal of 3 participants per household and at least 1 adult and 1 child (<18 years old) per household.

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.*

Households will be selected randomly. In each household that agrees to participate, we will interview 3 participants per household, including a goal of at least 1 adult and 1 child (<18 years old) per household. If the 1 adult and 1 child minimum requirement cannot be acquired in the household, the neighboring household will be interviewed as well. If a household declines participation, the neighboring household will be given the option to participate. Participation is voluntary. We estimate approximately 300 community members will participate.

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):

This will be a descriptive analysis of the knowledge of sources and risk factors for infection in and around Impfondo, ROC.

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):

Trained staff from CDC and MOH will conduct the interviews.

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):

Frequency of school, church/mosque, market attendance; frequency of entering the forest and activities in the forest.

Clinical information/symptoms (describe):

Contact information (describe):

Demographic information (describe):

Name, village, gender, age, occupation; number of occupants in each household.

Environmental factors (describe):

Materials used to build the home.

Exposures (describe):

Contact with domestic or wild animals, the types of animals, individuals in households who typically prepare meat.

Medical history (describe):

Risk factors (describe):

Contact with domestic or wild animals, the types of animals, individuals in households who typically prepare meat.

Specimen/lab information (describe):

Travel history (describe):

Other (describe):

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

12

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: Andrea McCollum, PhD
 Title: Epidemiologist
 Affiliation: NCEZID/DHCPP/PRB

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: NCEZID/DHCPP/PRB
 Name: Andrea McCollum, PhD
 Title: Epidemiologist

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: Andrea McCollum, PhD
 NCEZID/DHCPP/PRB
 Date of Certification: 07/02/2015

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

07/08/2015

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
EWB/DSEPD/CDC
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

Date/Time initial GenIC received
by ICRL

7/6/2015, 12:15PM

Date/Time final GenIC received
by ICRL

Date/Time submitted to OMB

Date/Time approved
