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 # 2016013 - XXX **Date** 03/22/2016

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 sources and risk factors for a Rift Valley Fever Outbreak—Uganda, 2016

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

State:	
City/County (if applicable)	
Country	Uganda

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

Agency:	Ugandan Ministry of Health
Name and Position Title:	Dr. Aceng Jane Ruth, Director General

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 March 15, 2016 the Ugandan Ministry of Health (MoH) reported an outbreak of Rift Valley Fever (RVF) in Kabale district, Western Uganda. RVF is a viral hemorrhagic fever that can cause severe disease in humans and animals, with concern for significant economic losses due to livestock infection. As of March 15, there are 2 lab confirmed human cases within Kabale district, both requiring hospitalization. There are no epidemiologic links connecting these two cases; however, they both have known livestock exposure. Additionally, 17 livestock abortions/deaths have been reported. Additional cases are suspected but have not yet been confirmed. Retrospective case investigations have revealed people with symptoms similar to RVF, especially abattoir workers and meat handlers. Hospital records show patients who reported to the health facilities in Kabale hospital that were treated and either recovered or died and had symptoms mimicking RVF. There is need to estimate the burden of RVF in Kabale district especially in high risk groups such as animal health workers, abattoir workers and meat handlers and veterinarians.

The MoH has established a multi-sectoral National Task Force composed of representatives from Ministries of Health, Agriculture, Animal Industry and Fisheries, and Water and Environment. They are being assisted by Uganda's Wildlife Authority, WHO, CDC, and MSF. The MoH requested additional assistance with the investigation to identify sources and risk factors for Rift Valley Fever in order to implement prevention and control measures.

The objectives of the investigation are to identify cases of and exposures to RVF in both humans and animals in Kabale and surrounding districts and identify high-risk areas and risk factors for RVF. Data will be used to inform prevention and control measures.

An investigation will be conducted to identify human and animal cases and determine risk factors for infection. Participants will be people at high risk for infection, including working at animal slaughter sites, animal handlers, and residents in the villages in which the recent RVF cases were identified. Participants will complete a risk factor questionnaire (Appendix 1). In addition, herders will be interviewed about their livestock using the livestock assessment form (appendix 2). To identify cases, blood samples will be collected from human participants (Appendix 1) and their animals (Appendix 2) at the time of interview. Blood samples will be submitted for serological testing for RVF IgM and IgG by ELISA at the Uganda Virus Research Institute following local protocols.

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):

  Participants will be people at high risk for infection, including working at animal slaughter sites, animal handlers, and residents in the villages in which the recent RVF cases were identified. Domestic livestock of village herders also will be included.

- ☐ 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.*

Participants will be people at high risk for infection, including working at animal slaughter sites, animal handlers, and residents in the villages in which the recent RVF cases were identified. Domestic livestock of village herders also will be included.

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):

☒ Cross-sectional Study (describe):

Villagers and their livestock will be assessed with a cross-sectional risk factor questionnaire and serosurvey.

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

Serologic testing of humans and livestock for RVF IgM and IgG by ELISA will be performed at the Ugandan Viral Research Institute following local protocols

☐ 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):

The risk factor questionnaire (Appendix 1) and livestock assessment form (Appendix 2) will be completed via face-to-face interview.

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

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample

Human and livestock blood specimens will be collected by the investigation team (Appendices 1 and 2)

☐ 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):

See Environmental Factors and Exposures.

☒ Clinical information/symptoms (describe):

Participants are asked if they or someone they know has suffered from an undiagnosed fever or illness (Appendix 1). Serosurvey sampling and results will be recorded for humans (Appendix 1) and animals (Appendix 2).

☐ Contact information (describe):

☒ Demographic information (describe):

Participants are asked their location (GPS coordinates), gender, age, marital status, education level, and occupation (Appendix 1)

☒ Environmental factors (describe):

Participants are asked about risk factors for infection, including mosquito exposure, net use, and flooding (Appendix 1).

☒ Exposures (describe):

Participants are asked details regarding exposure to domesticated or wild animals, consumption of raw milk or meat, and use of PPE when handling animals (Appendix 1).

☐ Medical history (describe):

☒ Risk factors (describe):

See Environmental Factors and Exposures.

☐ Specimen/lab information (describe):

☒ Travel history (describe):

Participants are asked if they traveled outside of their home village (Appendix 1)

☒ Other (describe):

Participants are asked detailed questions to assess their knowledge regarding RVF (Appendix 1). Herders are asked to provide information about their animals, including movement and grazing patterns, healthy status, and treatments (vaccination history, insecticide use (Appendix 2).

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

4 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:	Trevor Shoemaker
Title:	Response Lead, Epidemiologist
Affiliation:	NCEZID/DHCPP/VSPB

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/VSPB
Name:	Lawrence Purpura, MD, MPHTM
Title:	EIS Officer, VSPB Branch

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, Lawrence Purpura, 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:	Lawrence Purpura, MD, MPHTM
Date of Certification:	3/22/2016

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

03/24/2016

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
EWB/DSEPD/CDC
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