

**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 # 2015 - 001 Date 10/1/2014

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 mode of transmission and risk factors for Crimean-Congo Hemorrhagic Fever among Georgians - Tbilisi, Georgia, 2014

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).*

Since the start of 2014, Georgia's National Center for Disease Control and Public Health (NCDC) has identified 22 cases of Crimean-Congo Hemorrhagic Fever (CCHF). CCHF is a tick-borne zoonotic viral disease that is primarily transmitted through infected tick bites and tick handling. Secondary transmission can also occur from exposure to infected animal blood or tissues, ingesting unpasteurized milk, and exposure to blood or bodily fluids from a human infected with CCHF. Although it initially presents as a nonspecific febrile illness it can quickly progress to hemorrhagic symptoms leading to shock and death, with a case fatality rate reported to be as high as 60%.

Although CCHF is known to be endemic in this region since its discovery in 2009, this is the highest number of cases ever reported and above surveillance baseline for this Category A agent in the country of Georgia. The extent of the current outbreak is unknown due to likely under-reporting of

cases secondary to limitations in healthcare access across the region. Additionally, the mode of transmission and risk factors for this outbreak are currently unknown. NCDC has requested CDC to investigate and control the outbreak.

The objectives of this investigation are as follows:

OBJECTIVE 1: Review existing data to accomplish the following:

- a. Clarify case definitions of suspect, probable, and confirmed.
- b. Identify any recent modifications to the surveillance system including changes in laboratory assays used.
- c. Describe the characteristics and clinical presentation of each case.
- d. Investigate and identify known risk factors for each case.
- e. Identify the laboratory testing, if any, performed for each case.
- f. Determine the mode of transmission of CCHF in these case-patients.
- g. Link existing animal, entomologic, and human epidemiologic and serologic data.

OBJECTIVE 2: Conduct a field investigation to accomplish the following:

- a. Assess knowledge, attitudes, and practices (KAP) related to CCHF in the affected regions to identify risk factors for infection.
- b. Identify cases of CCHF infection and determine the scope of the outbreak among at-risk populations in the affected region.

The investigation will include assessments of clinical information on case-patients (medical course, laboratory test results, and potential exposures) previously collected in the electronic disease surveillance system (EIDSS), an assessment of risk factors (knowledge, attitudes, and practices; KAP) of at-risk populations, and case identification. Clinical information will be recorded on the CCHF Case Investigation Questionnaire (Appendix 1) via abstraction of medical records and from EIDSS by federal staff, the ministry of health (NCDC) and its partners, including the Defense Threat Reduction Agency (DTRA). Face-to-face or telephone interviews with case-patients or next-of-kin will be performed if more information is required. A field investigation also will be conducted in at-risk regions (defined as areas where CCHF transmission has been identified) to identify risk factors for infection and for case identification. The field investigation will include 1) a KAP Survey (administered face-to-face) to assess risk factors and 2) collection of a blood sample to be tested for CCHF infection for case identification and to describe the extent of the outbreak (Appendix 2, Appendix 3). Additionally, given the zoonotic component of transmission, environmental assessment for animal and vector exposure might be conducted in those areas identified as possible locations of transmission

Overall, the goal is to identify the mode of transmission and the risk factors for CCHF in this outbreak to effectively implement public health interventions to mitigate future CCHF risk and transmission.

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):

Respondents of the field investigation (Appendices 2-3) will be residents of villages with at least one reported CCHF case and residents in villages with no reported case-patients (controls).

Healthcare staff (describe):

Laboratory staff (describe):

Patients (describe):

If any additional information is needed that is not already available in the EIDSS, case-patients will be interviewed to determine their basic demographics, medical course, laboratory testing and risk factors for CCHF (Appendix 1).

Restaurant staff (describe):

Other (describe):

Respondents for the clinical investigation (Appendix 1) also will be federal staff, NCDC and its partners, including DTRA, who will abstract information from medical records or EIDSS.

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.*

The Case Investigation Questionnaire (Appendix 1) will be completed for all case-patients; information will be obtained via medical record abstraction and review of EIDSS. Federal staff, NCDC and its partners, including DTRA, will conduct the medical record abstraction. Any additional information, if necessary, will be obtained through case-patient interviews.

Households in regions where CCHF cases were identified will be selected for participation in the household interview (Appendix 2, Appendix 3). Households will be selected using simple random sampling in the 13 rural villages identified with a confirmed CCHF case. All adults in the household that meet the inclusion criteria will be interviewed and a blood sample obtained. Inclusion criteria for participation will be any adult (≥ 18 years old) member who can provide consent. Local procedures for biospecimen collection, storage, and transport will be followed.

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):

The first major objective of the study is to perform an existing data review. Working in collaboration with NCDC and its partners, including DTRA, federal staff will perform a medical chart review of all case-patients, including the extraction of pertinent clinical information and laboratory results. Data will also be extracted from the NCDC electronic disease surveillance system (EIDSS). Any missing information regarding known risk factors will be obtained by face-to-face or telephone interviews with each case using a standardized questionnaire (Appendix 1). If household interviews are not possible, telephone interviews will be performed. For those case-patients that died prior to the survey, the next of kin will be contacted for an interview.

These data will be used to describe the characteristics and clinical presentation of each case in addition to identifying known risk factors for each case.

Cross-sectional Study (describe):

The second major objective is the field investigation which will be conducted in those

regions with positive case-patients to identify risk factors for infection, identify cases of CCHF infection, and describe the extent of the outbreak. This information is critical for informing prevention and control measures. This will be conducted by performing household visits to administer the KAP questionnaire and collect a blood sample (Appendix 2, Appendix 3).

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Given the zoonotic component of transmission, any animal or tick samples previously collected from affected regions and tested for CCHF will be linked to the reported human case information.

Laboratory Testing (describe):

A 10 ml whole blood sample (Appendix 3) will be obtained and sent for CCHF diagnostic testing. Serum will be separated by centrifugation and will be split into two aliquots. One will be tested at the Lugar Laboratory for recent (within the past 2-4months) and past (within past 5 years) CCHF infection by anti-CCHF IgM and IgG, respectively. Testing will be confirmed at CDC Atlanta, Viral Special Pathogens Branch (VSPB) Laboratories. Results will be reported to participants with relevant interpretation materials. Local procedures for biospecimen collection, storage, and transport will be followed.

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):

Information that cannot be obtained from EIDSS or by medical record abstraction will be obtained by face-to-face or telephone interview with the case-patient or next-of-kin (Appendix 1). The KAP survey will be administered via face-to-face interview (Appendix 2, Appendix 3).

Telephone Interview (describe):

Information collected on the CCHF Case Investigation Questionnaire (Appendix 1) that cannot be obtained from EIDSS will be obtained by face-to-face or telephone interview with the case-patient or next-of-kin.

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

A medical chart review of all case-patients, including the extraction of pertinent clinical

information and laboratory results will be performed in addition to getting information from the EIDSS.

Biological Specimen Sample

A 10 ml whole blood sample (Appendix 3) will be obtained from an adult household member in households participating in the KAP survey for CCHF diagnostic testing. Serum will be separated by centrifugation and will be split into two aliquots. One will be tested at the Lugar Laboratory for recent (within the past 2-4months) and past (within past 5 years) CCHF infection by anti-CCHF IgM and IgG, respectively. Testing will be confirmed at CDC Atlanta, Viral Special Pathogens Branch (VSPB) Laboratories. Local procedures for biospecimen collection, storage, and transport will be followed.

Environmental Sample:

Previous samples obtained from ticks and animals that tested positive for CCHF in the at-risk areas will be obtained from the Lugar Laboratory and Ministry of Agriculture Laboratory.

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):

The KAP survey will evaluate the current behaviors that at-risk populations perform to protect themselves from possible CCHF risk factors (Appendix 2, Appendix 3). This includes practices regarding tick handling, removal, or avoidance as well as any animal slaughtering practices.

Clinical information/symptoms (describe):

The clinical presentation and course of each case will be obtained from EIDSS and from medical record abstraction, and will be recorded in Appendix 1.

Contact information (describe):

Participants' names and contact information will be obtained from NCDC in order to establish initial contact with the participant to facilitate scheduling interviews. This information will be maintained in a secure file at the primary investigator's location until the end of the study. All materials for this investigation including the questionnaires will have a unique identification number assigned to each case and no personal identifiers.

Demographic information (describe):

Basic demographic information including age, sex, race, educational status, and residence will be obtained (Appendices 1-3).

Environmental factors (describe):

Factors such as exposure to ticks, animals, slaughtering, and other outdoor activities will be obtained (Appendix 1).

Exposures (describe):

Known CCHF exposures will be asked as presented in Appendix 1.

Medical history (describe):

Medical history will be recorded as described in Appendix 1.

Risk factors (describe):

Risk factors will be obtained as described in Appendix 1 and Appendix 2.

Specimen/lab information (describe):

A 10 ml whole blood sample will be obtained from an adult household member in households participating in the KAP survey for CCHF diagnostic testing. Serum will be tested at the Lugar Laboratory for recent (within the past 2-4months) and past (within past 5 years) CCHF

infection by anti-CCHF IgM and IgG, respectively. Testing will be confirmed at CDC Atlanta, Viral Special Pathogens Branch (VSPB) Laboratories. Local procedures for biospecimen collection, storage, and transport will be followed.

Travel history (describe):

Migratory patterns (i.e. herding) and recent travel to other regions or countries in the last four months will be obtained.

Other (describe):

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

3 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: Ashley Greiner

Title: Epidemic Intelligence Officer

Affiliation: CDC/CGH/DGHP/GDD

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: CDC/CGH/DGHP/GDD

Name: Juliette Morgan

Title: Georgia – Country Director

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: Juliette Morgan

Date of Certification: 10/2/2014

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

10/5/2014

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

Date/Time final GenIC received
by ICRL

Date/Time submitted to OMB

Date/Time approved
