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 # 2019001 - XXX **Date** 11/14/2018

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 factors for long term sequela resulting from Rocky Mountain spotted fever—Arizona, 2018

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

State:	Arizona, multiple tribal communities
City/County (if applicable)	
Country	USA

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).*

Rocky Mountain spotted fever (RMSF), a life-threatening and rapidly progressive tickborne disease, is caused by infection with the bacterium *Rickettsia rickettsii*. Infection begins with non-specific symptoms like fever, headache, and muscle pain, but when left untreated the bacteria can cause damage to blood vessels throughout the body leading to organ and tissue damage. Delay in recognition and treatment of RMSF can result in irreparable damage leading to amputation of extremities, neurological deficits (such as hearing loss, paralysis, and encephalopathy), and death. RMSF is an emerging threat to Arizona tribal communities. In 2018, cases have more than doubled in number compared to what was reported last year at this time (13 cases between January and July 2017 compared to 27 cases in 2018 to-date). In addition, family members and providers in the area are reporting that patients, even those who have been treated, are experiencing long-term neurological dysfunction and severe outcomes leading to long-term disability following their discharge. The reason for these negative outcomes are unclear. There is growing concern among physicians and

patients that we have an incomplete understanding of the risk factors that lead to severe disease and neurologic sequela, impeding their ability to provide anticipatory guidance and timely access to appropriate follow-up services. There were 2 deaths from RMSF in 2017 and with the increased number of cases in 2018, there is concern that additional deaths could occur.

The Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Arizona Department of Health Services (ADHS), and tribal communities have been actively engaged in a public health response to the growing issue of RMSF on tribal lands by building sustainable RMSF prevention programs (using evidence-based prevention practices), expanded clinical education, and improving community outreach. While prevention of tick exposure is being scaled up through community campaigns, Arizona requests CDC assistance in rapidly identifying risk factors for severe RMSF illness resulting in neurological deficits and long-term disability so this can be prevented among those who are infected.

Objectives of this investigation will be to:

1. Identify cases of RMSF with persistent sequela or disability.
2. Describe impairments to cognitive, behavioral, motor, and developmental function following RMSF.
3. Characterize risk factors associated with such long-term neurological sequelae.
4. Recommend prevention and control measures to ensure patients receive rapid and effective treatment and follow-up to RMSF infection.

This investigation will involve a retrospective analysis of previously hospitalized cases (between 2002–2017) of RMSF at various stages of recovery. Patient medical charts have already been abstracted by federal staff for information about potential risk factors for severe disease progression, including RMSF testing history, their illness progression, previous medical conditions, type and timing of treatment for RMSF, length of hospital stay, neurologic signs and symptoms during hospitalization, sequelae observed at the time of discharge, recommended follow-up care, and other relevant clinical characteristics (appendix 1). Patients will be interviewed about their recovery (Appendix 2. Patient Screening Questionnaire) and a neurological exam will be performed to evaluate for abnormalities in neurologic function (Appendix 3. Neurologic Exam Form). The purpose of this GenIC package is to request OMB approval for the patient interview form (appendix 2) and neurological function form (appendix 3). Data from 250 previously hospitalized cases have already were collected using the medical chart abstraction form (appendix 1), for which PRA did not apply (data collection was conducted by federal staff).

Data collection for this investigation was initiated in July 2018 following OMB approval on 7/22/2018 under the Emergency Epidemic Investigations (EEI) Generic ICR(OMB # 0920-1011, exp 1/31/2020). Per the terms of the EEI Generic ICR, data collection is approved for 90 days and therefore the currently approved EEI GenIC expired on 10/22/2018. Between 7/23/2018 and 10/19/2018, data were collected from 22 patients (Appendix 2. Patient Screening Questionnaire) and 9 neurological exams (Appendix 2. Neurological Exam Form) were completed. Data collection was not able to be completed within the original 90 days due to delays in local approval processes. Tribal approvals are now in place and we believe the remainder of data collection can proceed. This GenIC requests OMB approval to collect data from the remaining patients. No new burden is associated with this GenIC; the burden was fully requested in the previously approved GenIC.

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):

☐ Healthcare staff (describe):

☐ Laboratory staff (describe):

☒ Patients (describe):

People who were hospitalized for RMSF between 2002–2017 in Arizona will be interviewed (Appendix 2) to identify and describe neurologic symptoms or ongoing sequelae. A parent or guardian will be asked to respond on behalf of children under 8 years. Among those who self-report changes in function or incomplete recovery since RMSF hospitalization, a neurologic exam will be conducted (Appendix 3).

☐ 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.*

State-surveillance data were used to identify patients who were hospitalized for RMSF infection during 2002-2017. Medical charts for these patients (n=126) already have been abstracted (Appendix 1). All patients meeting the case definition will be contacted to participate in the screening questionnaire (Appendix 2). Patients who report experiencing neurologic effects (pain, fatigue, changes in motor or cognitive function) since being diagnosed with RMSF will be asked to participate in the neurological exam (Appendix 3). We anticipate approximately half of the patients screened will report neurologic effects.

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):

☒ Cohort Study (describe):

This investigation will evaluate a cohort of persons hospitalized with RMSF between 2002–2017.

☐ 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):

Screening questionnaire (Appendix 2) will be administered in-person, when possible, or via telephone if necessary. Neurologic exam (Appendix 3) will be performed in person by a federal staff person who is a licensed medical provider. All exams will occur in one of 3 locations where most cases have occurred. Patients who cannot be present at one of these 3 locations will be excluded from the neurological assessment.

☐ 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):

☒ Clinical information/symptoms (describe):

Self-reported neurological symptoms following hospital discharge (Appendix 2). Clinical signs, motor function, and reflexes will be assessed during neurological exam (Appendix 3).

☐ Contact information (describe):

☐ Demographic information (describe):

☐ Environmental factors (describe):

☐ Exposures (describe):

☒ Medical history (describe):

Brief medical history will be requested in patient screening questionnaire (Appendix 2) and neurological exam (Appendix 3) relating to recovery and neurological history subsequent to their RMSF illness

☐ Risk factors (describe):

☐ 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

While the primary purpose of this data collection is public health response and not research, because the investigation includes a medical exam and data collection among children, it was sent forward with a research determination to ensure data collection is in compliance with IRB standards.

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

Name:	Naomi Drexler
Title:	Epidemiologist
Affiliation:	Rickettsial Zoonoses Branch, Centers for Disease Control and Prevention

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/DVBD/RZB
Name:	Naomi Drexler
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:	Naomi Drexler
Date of Certification:	11/13/2018

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

11/17/2018

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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