

**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 # 2014 - 006XXX

Date 05/30/2014

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 risk factors and agent in a suspected measles outbreak among a highly vaccinated population—Federated States of Micronesia, 2014

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

State:

Kosrae

City/County (if applicable)

Multiple

Country

Federated States of Micronesia

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

Agency:

Federated States of Micronesia Department of Health and Social Affairs

Name and Position Title:

Dr. Vita Skilling, Secretary

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).*

To date, there are 10 confirmed measles cases: 2 IgM+ (both ~6 months of age) and 8 nucleic acid positive by NP swab (out of 12 samples tested in Hawaii) in the Federated States of Micronesia. The age of those positive by NP swab range from 23-49 years of age. The children 6 months of age are ineligible for routine vaccination. Of the 8 positives by NP swab, 3/8 had 1 dose of MMR, 4/8 had 2 doses (all reportedly documented doses), raising concern for vaccine failure. The date of rash onset for the first case was 3/17 though preliminary contact investigation puts that person in contact with other people who had fever/rash before his/her illness, with potential cases appearing as early as February. Investigation of this is still ongoing. There are at least 80 suspect measles cases, though cases are also meeting an arbovirus case definition and an influenza case definition potentially meaning this is a mixed outbreak. >67% of cases have been hospitalized, there have been no deaths. Vaccination efforts have started, though it is unclear if this is having an impact on the outbreak yet,

and the effectiveness of this effort is uncertain given the identification of cases among those who are vaccinated. There is concern about spread to other islands in Micronesia which have much lower vaccination coverage than Kosrae. There has been an importation to US already.

An investigation is needed to 1) identify any other agents involved in this measles outbreak (influenza versus arbovirus) 2) determine the extent of the outbreak and who is affected to appropriately target ongoing vaccination efforts 3) determine if vaccine failure is an issue in this outbreak potentially leading to different vaccination strategies 4) determine other risk factors for measles transmission in this highly immunized population so as to mitigate them.

The investigation will include performing contact tracing and active case finding. Medical records might be reviewed to ascertain symptoms and clinical course of measles in this highly vaccinated population to better understand this unusual clinical picture so that appropriate prevention and control measures can be identified. If medical records are reviewed, a medical record abstraction form will be developed in the field. We expect we would abstract the following types of information: Patient age, gender, vaccination status including dates of vaccination, presenting symptoms and onset dates of symptoms. To confirm the etiology, serum (acute and/or convalescent) will be collected from suspect cases. Nasopharyngeal or throat swabs will be collected from cases to isolate measles virus as well as to potentially test for influenza. Samples will be tested at CDC for measles and arbovirus. Biospecimen samples will be collected by FSM personnel, or CDC if this assistance is requested by FSM. A case control study to understand risk factors for measles transmission and potential vaccine failure is planned. A brief questionnaire (Appendix 1) will be administered to both cases and controls. This questionnaire is preliminary and will be modified in the field to fit the specific needs of this investigation. Additional biologic samples might be collected as part of the case control study. Controls potentially could have their blood tested to ascertain immunity to measles. CDC's role in the collection of biospecimens as part of case confirmation or the case control study is not yet defined; CDC is standing by to assist upon request from FSM. Biological samples will be sent to CDC laboratory for testing.

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):

Control subjects will potentially be members of the general public who do not have measles. Biologic specimens might be collected from these individuals. We expect to include two controls for each case. If 150 cases are identified, we will recruit 300 controls.

Healthcare staff (describe):

Healthcare staff are at high risk for measles transmission. They are also administering vaccine as part of this outbreak response and as part of routine immunization. There is a potential for measles transmission to healthcare staff and they will be included if applicable. They might be interviewed regarding vaccine handling/storage if vaccine failure is determined to be a cause. If

interviews are conducted, the interview form will be developed in the field.

Laboratory staff (describe):

Patients (describe):

Confirmed and potential measles cases (patients with fever+rash+ either cough, conjunctivitis or coryza) will be the cases in the case control study. The number of cases will depend on whether additional cases are identified, but we estimate the study will include approximately 150 cases.

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.*

Cases will be selected from the line listing of suspect measles cases. Controls will be people from the community, potentially matched on age and other relevant factors. They will be identified using a door-to-door technique. Briefly, cases will be interviewed in their homes and controls will be sought in neighboring houses. Cases and controls will be interviewed using the same survey instrument.

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):

Suspect and confirmed measles cases will be described epidemiologically. This information will be used to inform vaccination campaigns.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

A case control study will be conducted to identify risk factors for measles transmission and potential vaccine failure whereby factors such as demographics, vaccination history, travel history, and other factors will be reviewed.

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Laboratory testing for suspect measles cases will be attempted. Serum (acute and/or convalescent) will be collected from suspect cases. Nasopharyngeal or throat swabs will be collected from cases to isolate measles virus as well as to potentially test for influenza. Controls potentially could have their blood tested to ascertain immunity to measles. Samples will be tested at CDC for measles and arbovirus. CDC's role in the collection, storage, and transport of these biological samples is not yet defined; CDC is standing by to assist upon request from FSM.

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):

Cases and controls will be interviewed in person by trained staff using a questionnaire (Attachment 1)

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Medical records might be reviewed to ascertain symptoms and clinical course of measles in this highly vaccinated population. If conducted, a medical record abstraction form will be developed in the field.

Biological Specimen Sample

Nasopharyngeal or throat swabs might be taken from cases and blood samples might be drawn from controls. If collected, biospecimen samples will be collected at the time of the face to face interview by FSM personnel, or CDC if requested by FSM. If CDC assists, FSM protocols will be followed.

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):

Fever, rash, cough, conjunctivitis, coryza as well as complications, hospitalization, vaccine history

Contact information (describe):

Time spent in contact with suspected or confirmed measles cases

Demographic information (describe):

Age, sex, ethnicity

Environmental factors (describe):

Exposures (describe):

School attendance and hospital/health facility visits will be queried as transmission has occurred in these settings in other outbreaks.

 Medical history (describe):

Past medical history data, such as underlying medical conditions will be collected.

 Risk factors (describe):

Vaccination history

 Specimen/lab information (describe):

Serum, nasopharyngeal or throat swab for active cases; blood samples from controls

 Travel history (describe):

Travel within Micronesia and outside will be ascertained

 Other (describe):

Contact tracing of measles cases will be executed to determine potential exposures who need to be protected as well as to determine the extent of the outbreak. Thus people who the case came in contact with will be identified.

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

2 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:

Mark Papania

Title:

Epidemiologist

Affiliation:

DVD

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:

NCIRD/DVD/EB

Name:

Mark Papania

Title:

Epidemiologist

Contact Information: *Provide complete contact information. Check box for preferred method(s) of contact during the OMB approval process.*

 Office phone:

404.639.8761

 Home phone: Cell/Mobile: E-mail:

myp7@cdc.gov

 Other:

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, Mark Papania, 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:

Date of Certification:

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

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

EI 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 submitted to OMB

Date/Time approved
