

**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 - 007

Date 04/24/2015

Title of Investigation:

Adverse Health Effects Associated with Synthetic Cannabinoid Use — Mississippi, 2015

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

State:	Mississippi
City/County (if applicable)	Jackson
Country	United States

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

Agency:	Mississippi Department of Health
Name and Position Title:	Dr. Thomas Dobbs, State Epidemiologist, Mississippi DOH

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 April 2, 2015, Mississippi Department of Health reports an increase in the number of adverse health events associated with synthetic cannabinoid use. Since that date, synthetic cannabinoids have been associated with 417 cases of illness, including eight suspected deaths. Forty-three percent of counties have reported at least one case. The Mississippi Department of Health requested the assistance of the National Center for Environmental Health to better characterize the outbreak, identify risk factors for severe illness and death, and prevent further illness.

The objectives of this investigation are to assist the Mississippi Department of Health to:

- 1) Characterize the epidemiology of the outbreak
- 2) Conduct medical record reviews
- 3) Provide medical toxicological subject matter expertise in describing deaths associated with the outbreak
- 4) Identify public health actions that could prevent future illness

The planned investigation will include abstraction of medical records from suspected case patients and interviews with case patients or family member proxies. The characteristics of the persons

affected will be described. CDC investigators will not have access to personally identifiable laboratory data, nor will they have access to any identifying keys.

This GenIC seeks approval for two data collection instruments. To identify potential risk factors and exposures of interest, medical records will be abstracted using Appendix 1 and interviews of case patients or family member proxies using Appendix 2.

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):

Case patients or proxies (family members or neighbors) for people who have died or are too ill to respond will be interviewed (Appendix 2).

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.*

Case patients will be identified by medical record abstractions (Appendix 1)

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):

Data describing the demographic characteristics, exposures, and clinical history of the people who became ill will be collected

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):
We will interview case patients or proxies either by phone or face-to-face interview (Appendix 2)

Telephone Interview (describe):
We will interview case patients or proxies either by phone or face-to-face interview (Appendix 2)

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):
Medical records from health care facilities from 4/2/2015--present will be reviewed by federal and state staff to create a line list of cases that meet the case definition. Information about patients' clinical courses and laboratory data will also be collected (Appendix 1).

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):
Type and frequency of exposure (Appendix 2)

Clinical information/symptoms (describe):

Description of symptoms, hospital course, final disposition (Appendix 1)

 Contact information (describe):

Address, phone numbers in order to conduct interviews (Appendices 1-2)

 Demographic information (describe):

Age, sex, race (Appendix 2)

 Environmental factors (describe):

Environmental exposures (Appendix 1)

 Exposures (describe): Medical history (describe):

Underlying medical condition (Appendices 1-2)

 Risk factors (describe):

Types of exposures (Appendix 1)

 Specimen/lab information (describe): Travel history (describe): Other (describe):

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: Amelia Kasper

Title: EIS Officer

Affiliation: NCEH/DEHHE/HSB

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: NCEH/DEHHE/HSB

Name: Dr. Alison Ridpath

Title: Medical Officer

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:

Alison Ridpath

Date of Certification:

04/24/2015

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

4/25/2015

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