

**REQUEST FOR APPROVAL UNDER THE GENERIC CLEARANCE
OF ASSESSMENT OF CHEMICAL EXPOSURES (ACE) INVESTIGATIONS DATA
COLLECTIONS (0923-0051)**

(Part B: Collections of Information Employing Statistical Methods)

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REQUEST FOR APPROVAL UNDER THE GENERIC CLEARANCE OF ASSESSMENT OF CHEMICAL EXPOSURES (ACE) INVESTIGATIONS DATA COLLECTIONS (0923-0051)

TITLE OF INFORMATION COLLECTION: Flint Rash Investigation

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents will be identified by physicians or the Poison Center, referral from the Environmental Protection Agency (EPA) staff testing water in homes, and self-referral through the 211 call line. Persons with Flint municipal water exposure reporting a current or obviously worsening rash with onset after October 15, 2015, and with no likely alternative etiology constitute the respondent universe. Statistical sampling will not be employed for recruitment.

2. Procedures for the Collection of Information

Persons with Flint municipal water exposure reporting a current or obviously worsening rash with onset after October 15, 2015, and with no likely alternative etiology, will be contacted by telephone and, if they consent to it, interviewed with a standardized questionnaire (Attachment B).

Medical records will be sought for all interviewees who have been evaluated by a health care provider. The medical records will be reviewed and data abstracted using a standardized data collection tool (Attachment C). Abstractions may take place at the physician's or dermatologist's office or be faxed into the secure fax at the Michigan Department of Health and Human Services (MDHHS).

The team lead from the MDHHS has the primary responsibility for the survey data analysis and the ATSDR team has the primary responsibility for medical chart data analysis. Descriptive statistics (including frequencies, means, and ranges) will be calculated to describe the demographics of the respondents and their potential exposure levels. Frequencies will be calculated for other types of data such as reported acute signs/symptoms and types of medical care received. Additional bivariate and multivariate analyses may be conducted to identify risk factors for rash or other illnesses. Statistical analysis beyond descriptive statistics will be conducted in consultation with a statistician/data analyst from the requesting organization, CDC, or ATSDR.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Participation is completely voluntary. Partners (EPA, the Poison Center, and 211 call line staff) will encourage participation. In addition a press release describing the investigation and how to participate has been distributed.

4. Tests of Procedures or Methods to be Undertaken

The rash questionnaire (Attachment B) was developed based on one used by CDC in an Epi-Aid in the past (conducted under OMB Control No. 0920-0008, expiration date 07/31/2014). They were used in the field to investigate three incidents, then, in 2011, the general survey was revised to improve clarity and ease of use and pilot tested by a contractor.

The medical chart abstraction form (Attachment C) was developed drawing some ideas from the ATSDR ACE medical record abstraction form. The ATSDR ACE form has been used in multiple investigations and modified based on lessons learned.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The investigators leading the ACE investigation field responses and analyzing the data are trained in biostatistics and epidemiology. Investigators will collaborate extensively with health officials at MDHHS throughout the process of data collection and analysis. The investigation will be supervised by MDHHS and ATSDR's experienced epidemiologists. Additional statistical resources are available at both ATSDR and CDC.

Because the investigation is a public health response and not a planned research study, the analysis will be descriptive. Statisticians will be consulted if sampling or a more complicated analysis is needed.