

**Standardized National Hypothesis Generating Questionnaire
Supporting Statement B**

**Request for OMB Approval
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Contact:

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

There will be no statistical methods used to select respondents for this data collection. Interviews will be conducted with cases of enteric disease identified as part of a multistate outbreak investigation. Based on the estimated number of cases of foodborne disease in the U.S. and the proportion of those cases that are outbreak associated, it is estimated that the SNHGQ would be administered to approximately 4,000 individual respondents across all jurisdictions each year.

2. Procedures for the Collection of Information

Participant Recruitment. Respondents will be cases of enteric disease, or their proxy, identified as part of a cluster or outbreak investigation. Officials in state and local public health departments will contact cases, or their proxy, to conduct the interviews.

Interviews. The SNHGQ is designed to be administered by state and local public health officials via telephone interviews with cases of enteric disease or their proxy.

Collection of the SNHGQ data elements will employ quantitative and qualitative methods, including telephone interviews, designed to elicit core elements exposures from respondents. Interviewers will be able to probe further about specific food or other exposures reported by ill persons using the open-ended elements included in the SNHGQ . For example, when an ill person reports eating food outside the home, the interviewer would ask about the specific name and location of the store as well as any specific food items the ill person recalled eating there. The burden associated with answering these open-ended elements of the SNHGQ was accounted for in the burden estimates provided in Part A. There are no research questions addressed; standardized data will be compiled on recent food consumption history and other exposures related to enteric diseases in the context of responding to acute multistate infectious disease outbreaks.

The SNHGQ will collect data on a vast array of potential exposures of importance for investigating multistate outbreaks of various enteric disease pathogens, including:

1. Demographics with no individually identifiable information
2. Travel history
3. Points of service for purchasing foods eaten at home and foods eaten away from home
4. Special diets and dietary restrictions
5. Meat, poultry, fish, and seafood
6. Eggs and dairy
7. Fruits and vegetables
8. Frozen foods
9. Nuts, grains, cereals, snack foods, and drinks
10. Animal contact

The SNHGQ is available in a fill-able PDF format that allows the interviewer to submit completed interview data via e-mail as an XML file format. The use of the fill-able PDF questionnaire limits the burden of needing to enter data from a paper-based form submitted via facsimile into an electronic format. The SNHGQ is also available for use in a non-fillable format for those who choose to not submit data electronically. In this case, data will be submitted via facsimile to CDC where ORPB epidemiologists transcribe the data into the fill-able PDF to obtain the XML file format of the submitted data. (See Attachment C).

3. Methods to Maximize Response Rates and Deal with No Response

In general, State and local public health officials will make every effort to contact cases identified as part of a multistate outbreak, as resources allow. Policies vary, but many jurisdictions attempt to contact a case at least three times before deeming them 'lost to follow-up'. The SNHGQ is designed to be administered in approximately 45 minutes via telephone interview, so the burden on cases to complete the interview should be sufficiently low to maximize response rates.

4. Tests of Procedures or Methods to be Undertaken

The SNHGQ was created collaboratively with public health officials who will be conducting the interview. Voluntary use of the elements included in the SNHGQ among some State and local public health officials has resulted in positive feedback indicating that the content is appropriate. Additionally, internal testing used fabricated exposure data to be sure that data elements will be ascertained and recorded accurately when using the SNHGQ.

Because information collected on the SNHGQ data elements is for hypothesis generation in multistate outbreak investigations, analytic work will focus on generating frequency distributions (using SAS) for demographic variables as well as food and other exposure variables included in the SNHGQ. These frequency distributions will also be cross-tabulated across demographic and exposure variables. The primary objective of the descriptive analyses is to identify food and other exposures with high reported frequency among cases and to describe the demographic characteristics of cases.

Once a group of exposure variables of interest are identified through descriptive analysis, the reported frequencies among cases are compared to frequencies from other data sources to assess whether reported exposure frequency among cases is higher than expected. This can be accomplished by comparing reported exposure frequency among cases to the proportion of persons in the general population reporting these same exposures using the FoodNet survey, a population-based survey of healthy persons in ten states. The comparison of reported exposure frequency among cases to the population exposure frequency is accomplished using a binomial distribution, and permits estimation of the probability of observing the exposure frequency among cases by chance alone given the population exposure frequency. As more SNHGQ data are reported to ORPB over time, a similar calculation may be performed comparing current outbreak-related cases to exposures reported among cases in past multistate outbreak investigations. Any additional analyses required to understand the relationship between exposures and illness in a multistate outbreak investigation exceed the scope of the SNHGQ.

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

Epidemiologists from federal and state agencies were involved in developing the SNHGQ.

The Outbreak Response and Prevention Branch will be responsible for managing and reviewing submitted data. The principal investigator and project director is Dr. Ian Williams. He can be reached by phone at 404.639.2210 or by email at iaw3@cdc.gov.