SALT SOURCES STUDY

New Request

OMB Supporting Statement: Part A

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Abstract

CDC requests OMB approval to collect information in an observational study and validation sub-study known as the **Salt Sources Study**, or the Assessment of the Proportion of Sodium Intake from a Variety of Sources. This is a new request. The data collection period is two years. OMB approval is requested for two years.

Respondents will be a convenience sample of adults aged 18-74 years, able to read and speak English, who have a telephone. Respondents will be excluded if they are pregnant, breastfeeding, have diabetes insipidus, or have chronic kidney disease. Information will be collected from the study participants by three study sites, one of the three sites funded through a research contract also will serve as the coordinating center. The contractor (coordinating center site) will transmit a final de-identified dataset to CDC at the completion of the study. Information collection will support 1) an observational study among 450 participants to estimate the proportion of sodium consumed from various sources (including sodium added during commercial processing and preparation, sodium inherent (naturally occurring) in foods, salt added at home during cooking and at the table, sodium from intake of supplements and antacids, and sodium from water) and 2) a sub-study among 150 of the participants in the observational study to determine the accuracy of estimates of total sodium intake and discretionary salt intake.

JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Justification and Background. Stroke and coronary heart disease are directly related to blood pressure, are the leading causes of morbidity and mortality in the United States, and account for billions of dollars in health care costs and productivity losses annually. About 67 million US adults, 31 percent of the population, have high blood pressure. Sodium intake directly and progressively increases blood pressure and subsequently increases the risk of heart disease and stroke. It has been estimated that an average reduction of as little as 400 mg of sodium daily, or about 11% of average U.S. sodium intake, would prevent more than 28,000 deaths and save 7 billion health care dollars annually. Recent evidence also indicates excess sodium can damage the heart, vessels, and kidneys aside from increasing blood pressure. Reduction in US sodium intake is one of CDC's *Winnable Battles*, a component of the *Million Hearts*™ initiative, and a *Healthy People* 2020 objective. The *Dietary Guidelines* (DGA 2010) call for Americans aged 2 years and older to reduce their sodium intake to prevent cardiovascular disease, about half to 1,500 mg per day (e.g., African Americans, individuals aged ≥51 years, and individuals with hypertension, diabetes, or chronic kidney disease) and the remainder to <2,300 mg per day. *Healthy People* 2020 objectives call for a reduction in average sodium intake to 2,300 mg per day.

Efforts to reduce sodium intake in the U.S. population have been ongoing for at least four decades and received support from Congress in fiscal year 2008 when appropriated funds were given to the Centers for Disease Control and Prevention (CDC) for an Institute of Medicine report to evaluate national strategies for sodium reduction and annual reporting of results. In spite of these efforts, the estimated average intake of sodium from all sources among Americans aged 2 years and older (~3,460 mg per day in 2009-2010) is in excess of both DGA 2010 and *Healthy People* 2020. A major reason for the inability to lower dietary sodium intake is the levels of salt added before purchase to processed and restaurant foods in the United States.

A study conducted in 1991 by Richard Mattes and Diana Donnelly identified that 77% of sodium consumed was from sodium added during commercial processing and preparation (packaged and restaurant foods), about 11% came from salt added at the table or during cooking, and 12% was naturally occurring (inherent) in food and beverages. Very small percentages (<1%) came from water or supplements. Results from this study are used repeatedly to inform and prioritize efforts to reduce sodium in U.S. processed and restaurant foods. The data is also used to inform estimation equations for discretionary sodium intake (salt added at the table) as part of *Healthy People* 2020 objectives to monitor average total sodium intake. The study by Mattes and Donnelly is over 20 years old and included a small convenience sample (N=62) of predominantly white adults from one geographic location. The applicability of the results of this study to current sodium intake and to people in other race-ethnic groups, age groups, or residing in other geographic locations is unknown. Food habits have changed over the past 20 years and could impact the amount of sodium consumed from different sources. These changes include, but are not limited to, increases in eating out and decreased fluid milk consumption. In addition, demographic shifts in age, race-ethnicity, and residence may alter these estimates due to differences in food patterns among different population subgroups. The intent of this project is to provide current baseline estimates of the sources (including sodium added during commercial processing and preparation, sodium inherent [naturally occurring] in foods, salt added at home during cooking and at the table, sodium from intake of supplements and antacids, and sodium from water) of dietary sodium intake in the United States in a larger, more demographically diverse sample of adults.

To reduce sodium intake the Institute of Medicine (IOM) (2010) recommended phased reductions in the sodium content of commercially processed foods and menu items. The Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service recently solicited public comments on this and other strategies. The IOM also recommended that industry voluntarily reduce sodium content of foods. Several food manufacturer and restaurants have committed to voluntary reductions in some of their food products, some as part of New York City-led National Salt Reduction Initiative. In addition, local efforts such as the Sodium Reduction in Communities program funded by CDC support national initiatives by

implementing strategies to reduce sodium in local restaurants and other food service outlets.

There is a critical need to update the >20 year old estimates of the proportion of total sodium intake added during commercial food processing and preparation and to describe sociodemographic and other characteristics associated with these estimates. Along with nationally-representative data from the National Health and Nutrition Examination Survey (NHANES; OMB No. 0920-0950, exp. 11/30/2015), the new estimates produced by the Salt Sources study may inform estimates of total sodium intake used to monitor *Healthy People 2020* objectives.

The Salt Sources Study will update and expand the previous study conducted by Mattes and Donnelly to include a convenience sample of participants in three geographic locations (Minneapolis-St. Paul, Minnesota; Birmingham, Alabama; and Palo Alto metropolitan area, California) in separate U.S. census regions. Study centers in each of three geographic locations will recruit 150 participants each (total N=450) through fliers, brochures, or lists of persons who have participated in previous studies or agreed to be contacted for participation in studies with the aim to recruit an equal number of adults ages 18-74 years by approximately 10-year age groups in each sex-race group, including whites, blacks, Hispanics, and Asians. The contractor (coordinating center) will recruit and collect data from participants at their site and will work closely with investigators in two other sites to recruit participants and collect the data and provide current and accurate estimates of the amount of sodium consumed from various sources (including sodium from processed and restaurant foods, sodium inherent in foods, and salt added at the table and during cooking). The investigators at all sites are highly experienced and collaborative and have established infrastructures for recruitment and data collection at all three sites. Observational protocols will be developed collaboratively with CDC and the study sites. De-identified data will be transmitted to the contractor. CDC will receive a de-identified analysis data set and final report from the contractor. These activities are authorized by section 301 of the Public Health Service Act (42 USC 241, Part A, Research and Investigation (See **Attachment 1).**

A.1.1 Privacy Impact Assessment

Overview of the Data Collection

The Salt Sources Study will involve three geographically dispersed study sites of which one includes the contractor (coordinating center). Participants will be equally enrolled across the three sites. For each participant who is screened by telephone and consents to participate, data will be collected during an 11-day period according to the scheme shown in the **Table A.1** below. This table is also provided in Attachment 3, Overview of Data Collection Protocol.

Table A.1. Study participant activities that will be completed over 11 days

Activity	Baseline visit	T 1	FUV 1[a, c]	T 2	FUV 2[a]	T 3	FUV 3[a]	T 4	FUV 4[a]
Consent	**X**								
24-hour recall instructions[b] /recall appts scheduled	**X**								
Survey	**X**								
24-hr diet recalls, food record and duplicate salt sample collection[c]		**X**		**X**		**X**		**X**	
Urine collection instructions/kits distributed [a]	**X**		**X**		**X**		**X**		
Return 24-hr urine samples[a]			**X**		**X**		**X**		**X**
Study salt distributed[a,d]			**X**		**X**		**X**		
Study salt returned[a]					**X**		**X**		**X**
Incentives disbursed[e]			**X**		**X**		**X**		**X**

T = telephone diet interview; FUV = follow up visit

[a] Only for those participating in the sub-study.

[b] Includes providing food amount booklet; duplicate salt collection kits.

[c]Food recording and duplicate salt sample collection and recording will take place the day before the 24-hour dietary recall is scheduled.

[d]Provide the study salt supplement to participants enrolled in the sub-study beginning at FUV 1

[e]The incentive for completing the 24-hour dietary recalls will be mailed to those not participating in the sub-study.

Data will be collected through:

1) an observational study of sources of sodium intake among all participants aged 18-74 years (N=450 participants, 150 per site); and

2) a sub-study on 1/3 of the participants in the observational study (N=150 participants aged 18-74 in the observational study [50 per site]).

Personal identifying information (PII) from all study sites will not be sent to CDC, but will be kept locally at the study sites. A de-identified dataset will be sent to CDC at the completion of the study. All study personnel including the contractor and subcontractors will be trained in the appropriate management and security of study data.

Items of Information to be Collected

The information collected from all participants will include detailed information about the sources of sodium intake including foods and beverages (including water), supplement use, salt use at the table and in cooking, as well as measured height and weight. A subset of these participants will use study supplied salt and collect 24- hour urine for the substudy. A list of data collection instruments and supplementary documents is shown in **Attachment 3.** Data collection forms for the study are included in **Attachments 4A-17A. Supplementary d**ocuments supporting data collection are included in **Attachments 4B-17D.**

Contractor and Subcontractor Sites

The contractor site is the University of Minnesota and the two subcontracted study sites are the University of Alabama and Stanford University. Additional contact details are listed in **Attachment 18.**

A.2 Purpose and Use of the Information

The Salt Sources Study will produce current estimates of the sources of sodium intake across a diverse convenience sample of adults aged 18-74 years living in the United States. Estimates will include, but not be limited to, objective measurement of the proportion of sodium consumed from discretionary sources (salt added at the table or during home cooking and food preparation, estimated at ~11% of total sodium intake in a >20 year old study). Other sources of sodium intake include the amount of sodium consumed from sodium naturally occurring (inherent) in foods, from sodium in drinking water, and from sodium in antacids and supplements.

The amount of sodium added during commercial food processing and preparation in a food will be estimated by subtracting sodium from all other sources from total sodium content in that food. Aside from sodium added during commercial food processing and preparation (i.e., salt and other sodium-based ingredients or compounds), total sodium content of a food can include sodium inherent (naturally occurring) in a food, sodium added during home cooking or food preparation, sodium added at the table, and sodium in water. Estimates will be adjusted for sodium lost through food preparation or processing, e.g., sodium in lost in cooking water or sodium from draining and rinsing canned legumes.

Information from the study will be used to explore key sociodemographic (e.g., age, sex, race-ethnicity, place of residence) and other determinants (e.g., season) of differences in the ratio of sodium added during commercial food processing and preparation to total sodium intake. This information may be used to generate hypotheses regarding the sources of sodium intake among adults, and may contribute to the development of public health interventions.
The specific aims of the observational study are to:

1)
2) Update and improve upon >20 year old estimates of the proportion of total usual sodium intake (from all sources) added during commercial food processing and preparation among a convenience sample of adults aged 18-74 years. Determine whether sociodemographic characteristics of study participants (i.e., race, sex, age, place of residence [e.g., Palo Alto vs. Minneapolis]) as well as other characteristics (e.g., season of the year) are associated with the ratio of sodium consumed from sodium added during commercial food processing and preparation to total sodium intake.
3) Determine the correlation between estimated sodium intake from self-reported use of discretionary salt with objectively measured intake of discretionary salt using duplicate portion assessment.

The specific aim of the sub-study are to:

1) Assess the accuracy of estimates of discretionary sodium intake (salt added at the table and during home cooking and food preparation) compared with biological markers (the amount of lithium in 24-hour sodium excretion). Estimates of discretionary sodium intake include a) self-reported frequency of use of table salt and cooking salt and b) sodium assessed from the duplicate salt portion method.
2) Assess the accuracy of estimates of total sodium intake (from all sources) compared with 24-hour urinary sodium excretion. Estimates of total sodium intake from all sources include estimates from a) 24-hour dietary recalls, supplement and antacid use, and self-reported frequency of table salt use (*Healthy People 2020 model)* or b) 24-hour dietary recalls, supplement and antacid use, and the duplicate salt portion method.

To meet the objectives and aims of the Salt Sources Study, the following actions will be carried out and information will be collected:

1) Telephone Recruitment and Screening questions including demographic characteristics, health characteristics, and determination of access to a telephone (see **Attachment 4A**). Cover letters and the study fact sheet (FAQ) will be sent by mail to those who are unsure about participation or cannot be contacted by telephone (see **Attachments 4B-4C)**.
2) A Participant Questionnaire will be administered at the baseline visit (see Table A.1) to review study procedures, to administer informed consent, and to collect contact

information as well as confirm information on demographic characteristics from the Recruitment and Screening form, and collect information on smoking status, self-reported high blood pressure and diabetes, and use of medications for high blood pressure and diabetes (see **Attachment 5)**.

3) Questions used in NHANES to assess the use of salt added at the table and during cooking at home also will be asked at the baseline visit after the participant questionnaire (see **Attachment 6).**
4) Participant's Height and Weight will be measured and recorded at the baseline visit using a standard form, protocol, and equipment (see **Attachment 7**).
5) At the baseline visit, the procedures for four telephone 24-hour dietary recall interviews including questions about supplements and duplicate salt sample collections will be explained to the participant and will be scheduled over the next 11 days with one scheduled on a weekend day. Among the study participants, the forms and explanations (instructions) are slightly different for sub-study and non-sub-study participants because sub-study participants are replacing their household salt used at the table and during cooking with the study salt **(Attachment 8 and Attachment 9)**.
6) Also at the baseline visit, all participants will be asked two questions about their a) source of tap water and b) use of a water softener or filtration system (See **Attachment 10A1**). Participants who report their home tap water is from a private well or cistern will be given a home water collection kit with instructions on how to collect the water and send the sample through the mail in pre-stamped envelopes (see **Attachment 10A2**). Instructions for study staff are provided in **Attachment 10B.**
7) On **four** subsequent days (see Table 1, T1-T4), the 24-hour dietary recall interview will be collected **from each participant** using the 2012 version of the Nutrition Data Systems for Research (NDSR) nutrient calculation software. NDSR is a computer-based software application developed by the Nutrition Coordination Center (NCC) at the University of Minnesota. The application allows for direct entry of dietary data in a standardized fashion. The NDSR uses a multiple-pass technique to prompt for complete food and beverage recall and descriptions. At the beginning of each 24-hour dietary recall interview, the participant is read an introduction script. The introduction script, screen shots, and the instructions for the 24-hour dietary recall Interview are included in **Attachment 11A**. A food amount booklet provided to participants at the baseline visit will be used to help participants estimate food and beverage amounts during the 24-hour dietary recall **(Attachment 11B).**
8) To assist with the 24-hour dietary recall interview, the participant also will record foods and beverages consumed on the day prior to each of the 24-hour dietary recall interviews (procedure explained at the baseline visit). The food record form and instructions are included in **Attachments 12A** and **12B**, respectively.
9) The participant also will collect salt added at the table and during cooking on the day prior to each of the four 24-hour dietary recall interviews (T1-T4 in Table 1). The duplicate salt sample collection form will be filled out by study participants (both non-sub-study and sub-study) on the day prior to the 24-hour dietary recall interview (**Attachments 13A and 14A).** Each participant will be instructed to collect a duplicate

portion of salt used at the table in one bag and salt used during home cooking in a second bag and record the foods to which salt was added and the type of salt used (**Attachments 13B and 14B)**. Pre-addressed stamped envelopes will be provided to the participant for mailing. This technique has been used in previous studies for the objective measurement of discretionary salt and allows the participant to use their own salt (non-sub-study participants). Participants in the sub-study will use the study salt and have slightly different forms and procedures because of this.

To meet the objective of the sub-study, the following additional actions will be carried out and information will be collected from the sub-study participants:

1) At the baseline clinic visit, the participant will be provided with instructions and equipment for collecting 24-hour urine. The participant will be asked to record the start/end date and time of each 24-hour urine collection and return the collection jug(s) with urine to the clinic on the day following collection (the form is provided in **Attachment 15A** and participant instructions in **Attachment 15B**).
2) At each of the 4 follow-up visits (see FUV 1- FUV 4, Table 1), the participant also will be asked about their 24-hour urine collection (**Attachment 16A).** Participants who were unable to successfully complete the 24-hour urine collection will be asked to re-collect it.
3) At the first follow-up visit for 24-hour urine collection (FUV 1), the participant will be instructed regarding the use of study salt supplement (study salt) and will be provided with study salt to use at the table and during cooking. The study salt contains a small amount of lithium that is excreted in the urine. This marker is used to assess the amount of discretionary sodium consumed. At the 2nd, 3rd, and 4th follow up visits (FUV 2 – FUV 4), the participant will be asked about his/her use of the study salt (**Attachment 17A).**

A.2.1. Privacy Impact Assessment

As part of this study there will be no collection of protected health information (PHI)* from subjects in the course of providing treatment/experimental care and there will be no access to PHI* in the subjects' records. Any health-related information will be obtained directly from the research participant. Medical records will not be accessed or used to document study information. Participants are not provided treatment/experimental care as part of this study.

Information on participants will be de-identified before being sent to CDC. First, each study site assigns a unique identifier (ID) code to each participant identified at the site. For collecting the 24-hour dietary recall, each site will send the Nutrition Coordinating Center (NCC), which is located at the contractor site, the ID code, the first name of the participant, and phone number, and scheduled interview times at which to reach them in an encrypted EMAIL from the study site to NCC**.** Upon completion of the dietary interviews, the NCC will destroy the identifiers. Information on diet and nutrient intake reported from the NCC to the contractor will include the ID code, but no other identifiers. Except for the information sent to the NCC, the

information sent from the two study sites to the contractor does not include names, phone numbers or other participant identifiers. Urine specimens collected from the three study sites and sent to the laboratories (see Part B) via FedEx will include the ID code, but no other identifiers. The contractor will not accept a method of record identification from the other two study sites such as a social security number that can be linked to other databases.

The identifying information provided to the contractor with data collection forms will include a randomly generated site specific participant ID code, the state of residence, age (in years) and race-ethnicity (in one of four categories). Each site must enroll a minimum of 25 participants in a race-ethnic category. Each of the three study sites (including the contractor) is solely responsible for maintaining a unique list linking the site specific ID code with the participant's name as well as the encryption information associating their unique ID codes with personal identifiers maintained by the site. Identifiers will be stored in a locked file cabinet. Personal identifying information will be destroyed at the completion of the study. Neither the encryption scheme nor identifying information, other than the variables noted above, will ever be provided to the contractor.

Computer files with participant information are maintained on a secure division/department internal network drive systems at each study site and by the NCC. Generally, files are protected by two levels of security. First, Windows authentication prevents anyone except the Principal Investigator (PI) or Project Coordinator at each study site from having access to the file. Second, the file is password-protected, and only the PI and Project Coordinator at each site have the password. During the active phase of the study, participant study forms will be kept in a locked file cabinet in each study center in the Project Coordinator's office (also locked). During the study data collection phase, data from the questionnaire and tracking forms will be directly entered by each study site into a password protected computer configured with the latest operating system and ant-virus software patch levels. Specimens will be sent by overnight delivery to the contractor laboratories. No data will be transferred by EMAIL with the exception of the first name, id number, and phone number sent by each study site to NCC by encrypted EMAIL. The study personnel will have digital certificates that their email software will automatically encrypt all emails sent to each of the study clinics. Email content will be readable only by the intended recipient, and messages will be assured to have come from the indicated sender. The original study forms at each university will be maintained in a secure medical records room, a "high security level," which means that access is strictly restricted to specifically authorized personnel only. No other staff is permitted unless they are under direct observation. Doors are locked at all times except for authorized entry/exit.

The data provided to the contractor and the NCC will be archived on secure network servers with user ID and password restricted access at the location of the contractor. Access rights and restrictions to the network resources are determined by user ID and a study specific password. Network systems are maintained in a locked room with access strictly limited to essential employees. A de-identified dataset will be provided to CDC at the conclusion of the study.

A.3 Use of Improved Information Technology and Burden Reduction

The Salt Sources Study staff at the NCC will collect information on diet over the telephone (4 times) using a computer based software application that allows for direct entry of dietary data in a standardized manner, the 2012 Nutrition Data Systems Research (NDSR) nutrient calculation software. The NDSR provides the capability to collect diet information using automated methods that are fast, cost-effective, and convenient. Additional data collection includes in person interview, duplicate portion collection of salt added at the table and during cooking, and in limited subgroups, water collection and 24-hour urine collection. The use of duplicate portion collection of salt added at the table and during cooking provides a less burdensome and more accurate collection than through detailed questionnaires or paper records. Water collection will be limited to participants who report their home tap water is from a private well/cistern or that they have a home water softener or water filtration system. From previous data, it is believed this will be a very small subset of the participants (at the most 10 per site over the two years). For certain collections, such as recording start and stop time of urine collections, paper questionnaires were chosen for participant convenience.

A.4 Efforts to Identify Duplication and Use of Similar Information

Through consultation, it was determined that other federal agencies are not engaged in duplicate data collection activities, including the National Heart Lung and Blood Institute of the National Institutes of Health, the Food and Drug Administration, and the U.S. Department of Agriculture, Agricultural Research Service.

The Salt Sources Study data are unique in that no other current data source includes direct and objective measures of individual sodium intake from discretionary salt (i.e., salt added at the table and during cooking). As indicated previously, data from the National Health and Nutrition Examination Survey (NHANES) can be used with other data to crudely estimate the amount of sodium from a brief set of questions about the frequency of salt added at the table or during cooking. However, the questions used for these estimates rely on other data (i.e., observational nutrition studies, such as that conducted by Mattes and Donnelly in 1991 and proposed in the current study) for estimates of the measured amount of salt added at the table.

Similar to NHANES, the NDSR software employs a state-of-the-art, automated multi-pass 24-hour recall interview method administered by trained interviewers to assist the individual in accurately recalling the foods consumed in the previous 24-hours. As part of the interview, participants are asked to recall brand names and flavor/varieties of the foods and beverages consumed. The NCC Food and Nutrient Database used with the NDSR-assisted recall includes more brand name products than NHANES, about 7,000 leading brand name products in the NCC Food and Nutrient Database. For brands

included in the database, all favors/varieties of the brand are generally included. Similar to the nutrient database used with NHANES, the Food and Nutrient Database for Dietary Studies, the sodium content of foods in the NCC Food and Nutrient database is updated yearly based on several sources including the National Nutrient Database for Standard Reference. Sodium content data from 2012 or later will be used to calculate intakes. The nutrient information of reported foods that are not in the NCC Food and Nutrient database used with the NDSR software is ascertained through internet searches and manufacturers and entered in the database as needed. Data collection and coding also generally account for salt lost during cooking and draining and rinsing of vegetables.

Unlike NHANES which employs two 24-hour dietary recalls, participants in this study will participate in up to four 24-hour dietary recalls over an 11- day period. In addition, participants will be asked to prospectively record the foods they consumed to assist in their recall and to record the foods to which salt was added during home cooking or preparation. As explained earlier, participants also will be asked to collect duplicate portions of salt added at the table and during home cooking and preparation. Finally, during the same day for which the foods and beverages are reported, a subset of participants will be asked to collect four 24-hour urine samples to validate total sodium intake and to use labeled salt at the table and during home cooking to assess the amount of sodium from discretionary salt.

Due to the need for multiple days of data collection and salt collections and, in a subset of participants, 24-hour urine collections and use of study salt, the participants recruited in this study are not representative of the U.S. population.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6 Consequences of Collecting the Information Less Frequently

This is a single two year project, with no current plans for repetition. Participants are asked to collect four 24-hour dietary recalls and for some, four 24-hour urine collections, over an 11 day period with some of the recalls 3 or more days apart. The multiple collections are needed to account for within-individual variation in sodium intake. Because of weekend versus weekday differences in diet, it is preferable to have respondents complete the diet recalls or 24-hour urine collections on as many different days of the week as possible with one collection on a weekend day. Participants are asked to collect four 24-hour recalls or urine collections as evidence suggests that this is more accurate compared with data collection methods that are administered once and require participants to recall their diet over a period of time (e.g., one month).

Collecting information less frequently would result in an incomplete assessment of diet on the individual level.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data collection described in this request is consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances.

A.8 Comments to the Federal Register Notice and Efforts to Consult with Outside Agency

The 60-Day Federal Register notice soliciting comments on this study was published in the Federal Register on March 4, 2013, Vol. 78, No. 42, pp. 14092-14093 (**Attachment 2A).** One non-substantive public comment was received and acknowledged (see Attachment 2B, Summary of Public Comments and CDC Response).

The study was developed with consultation from scientists within and outside the agency. The OMB application was sent for review to scientists at the National Institutes of Health, the Food and Drug Administration and U.S. Department of Agriculture (see **Attachment 18** for a list of those consulted).

A.9 Explanation of Any Payment or Gift to Respondents

All participants in the Salt Sources Study will be offered up to $40 to show appreciation for their participation and those in the sub-study will be offered an additional $80 (a total of up to $120 for participation in both the main observational study and the substudy). Specifically, participants will receive $10 to show appreciation for each of the telephone 24-hour diet recalls and duplicate salt collections for a total of $40 if all four days are completed. Participants selected for the sub-study may receive up to an additional $80, $20 for each time a urine sample is brought to the clinic. The $20 per urine sample acknowledges the time and effort associated with both urine collection and transportation to the clinic. Parking is free at the clinic.

The level of token of appreciation offered in this study has been offered in previously conducted studies with good participation rates including the examples listed below:

a) INTERMAP: The Minnesota Center offered their participants about $80 for 4 visits, including four 24-hour recalls and two 24-hour urine collections; 4 X $10 per 24-hour recall and 2 X $20 per urine collection = $80. The participation rate was about 90%.

b) CARDIA offers their participants about $50 for a 5-6 hour visit. Since this is a cohort study, the incentive or response rate may not be applicable to the proposed study. Response rate varies between field centers from 83% to 76%.

c) Minnesota Heart Survey has offered $35 to $60 for two visits over the past several surveys, although participants were not asked to collect 24-hour urine collections. Participation rate in MHS was 65% to 69% across the various cross-sectional surveys in 1980 to 2007.

A.10 Assurance of Confidentiality Provided to Respondents

A.10.1 Privacy Impact Assessment Information

The Salt Sources Study information collection has been approved by the IRBs at University of Minnesota (contractor), and the subcontractor sites (Stanford University and University of Alabama) (see **Attachment 20 for IRB approval from University of Minnesota)** and CDC. Each participant in the study is administered and signs an informed consent document describing the voluntary nature of participation and states the procedures to keep information private (see **Attachment 21**).

Access to study data is limited to staff working on the study (clinical managers and diet interview staff) at each study site. Local access to data is governed by requirements of the local IRB. Additional safeguards include a process to de-identify at the clinic site as described below.

A. Privacy Act Determination. This submission has been reviewed by National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and CDC's Information Collection Review Office, which determined that the Privacy Act applies to participant-level information collected by the study sites. The applicable System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. The Privacy Act does not apply to the de-identified information collected by the coordinating center study site and subsequently transmitted to CDC, as the coded information cannot be filed or retrieved by participant name. The de-identification process is described in more detail below.

   The three study sites (one of which is the contractor) remove patient name and other direct identifiers from all data collection forms and assign a randomly-generated, site-specific participant ID code to each record before transmission outside of the study site. Each study site maintains and protects the information that links direct participant identifiers to the site's participant ID codes. The combined de-identified data will be transmitted to CDC from the contractor. CDC does not have the capacity to re-link the de-identified coded information that it receives to direct participant identifiers such as name, address, or phone number.

B. Administrative Safeguards. All study personnel will be trained in the appropriate and sensitive means of data collection.

C. Physical and Electronic Safeguards. Information will be obtained from multiple sources: In Person Surveys, Telephone Surveys (24-hour diet recalls), In Person Visits (including

height and weight, questionnaires, laboratory studies of urine). Electronic and paper forms used for data collection will be distributed to the study sites by the contractor.

Data from the study sites collected for the Salt Sources Study will be directly entered into a a standard form using independent computers at each study site. Data will be sent from each study site to the contractor on encrypted flash drives using overnight delivery. Access to the study's data will be restricted to the members of the study team by username and password.

Urine specimens collected from participants in the sub-study will be sent from the study sites to the contractor Laboratory by overnight delivery. Data from the University of Minnesota laboratory will be entered in an independent computer at the main contractor site as indicated below. Data from the outside sub-contracted laboratory will be sent on an encrypted flash drive using overnight delivery. The outside laboratory will not have access to the contractor website or server. Data from the 24-hour dietary recalls collected by the NCC will be entered by NCC into their own software (NDSR software on NCC computers). The resulting data from NCC, the laboratory, and other study sites, will be placed on the University of Minnesota computer and will be password protected. The computers used for data collection, storage, and analysis will be configured with the latest operating system and anti-virus software patch levels.

D. Consent. The research at each clinical site is overseen by its Institutional Review Board. As required by 45 CFR 46, each site obtains consent from the adults who participate in the research (**Attachment 21**).

E. Nature of Response. Respondents are the study participants at each clinical site. Transmission of a de-identified dataset to CDC via the contractor is required under the terms of the contract that provided funding for the research.

A.11 Justification for Sensitive Questions

PII is being collected in this study. In conducting this study it is important to capture data on medical conditions, diet and socio-demographic characteristics. Additionally, name, home address, email address, and phone number will be collected and retained throughout the active study period because this information is necessary for maintaining contact with the participant. The data sets created will contain no means of identifying individual participants.

Salt Sources Study investigators collect potentially sensitive information on baseline forms. Study aims cannot be achieved without the collection of sensitive, or potentially sensitive, information. The justification for each item is detailed below.

- Racial/ethnic group - necessary for subgroup analysis by race/ethnic group to evaluate differences in sources of sodium intake.

- Living arrangements – Living alone means one has more control over foods cooked and consumed. Having less control over salt used during cooking may affect assessment of sodium intake.

- Medical issues – questions and measures pertaining to acute and chronic health conditions related to high blood pressure, diabetes insipidus, diabetes mellitus, kidney disease, pregnancy or lactation, are necessary as these measures can affect diet or assessment of sodium from 24-hour urine collection.

- Smoking status – questions about smoking status are collected because smoking influences appetite. Calorie and sodium intake are highly correlated. Thus, this question may help explain low sodium intakes.

- Dietary or food intake – this is the main purpose of the study. Nutritionists trained to assess dietary intake using neutral probing techniques and following a standard protocol.

A.12 Estimates of Annualized Burden Hours and Costs

Respondents will be the Salt Sources Study participants in all three geographic locations. All information will be transmitted to the contractor for data entry, aggregation, and analysis. The information collection has the following components:

- In the Salt Sources Study information will be collected from adults aged 18-74 years at three geographic sites. CDC estimates that each site will enroll 150 adults, for a total of 450 participants across all three sites over a period of two years. Half the participants will be enrolled in the first year and half in the second year. Thus, the number of participants in the annualized table is divided by two (e.g., 450/2=225). The items collected for each respondent are described in **Section A.2**, below in **Table A.12-A**. Draft copies of instruments related to this collection are included in **Attachments 4A – 10A1, and Attachments 11A-14A.** The total estimated annualized burden for this information collection is 1052 hours.
- It is estimated that 30 participants over two years across the three sites will be asked to collect their water (about 15 participants per year) as described in **Section A.2**. A draft copy of the collection instrument is provided in **Attachment 10A2**. The total estimated annualized burden for this collection is 1 hour (see **Table A.12.A**.).
- Participants in the sub-study will be asked to collect additional information. It is estimated that 150 Salt Sources Study participants across the three sites over the two years (75 participants per year) will collect this additional information (see **Section A.2, Table A.12-A** below and **Attachments 15A-17A**). The total estimated annualized burden for this information collection is 319 hours.

The estimated annualized burden per respondent is 4 hours and 40 minutes for all Salt Sources Study participants. The total additional estimated annualized burden per respondent for those who collect water is 10 minutes. The total additional estimated annualized burden per respondent for those who participate in the sub-study is 4 hours and 15 minutes.

The total estimated annualized burden for all sites is 1,372 hours as shown in **Table A.12-A.**

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Form Name	No. of responses per participant	Average Burden per Response	Total Burden (in hours)
Adults aged 18-74 years	225	Telephone Recruitment and Screening	1	10/60	38
		Participant Questionnaire	1	10/60	38
		Discretionary Salt Use Questions from NHANES 2009	1	5/60	19
		Height and Weight	1	10/60	38
		Study Orientation (for non-Sub-study and Sub-study participants)	1	20/60	75
		Home Tap Water Questionnaire	1	5/60	19
		24-Hour Dietary Recall	4	30/60	450
		Food Record Form	4	15/60	225
		Duplicate Salt Sample Collection (for non-Sub-study and Sub-Study participants)	4	10/60	150
	15	Water collection form and instructions	1	5/60	1.25
	75	24-hour urine collection	4	50/60	250
		Follow-up Urine Collection Questionnaire	4	10/60	50
		Study Salt Supplement Questionnaire	3	5/60	19
				Total	1,372

The total estimated cost to study participants is **$29,779** as shown in **Table A.12-B**. The cost to respondents is based on an average hourly wage rate of $21.74 (mean hourly wage for adults, 2011, U.S. Bureau of Labor Statistics).

Table A.12-B. Estimated Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Form Name	Annual Burden Hours	Hourly Wage Rate	Total Respondant Cost
Adults aged 18-74 years	225	Telephone Recruitment and Screening	37.5	$21.74	$815
		Participant Questionnaire	37.5	$21.74	$815
		Discretionary Salt Use Questions from NHANES 2009	18.75	$21.74	$408
		Height and Weight	37.5	$21.74	$815
		Study Orientation (for non-Sub-study and Sub-study participants)	75	$21.74	$1,631
		Home Tap Water Questionnaire	18.75	$21.74	$408
		24-Hour Dietary Recall Interview Guide	450	$21.74	$9,783
		Food Record	225	$21.74	$4,892
		Duplicate Salt Sample Collection (for non-Sub-study and Sub-Study participants)	150	$21.74	$3,261
	15	Water collection form and instructions	1.25	$21.74	$27
	75	24-hour urine collection	250	$21.74	$5,435
		Follow-up Urine Collection Questionnaire	50	$21.74	$1,087
		Study Salt Supplement Questionnaire	18.5	$21.74	$402
				Total	$29,779

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The estimated total cost to the government for the services of the study contractor over the duration of the study will be $1,000,000 with an annualized cost of $500,000. These costs include all management of the study including development of materials, establishment of the study clinic site, recruitment, data collection, response tracking, coding and processing the data, analysis of and urine, and delivery of final data files.

Staff time required to participate in planning and design activities, monitoring the study, and in analysis of this data is estimated to average 0.3 FTE for scientific staff over the 24-month study period. This figure corresponds to a total of $60,000 over 24 months, or an average annualized cost of $30,000. The average annual cost to the government over the 12-month period is approximately $547,000.

The overall government distribution is summarized in **Table A.14-1.**

Table A.14-1 Annual Cost to the Federal Government

	Total	**Annual Average**
Contractor Costs	$1,000,000	$500,000
CDC Personnel Subtotal	$60,000	$30,000
CDC Analysis	$24,000	$17,000
Grand Total	$1,084,000	$547,000

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The data will be analyzed to quantify the amount (mg/day) and proportion (% of total sodium intake) from the following sources: salt added at the table, salt added during home cooking and food preparation, sodium that is naturally occurring (inherent) in foods and beverages, salt or other sodium-based ingredients added during commercial food processing and preparation, and sodium from dietary supplements and antacids. The estimates will be derived using methods similar to those previously described in Mattes and Donnelly, 1991. For many combination foods the process will rely on the recipe/formulation of the food and will require estimation of the sodium inherent in each food component. We will estimate the proportion of total sodium intake from each source for participants as a whole and among subgroups as indicated by Krebs-Smith , Kott, and Guenther, J Am Diet Assoc 1989;671-676, acknowledging that participants in this study are selected as part of a convenience sample and not representative of any specific population.

We will use measurement error models to examine the associations between sodium intake and sociodemographic and other characteristics. A sodium intake variable of interest, for example, is the ratio of intake of sodium added during commercial food processing and preparation to intake of sodium from all sources. Sociodemographic characteristics include age, sex, race-ethnicity, and place of residence (e.g., Palo Alto) and other characteristics include, for example, season of assessment (spring, summer, fall, winter). Measurement error models account for within and between person variability in intake.

To evaluate validity of estimates (e.g., dietary vs. urinary) Pearson correlations will be used.

Estimates from this study will be derived from volunteers recruited via announcements, brochures, or lists of persons who participated in previous studies or agreed to be contacted about potential study participation (see Supporting Statement B). Recruitment of participants will be balanced by geographic location, sex, race-ethnic group, and age group. Results are likely to differ from those of the previous study (Mattes and Donnelly, 1991) not only due to differences in dietary practices over time, but also differences in participant recruitment and in methods of dietary data collection. It also is likely the results from this study will differ from results from NHANES, as NHANES participants are recruited from a nationally representative probability sample (vs. a convenience sample) and because of differences in dietary assessment (as outlined previously). We will compare our estimates of total sodium intake from food and beverages (excluding salt added at the table and sodium in supplements and antacids) with NHANES estimates, and if determined relevant, among subgroups with similar demographic characteristics, e.g., non-Hispanic black males. These comparisons may help determine whether we can extrapolate our data to a broader population.

As part of the research contract, investigators will work collaboratively with CDC to prepare at least two publications for peer-reviewed journals. Quarterly recruitment reports will be

submitted to CDC after the start of data collection. A final report will be submitted to CDC at the end of the project. We are seeking OMB approval for 2 years to allow time for data collection and any adjustment of start-up time.

Table A.16-1. Project schedule for completing data collection, processing, and analysis.

Activity	**Time Schedule**
Respondent Recruitment	1-20 months after OMB approval
Data collection	1-21 months after OMB approval
Complete field work	21-22 months after OMB approval
Data Validation /Classification	2-23 months after OMB approval
Laboratory Analyses/Validation	7,15, 23 months after OMB approval
Data Analyses	22-24 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

All instruments will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.