SALT SOURCES STUDY

New Request

OMB SUPPORTING STATEMENT: PART B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

To accomplish the study objectives a convenience sample of 450 adults aged 18-74 years will be recruited from three geographic locations (Minneapolis St Paul, Minnesota; Birmingham Alabama; and Palo Alto, California metropolitan areas) (**Table B.1-A**).

Table B.1-A. Enrollment of a racially diverse population at 3 geographic locations

Location	White (n=150)	Black (n=100)	Hispanic (n=100)	Asian (n=100)	Total (n=450)
Midwest (UMN)	50	25	50	25	150
South (UAB)	75	75	--	--	150
West (Stanford)	25	--	50	75	150
Total	150	100	100	100	450

Each center will recruit 150 participants (total n=450) for the **Salt Sources Study** with the aim to select an equal number of men and women ages 18-74 years by approximately10-year age groups in each race-ethnic group as specified in Table 1. Initial sample size estimates by race and recruitment strategies have been customized for each study site in order to maximize responses and allow collection of one race-ethnic group across at least two sites. It is anticipated that 500 potential participants will need to be approached and screened at each site (N=1500 total) in order to achieve a sample size of 150 participants per site (N=450 total) according to the stratification criteria above (N=450 total). Of the 450 who agree to participate, response (complete information on all four recalls) is expected to be high, more than 85%.

As part of the informed consent process for the Salt Sources Study adults aged 18-74 years will be invited to participate in an additional sub-study. The enrollment targets for the sub-study are 50 participants per center to achieve a total sample size of 150, with similar age, sex, race distribution as the main observational study. The total sample size of 150 for the sub-study was selected in anticipation of 15%-33% with incomplete 24-hour urine collection.

Recruitment of participants varies slightly by center. In Minnesota, study participants enrolled in the Minnesota Heart Survey (MHS) 2007-09 who agreed to be contacted in the future (N ~ 5000 adults and children of diverse race/ethnic groups) will be selected by age, sex, and race criteria and asked to participate. In Alabama, participants will be recruited using databases of potential participants in current and past studies conducted at the University of Alabama (UAB) Division of Preventive Medicine who agreed to be contacted for future studies (N ~ 500); study fliers and posters posted around the UAB campus and surrounding communities; and advertisements placed in the UAB campus newspaper and other newspapers. In California, the primary recruitment strategies will include e-mail lists of potential study participants who agreed to be contacted for participation in future studies (N ~ 10,000), campus mailings to Stanford employees (N ~ 13,000), and media advertisements as needed.

Study eligibility criteria are as follows: age 18-74 years, English speaking, and have a telephone; exclusionary criteria include being pregnant or breastfeeding, or have diabetes insipidus or chronic kidney disease.

Sample Size

In the 1991 study conducted by Mattes and Donnelly among a convenience sample of 62 participants, 77% of sodium intake was estimated to come from salt added during commercial food processing and preparation, 12% from sodium inherent (naturally occurring) in foods and 11% from discretionary salt (salt added at home when cooking or at the table). In other studies, conducted in the 1980s in the United Kingdom and Australia it was estimated that ~60%-80% of sodium intake was from processed and restaurant foods and ~20%-30% from discretionary salt. The standard deviation for these estimates is not reported. A minimum sample size of 417 participants for the Salt Sources, Main Observational Study will allow the determination of the proportion of sodium intake (77%) from sodium added during commercial food processing and preparation with a 95% confidence interval of plus or minus 4% in adults of similar select groups.

In the Salt Sources Study, Main Observational Study a minimum of 100 participants will be enrolled in each race-ethnic group, 150 in each geographic location, a minimum of 200 in broad age groups (e.g., 18-44 years vs. 45-74 years) and 225 males and females. The sample size to determine whether sociodemographic and other categorical characteristics (e.g., season) are associated the ratio of sodium added during commercial food processing or preparation to total sodium intake is based on a difference in means between two subgroups (e.g., black vs. white race). As the mean difference and standard deviation is unknown, we estimated the sample size for a range mean differences (0.10-0.25) and standard deviations (0.2 to 0.8) (see Table B.1-B. For example, if we assume the mean ratio is 0.8 (i.e., 80% of sodium consumed is from sodium added during commercial food processing and preparation among women in our sample), it might be reasonable to assume the standard deviation would be 0.4. In order to detect a mean difference in the ratios of 0.2 (e.g., beta-coefficient in a regression model for women vs. men), a sample size of ~63 persons is required per group.

Table B.1-B. Minimum sample size per group required to detect differences in means

Standard Deviation	Difference in mean ratio between two categories			
	0.10	0.15	0.20	0.25
0.2	63	28	16	11
0.4	252	112	63	41
0.6	566	252	142	91
0.8	161	447	252	161

ND = not determined, not relevant. Note: sample sizes based on 80% statistical power, two sided test with an α (type 1 error rate)=0.05.

Thus, the sample size (see **Table B.1-A**) of the planned study shouldl be adequate to detect major differences in the proportion of total sodium intake from sodium added during commercial food processing and preparation by sociodemographic and other characteristics.
In the study conducted by Mattes and Donnelly (1991), the correlation between urinary excretion of sodium and total dietary sodium was 0.31. The correlation between urinary lithium levels and sodium from table salt was 0.62. The correlation between total sodium intake based on 24-hour urine sodium excretion and that based on dietary recalls was 0.30 in the NIH-sponsored TONE (Trials of Non-pharmacologic Interventions in the Elderly) study which also used multiple 24-hour dietary recalls with the University of Minnesota NDSR. In relation to the Validation Sub Study, a sample size of approximately 100 participants will allow us to detect at a minimum a correlation of 0.28 between sodium intake based on 24-hour urine sodium excretion and sodium intake based on the 24-hour dietary recalls, duplicate portion assessments, and other measures with a power of 0.80 and a two-tailed alpha of 0.05 (Table 3). Given that 150 participants will be enrolled and 15% to 33% may have incomplete 24-hour urine collection, the sample size should be adequate to check the validity of the dietary data and duplicate salt collection (see **Table B.1.-C**).

Table B.1-C Minimum Detectable Correlations

α level	Sample Size	Power 0.80	0.85	0.90	0.95
0.05	100	0.283	0.303	0.327	0.365

B.2. Procedures for the Collection of Information

The contractor will attempt to contact and invite people to participate by telephone (**Attachment 4A**). The telephone script contains information about the study requirements and describes the study procedures, questionnaires, and compensation offered for participation. Two attempts will be made to contact the participant by telephone. Participants who cannot be contacted by telephone or who are contacted by telephone but are unsure about participation will be sent a tailored invitation letter and study fact sheet **(Attachments 4B-4C)**. This information includes a local number that participants can call to determine if they are eligible and allow them to ask questions about the study. Participants sent information through the mail who do not respond within a month, will be sent a second invitation letter and fact sheet.

All potential participants will be administered a telephone pre-screening interview (**Attachment 4A).** As indicated previously, the inclusion criteria specify ages between 18-74 years and having daily access to a telephone. Non-English speakers, individuals with chronic kidney disease or diabetes insipidus, and participants who are pregnant or breastfeeding will be excluded. Recruitment goals therefore have requirements for age, sex, and race-ethnic groups.

At the baseline visit, participant eligibility will be confirmed and contact and demographic information will be collected (**Attachment 5)**. The informed consent will be reviewed with the participant and any questions from the potential participant will be answered by the clinic coordinator and the form will be signed and witnessed by a member of the study staff (**Attachment 21)**. Questions used in NHANES will be asked that crudely assess the frequency of salt added at the table and during home cooking (**Attachement 6)**. Height and weight will be measured, study procedures reviewed, data collection materials provided, home tap water source ascertained, and 24-hour dietary recalls and duplicate salt portion collections will be scheduled **(Attachments 7-10A1)**. Participants who report their home tap water is from a private well or cistern will be asked to collect a sample of this water (**Attachment 10A2**).

Over an 11-day period, **four** telephone 24-hour dietary recalls will be conducted with each participant (see **Table B.2**, and **Attachments 11A)**. On the day before the 24-hour dietary recalls, participants will be asked to collect duplicate portions of salt added during cooking and at the table and to record the foods they consume and to which they add salt **(Attachments 12A-14A)**.

One third of the participants in each site (n=150, 50 each site over two years) will complete a biomarker Validation Sub Study in which they will be required to replace the salt they use at home with the study salt (lithium tagged salt) in home cooking and at the table. They also will be required to collect **four** 24-hour urine samples over the same time period for which the 24-hour dietary recalls are collected (**Attachments 15A and 15B**). On the return of the urine to the study clinic sites, the volume of the urine samples will be measured and questions will be asked to participants to assess completion **(Attachment 16A)**. Urine will be analyzed for sodium, potassium, creatinine, and lithium concentrations. The analysis of sodium, potassium and creatinine will be performed in the ARD Laboratory. ARDL is a CLIA-certified laboratory at the University of Minnesota that routinely performs electrolyte and creatinine analysis for numerous federally-funded studies. The lithium analysis will be performed by Columbia Analytical Services, recently renamed ALS-Kelso, which is a full-service analytical laboratory established in 1986. It maintains various certifications and accreditations with federal and state agencies and regulatory programs.

Table B.2 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		**X**		**X**		**X**		**X**	

duplicate salt sample collection[c]									
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.

University of Minnesota's Nutrition Coordinating Center will collect and analyze data from the 24-hour dietary recalls to ensure uniform data collection and analysis. University of Minnesota School of Public Health (contractor) also will manage all data collection systems including information collected during the screening interview, information collected at the study clinic, and information entered by other study sites. To ensure data quality, data will be keyed directly by study sites into the same central data collection system. Study forms, materials, and supplies will be standardized across sites by the contractor, University of Minnesota.

B3. Methods to Maximize Response Rates and Deal with Non-response

Main Observational Study

As stated earlier, the study recruitment methods will be slightly tailored to participants in each site. Each site will recruit participants from databases of persons who have volunteered to be contacted for participation in studies which may be supplemented with local advertising. The study recruitment scripts, fact sheets and letters emphasize the important ongoing research and state the need for participation and compensation for the different aspects of the study and are the same across sites. Participants will be compensated $10 for each completed 24-hour dietary recall and duplicate portion salt collection, at total of $40 for the main

observational study. Participants who choose to also take part in the sub-study (described below) will be additionally compensated.

Potential participants who want more information or who cannot be contacted by telephone will be mailed information inviting their participation. If the participant does not respond within one month of the first invitation letter s/he will be mailed a second invitation letter.

To maximize 24-hour dietary recall completion rates and adherence to the duplicate salt collection procedure, an email will be sent and/or a telephone reminder call made to participants the evening prior to each scheduled 24 hour recall period. In the email and phone call, participants will be reminded of the date and time of their scheduled telephone recall, and the phone number at which they should be reached will be confirmed. In addition, they will be reminded to use one of the home salt collection kits they were given to collect duplicate samples of the discretionary salt used during the recall period and to record foods consumed.

At the start of each 24-hour dietary recall participants will be asked if they remembered to collect duplicate salt samples for the recall day. If they did not a new recall date will be scheduled. If they did, the recall will proceed.

All recalls will be collected over the telephone by University of Minnesota Nutrition Coordinating Center (NCC) staff trained and certified in the collection of dietary recalls using NDSR. Interviewers fluent in Spanish will be available for conducting interviews with Hispanic participants who prefer the interview be conducted in this language. Staff will undergo a two day training in which they are oriented to the recall collection and data processing procedures for this study. In addition, each interview will successfully complete a certification process in which they must demonstrate the ability to collect recalls following the study procedures. As part of the certification process interviewers will receive feedback on their performance. In addition, feedback will be provided to interviewers on an ongoing basis as part of quality assurance activities. NCC has a long history of providing dietary assessment services to researchers including collecting 24-hour dietary recalls over the telephone from multiethnic populations.

The 24-hour diet recalls will be collected over the telephone using the 2012 version of Nutrition Data Systems for Research (NDSR) nutrient calculation software. NDSR is a computer based software application developed by the Nutrition Coordinating Center (NCC) at the University of Minnesota that allows for direct entry of dietary data in a standardized fashion. When collecting recalls using NDSR the multiple-pass interview technique will be used to prompt for complete food and beverage recall and descriptions. A food amount booklet adapted from that used successfully in previous studies will be provided to participants for use in estimating food and beverage amounts (see **Attachment 11B).**

The NCC Food and Nutrient Database serves as the source of food composition information in NDSR. This database includes over 18,000 foods including 7,000 brand name products, twenty-three restaurants; and many ethnic foods. Foods reported by participants that are not among

those available in the program will be added to it using a tool within NDSR designed for incorporating missing foods (User Recipe feature). The database is updated on an ongoing basis with updates included in each annual NDSR release.

Quality assurance procedures will be conducted at several levels during recall collection and processing to minimize response errors. First, interviewers will review and edit dietary recalls immediately after collection. Second, NCC quality assurance scientists will review interviewer notes and food and nutrient outlier and error reports for 100% of recalls. In addition, a 10% random sample of recalls will be selected for a 100% quality assurance review. This will include a review of the record header and food, dietary supplement, and trailer question tabulations for completeness and accuracy.

Dietary supplement use over the recall period, including use of antacids, will be assessed using the Nutrition Data Systems for Research (NDRS) Dietary Supplement Assessment Module (DSAM). This module, which is designed for use in conjunction with the collection of dietary recalls, ascertains use of dietary supplements and antacids through a three-tier interview process in which products used and amounts taken are quantified. Over 2,000 dietary supplements and antacids are included in the database that supports the module. Products reported by participants that are not included in the database will be added using a 'user product' feature of NDSR.

A duplicate salt portion method similar to that developed by and successfully implemented by previous researchers will be used in conjunction with the 24-hour dietary recall to aid in quantifying sodium intake from salt added at the table and in home cooking. As mentioned earlier, at the baseline clinic visit participants will be given four home salt collection kits (one to be used for each day for which a 24-hour dietary recall is to be collected). Postage paid preaddressed envelopes will be included with each kit for return of the salt samples. Verbal and written instructions will be provided at the time kits are given to participants. Participants will be asked to share the 'salt added in home cooking' instructions with everyone in the household who cooks (multiple copies of the instructions will be provided). Participants also will be instructed to carry and use the bags when they are eating out.

Participants will be asked at the initial study visit about the main source of the tap water they drink in their home (community water or private well/cistern) and whether they have a home water softener or water filtration system. For most participants community water is expected to be the main source, eliminating the need for separate water collection. For those who have a private source of tap water, a collection kit will be provided with a preaddressed postage paid envelop.

Participants will be encouraged to contact study personnel whenever they have a question about any aspect of the Salt Sources Study or sub-study.

Sub-study

Participation in the sub-study will be described during the initial contact with potential participants. Participants in the sub-study will be compensated an additional $20 for each 24-hour urine collection, for a possible total of an additional $80 per participant. To maximize participation, any participant who takes part in the Salt Sources Study is also eligible to participate in the sub study until enough participants have been recruited in the specified demographic subgroups, e.g., white, 18-29 year old females. Participants will be counseled about the importance of a complete urine collection, and provided sufficient collection bottles to allow for high volumes of urine.

When 24-hour urine samples are returned to the clinic, the clinic manager or lab technician (in each center) will review the start/stop date, start/stop time on the bottle/form. The lab tech will measure and record the volume of urine in each bottle and ask questions to assess completion similar to those used successfully in previous studies. Incomplete urine collection will be assessed based on urine volume, responses to a follow-up questionnaire, and creatinine excretion as in previous studies. Non-compliance for returning complete 24-hour urine samples is a problem, however. Some studies reported 15- 25% of samples as incomplete collections. The contractor will enroll 150 participants in the Sub Study anticipating 25% incomplete samples and potential drop off in participation.

Changes in subject behavior is a concern with the lithium tagged sodium method because participants could potentially change their salt use habits (frequency and or amount of salt added) due to provision of special containers and the requirement that they carry the shaker with them throughout the day for use whenever they want to add salt to food at the table. We will attempt to discern the extent to which this may occur by comparing the discretionary sodium intake (determined via duplicate salt portion method) of sub-study participants and those not participating in the sub-study with potential confounders (e.g. education level, vigorous physical activity, sex, age, etc.) included as covariates in the analysis. Results from this analysis will be considered in interpreting study findings related to the contribution of discretionary sodium to total sodium intake.

B4. Tests of Procedures or Methods to be Undertaken

Dietary Analysis

Many aspects of the Salt Sources Study have been previously tested and improved upon to minimize burden and improve utility. The 24-hour diet recalls will be collected over the telephone using the 2012 version of Nutrition Data Systems for Research (NDSR) nutrient calculation software. NDSR is a computer based software application developed by the Nutrition Coordinating Center (NCC) at the University of Minnesota that allows for direct entry of dietary data in a standardized fashion. This approach was previously used large national population-based studies including the National Health and Nutrition Examination Survey (NHANES) and with the International Population-Based Study on Medications and Blood Pressure (INTERMAP). When collecting recalls using NDSR the multiple-pass interview technique will be used to prompt for complete food and beverage recall and descriptions. A

food amount booklet adapted from that developed by Van Horn and colleagues will be provided to participants for use in estimating food and beverage amounts (**Attachment 11B**).

Dietary supplement use over the recall period, including use of antacids, will be assessed using the NDRS Dietary Supplement Assessment Module (DSAM) previously used in other studies. This computer-based module, which is designed for use in conjunction with the collection of dietary recalls, ascertains use of dietary supplements and antacids through a three-tier interview process in which products used and amounts taken are quantified. The medication inventory method, commonly used in pharmaceutical research, serves as the basis for the module's assessment approach.

Quantifying sodium intrinsic to food and added during processing will require use of some information not found in the NDSR output files. To elaborate, the sodium content of each food and beverage reported by participants will need to be partitioned into the amount that is added during processing, naturally occurring, and added during home preparation. For some foods the distinction may be readily determined (e.g. all of the sodium in an apple may be considered intrinsic). However, for many foods the process will be more complex with the recipe/formulation for the food relied on to determine the amount of sodium by source. The recipes/formulations for some foods are provided in the NDSR output files (e.g. the individual ingredients and their sodium content are provided in the 'component/ingredient output file' for a food like French fries). But, for some other foods (e.g. pickles, cheese, ready to eat cereals, etc.) this information is not provided. However, NCC has recipes/formulations for these foods in the program that are used to maintain the database. Thus, we will access this information for foods for which this information is not provided in the NDSR output files.

A duplicate salt portion method similar to that developed by Melse-Boonstra et al. (1999) will be used in conjunction with the 24-hour dietary recall to aid in quantifying sodium intake from salt added at the table and in home cooking. The pros and cons of each potential approach to ascertaining the amount of salt added to foods in home preparation and at the table determined that a duplicate sample portion method was preferable to the weighed shaker and salt container method for the following reasons: 1) greater precision for assessing salt added in cooking because the weighed approach does not allow for quantifying the amount of salt added in cooking specific dishes, and hence adjustment for fraction of dish consumed cannot be made for specific foods; 2) less subject reactivity likely with duplicate portion method because the participant's usual sources of table salt (shaker at home; salt packets at fast food restaurants; etc.) and salt added in cooking may be used. Among the subsample of participants who will receive the salt supplement, the salt shakers will be weighed before distribution and after collection in order to compare these methods.

<u>Urine Analysis</u>

A 24-hour urine collection is considered the gold standard in estimating total sodium intake. In addition, collecting four 24-hour urine samples will decrease the variance found with estimates of sodium intake in the population. Procedures used in INTERMAP and The Trials of Hypertension Prevention will be modified for this study.

As in several previous studies including the previous smaller study in 1991 on Sources of Sodium Intake conducted by Mattes and Donnelly, a subset of participants used shakers and salt containers filled with lithium-tagged salt. As participants will be provided the tagged salt after the first-24-hour urine collection, a baseline value of lithium concentration will be determined to distinguish change in lithium level between baseline and subsequent urine collections and better estimate the amount of sodium consumed from discretionary salt (added at the table and during cooking).

Sodium and Potassium. Sodium and potassium in urine will be measured by an ion-selective electrode (ISE) method on the Roche Modular P (Mod P) Chemistry analyzer (Roche Diagnostics Corporation). The laboratory interassay CVs for sodium and potassium are 1.0%. *Creatinine***.** Creatinine is measured by the Roche enzymatic method (Roche Diagnostics, Indianapolis, IN 46250) on a Roche Modular P Chemistry Analyzer. (Roche Diagnostics Corporation). This method has the advantage over the Jaffe method in that it is not susceptible to interferences from no-creatinine chromogens. The method is calibrated using a National Institute of Standards and Technology (NIST) standard traceable to reference material SRM 909b (Isotope Dilution Mass Spectroscopy (IDMS)). The laboratory CV is 2.3%. *Lithium***.** The measurement of lithium will be performed using an acid digestion of the sample and then analysis for lithium according to EPA Method 200.7 using an inductively coupled plasma optical emission spectrometer. The laboratory CV is 2%.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC consulted with the contractor, the study sites, and CDC partners. The contractor (University of Minnesota) and the two subcontracted study sites (University of Alabama and Stanford University) are responsible for the data collection from the **participants (see Attachment 18)**. The contractor is responsible for collecting the data from the study sites. Data management and analysis will be performed by the contractor at University of Minnesota and at CDC. Specific data analysis plans are developed in collaboration with the study sites, the contractor, and CDC.

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Principal Investigators for University of Minnesota (the contractor), responsible for overseeing the data collection from the study sites (University of Minnesota, University of Alabama, and Stanford University) and data analysis.
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