The Community Health Survey Heart Follow-Up Study (HFUS)
Clinical Protocol

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Cardiovascular Disease Prevention and Control Program, Bureau of Chronic Disease Control
&
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A. Study Introduction

This manual provides the clinical protocol for conducting the Community Health Survey, Heart Follow-up Study as a subcontractor for Abt-SRBI, under the direction of the New York City Department of Health and Mental Hygiene. All of the necessary protocols and scripts are included in this protocol.

Decreasing population sodium intake is a public health priority (Healthy People 2010)\(^1\); reductions which would lead to lower blood pressure and subsequently lower risk for cardiovascular disease (CVD). CVD is the leading cause of death in the United States (US)\(^2\) and New York City (NYC).\(^3\) The NYC Department of Health and Mental Hygiene (DOHMH) is undertaking a surveillance project to assess NYC population sodium intake using the gold standard measurement of 24-hour urine collection.\(^4\) The project will assess the primary outcome of interest, current population sodium intake, against which future population intake changes can be assessed. This surveillance project is a critical component of the National Salt Reduction Initiative, a nationwide effort to reduce sodium intake\(^5\) through voluntary industry reductions in processed food sodium content. It is coordinated by NYC in partnership with over 40 cities, states, and health organizations. This initiative’s goal is to reduce population sodium intake by 20% over five years, or approximately 700mg/sodium per day. This reduction in intake would lead to decreased blood pressure and cardiovascular risk. Collectively these changes are expected to result in an estimated 150,000 premature deaths averted each year\(^6\), and will contribute to the ongoing efforts to eliminate related health disparities.

B. Study Design

The project will use the NYC Community Health Survey (CHS), an annual telephone survey of approximately 10,000 (8,500 in 2010) adults, as the recruitment vehicle to identify participants for urine collection. Approximately 1784 participants will be recruited; resulting in an estimated 1,586 usable observations after accounting for non-usable urine samples (12.5%) and canceled appointments (4%). Participants 18 years and older will be recruited such that it assures a representative sample of adult New Yorkers. Participants will complete an additional brief interview at the end of the CHS to collect additional information about blood pressure, and other cardiovascular disease factors. Participants will be called to schedule an in-home visit and participants will complete the urine collection on the day of the visit. Participants will be asked if they could complete the collection on a weekday or weekend randomly. Upon scheduling a home visit, a kit with a written instruction booklet will be sent via express mail to their home. At their in-home visit the participant will be asked to provide a sample from a 24 hour urine collection and have a multiple seated blood pressure and anthropometric measurements taken.

C. EMSI Services

EMSI will be responsible for scheduling and conducting the home visit, distributing the $90 incentive checks at the home visit, as well as answering participants’ questions about how to
complete the urine collection. EMSI will also be providing a toll free helpline to assist participants with questions about the urine collection and offer optional pre-collection visits if participants require more explanation. In addition, the examiner, making the home visit, will aliquot and package the urine samples and ship them to the laboratory for analysis. All EMSI personnel performing services for this study must have completed the National Institute of Health's Protecting Human Research Participants training and the online training specific to the CHS Heart Follow-Up Study.

I. Scheduling Home Visit Appointments

Once recruitment begins, Abt/SRBI will send participant contact information to EMSI through a secure method on a daily basis. The scheduler will call participants within 48 hours of receiving the secure file to schedule a home visit appointment.

Please note that the EMSI examiner who performs the home visit should be a female for female participants and a male or female for male participants.

During the call, the scheduler will use the home visit scheduling call script (Appendix A) and cover the following points:

- Describe what is involved in the 24-hour urine collection
- A kit will be sent to the participant’s home and will contain all the materials that will be needed to complete the urine collection, including a kit letter, detailed instruction booklet, a participant frequently asked questions (FAQs) sheet, a study time log, and an informed consent form. (all documents in Appendix B)
- A tollfree helpline will be provided (1-800-351-4321) for participants who have additional questions. The DOHMH has provided EMSI with scripted help to use on the helpline (EMSI FAQs – Appendix A) that is based on the participant instruction booklet.
- The participant must collect all their urine every time he or she uses the bathroom/voids over a 24 hour period.
- An EMSI examiner will go to the participant’s home to complete a home visit which will include: asking questions about the participant’s experience collecting their urine, measuring their blood pressure, height, weight, and waist circumference as well as taking a sample of their collected urine. At the end of the visit, the EMSI examiner will also administer the $90 incentive check to the participant for completing the collection.

- Assist the participant with selecting a 24-hour period to complete the collection
- Participants will be asked if they can complete the collection on a weekday or weekend day in a random fashion.
  - If the participant indicated they could complete the collection on the randomly assigned weekday/weekend day, they will be asked to choose one of those days. If they are unable to do this or if they earlier indicated they
were unable to complete the collection on the requested type of day, they
will be asked what day is convenient.

- The day that the participant chooses to begin the collection must be at least seven
days after the scheduling call to allow enough time for the kit to arrive at their home
and for them to review the [instruction booklet](#).

- The examiner will explain to the participant that a travel cooler bag and orange
storage container are included in the kit so he or she can do the collection while at
work or outside of the home on the day of the collection.

- The participant should commit to a day that he or she can assure the urine will be
collected. Care should be taken to help the participant pick a collection period when
they do not have other planned (work or personal) activities that would interfere
with their ability to successfully complete the collection. The participant also needs
to be available on the day the urine collection is completed for the EMSI examiner to
do the home visit.

- Female participants should not choose a collection date that is during or near their
menstrual cycle (having their period). Urine collected while a woman is
menstruating cannot be used for the study.

- If the participant feels uncomfortable about collecting their urine during the work
week, they will be scheduled to collect their urine on a day off or over a weekend.

- Schedule the home visit to coincide with completion of the urine collection
- The visit must be scheduled on the same day the urine collection is completed.
- For example, if a participant begins their urine collection on Thursday April 1st at
8:00am he or she will finish on Friday April 2nd around 8am. The home visit must be
scheduled on Friday April 2nd after 8am.

- Offer pre-collection visits (part of the [home visit scheduling call script](#))
- If the participant would like a pre-collection visit to review the materials and
instruction booklet, schedule the pre-collection visit the day before the collection
starts.
- For example, if a participant begins their urine collection on Thursday, the pre-
collection visit should occur on Wednesday. The home visit must be scheduled on
Friday.

### i. Rescheduling home visit appointments

- Participants will call the scheduling line to rescheduling their home visit
appointment for many reasons.

- **Rescheduling appointment before completed urine collection:**
  - At any time prior to the start of their urine collection participants can
    reschedule their urine collection day and the home visit.
- Ask the participant to pick a day that is convenient for them using the criteria outlined above in “Scheduling Home Visit Appointments”. Keep in mind their randomly (weekday/weekend day) assigned day of the week to do the collection.

- Rescheduling appointment after completed urine collection:
  - If the participant is unable to keep their home visit appointment but has completed the urine collection, reschedule the home visit appointment within 3 days.
    - Instruct the participant to keep the urine collection container in the refrigerator in the biohazard bag until the rescheduled home visit.
  - If a new appointment can not be made within 3 days, ask the participant if he/she is willing to redo the collection.
    - If the participant is willing to redo the collection:
      - Contact Clinical Services immediately by calling 1-866-202-5310 to have a new kit sent to the participant.
      - Schedule a new home visit appointment at least 7 days after this call.
      - Ask the participant to set aside the urine collection materials and to pour their urine down the toilet.
    - If the participant is unwilling to redo the collection:
      - Ask the participant to set aside the urine collection materials and to pour their urine down the toilet.
      - Schedule a time to go to the participant’s home to collect all of the materials (to be discarded) and administer the $90 incentive check.

ii. No-shows
- If a participant is not at home for a home visit appointment, the examiner will try to reach the participant by calling them.
  - If the examiner speaks to the participant:
    - Follow the protocol above for “Rescheduling appointment after completed urine collection”
  - If the participant is not reached, a message will be left on their answering machine using the answering machine script (Appendix A).
  - At least 5 attempts will be made to contact them. If not reached, consider the participant lost to follow-up and report to Abt/SRBI.

iii. Refusals
- Some participants may decide they do not want to complete the urine collection portion of the study after they receive the kit and will call the scheduling line to cancel their appointment. The participant will be considered lost to follow-up and reported to Abt/SRBI.
iv. IRB/consent form issues

- Some participants may have questions on the consent form either before or after they have collected their urine. They may have called DOHMH and not yet heard back. If this is the case, reschedule the home visit as per the protocol on page 4 “Rescheduling Home Visit Appointments”.

II. Assembling Collection Kits

The collection kits must be mailed to the participant’s home within 24 hours of scheduling the home visit. Labels with the participant’s ID number must be affixed to the urine collection tubes, the site contact report form, the redo form, the study time log, and the lab requisition form (all documents can be found in the Appendices). Quality control measures must be in place to ensure the correct ID number is placed on the kit materials for each participant. The accuracy of this ID is very important because it will link the participant’s home visit information and urine analysis with their telephone survey answers.

The kits will include the following materials:

- Participant collection materials
  - Urine hat (for women only)
  - Collection cup
  - Funnel w/resealable bag
  - Large biohazard bag
  - Home cooler bag (silver)
  - Travel cooler bag (black, red, or blue)

The kit contains more than one of the following and they are identical to each other:

- 2 3-liter orange storage containers (each contains a 1 gram tablet of boric acid)
- 6 ice packs
- 2 safety pins in a plastic bag

- EMSI examiner package: These materials should be placed in a box that will also serve as the box for shipping the samples to the laboratory. The box should be labeled with two labels: “Do not open. Examiner use only.” and “Exempt – Human Specimens”
  - 2 aliquotting tubes labeled with participant ID
  - 1 Vacutainer urine transfer unit
  - Small beaker
  - Small biohazard bag
  - Small absorbent pad
  - 1 pair of gloves
  - Mini sealable thermal bag for shipping to lab
  - Lab requisition form labeled with participant ID number
  - Site contact report form labeled with participant ID number on every page.
o **Redo form** labeled with participant ID number
o Preprinted Fed Ex shipping label

- Printed materials for the participant: These materials will need to be assembled in the following order, top to bottom, by EMSI (all of these documents can be found in Appendix B).
  1. Kit letter
  2. Consent form
  3. Instruction booklet
  4. Participant FAQs
  5. **Study Time Log** (labeled with participant ID number)

### III. Home Visit Reminder Call

The gender-specific examiner assigned to complete the home visit will call the participant at least 48 hours before the scheduled visit to confirm the appointment and to answer any questions the participant may have about collecting their urine or about the home visit. During the call, the examiner will use the **home visit reminder call script** (Appendix A) and cover the following information:

- Confirm the date and time of the home visit appointment,
- Confirm the participant’s address,
- Instruct the participant briefly on how to do the urine collection,
- Answer questions about the home visit,
- Remind the participant of the following to assist with taking the blood pressure:
  - To wear a short sleeve shirt.
  - To not drink caffeine, exercise, or smoke 30 minutes before the scheduled visit, and
- Remind the participant to wear pants or a skirt so that the waist circumference can be measured.

- If the participant needs to reschedule their home visit, please refer to the “Rescheduling home visit appointments” section on page 4.

- If the examiner is unable to contact the participant, a message will be left on their answering machine or voicemail. The examiner will use the **answering machine script** (Appendix A) to provide the following information to the participant:
  - Confirm the date and time of the home visit appointment.
  - Explain if the participant is unable to keep the appointment that he or she needs to call to reschedule.
  - Remind the participant that he or she needs to review the **instruction booklet** (Appendix B) for the urine collection and can call the toll free number for assistance.
IV. Pre-collection visit

It is estimated that about 20% of the participants will request additional assistance to correctly complete the 24-hour urine collection. Participants will be offered a pre-collection visit during the scheduling call and reminder call. In addition, if participants ask a lot of questions about the instruction booklet (Appendix B) during inbound help line calls, then these participants should be asked if they would like to have an examiner come to their home to go over the instruction booklet with them. During this pre-collection visit the examiner will review with the participant the instruction booklet, the collection materials and answer more specific questions about the collection process using the EMSI FAQs (Appendix A).

Participants who want the pre-collection visit may need to reschedule their urine collection and home visit appointment with the examiner or the call center staff. The pre-collection visit should take place the day before the participant begins his or her urine collection.

V. Preparing for Home Visit

The examiner will need to bring the following to the home visit:

- 2 extra EMSI examiner packages (for contents see list above on page 6)
  - This package will be used if contents of the EMSI examiner package sent to the participant’s home are damaged or missing.
  - It is the responsibility of the examiner to maintain complete exam kits.
- *1 extra collection kit to be given to participants who need to redo their urine collection as possible.
- 1 5-liter container (for mixing urine volumes >3 liters)
- 2 extra informed consent forms
- 1 copy of the EMSI FAQs (Appendix A)
- 2 copies of the Redo form (Appendix A)
- 3 copies of the Understanding Your Blood Pressure Today form (Appendix A)
- 1 blood pressure monitor (Omron 907XL) to be used for this project only
  - Make sure to double check that the blood pressure monitor is adequately charged. The monitor does not run with the adaptor cord only. The adaptor cord can only be used for charging the battery.
- 1 small (child-size), 1 regular, 1 large, and 1 extra large BP cuff (included with the blood pressure monitor)
- 1 scale to measure weight
- 1 tape measure at least 7 feet tall
- 1 soft tape measure
- 1 Fed Ex label per scheduled visit.
- 1 $90 incentive payment check per scheduled visit

VI. Conducting the Home Visit

The examiner will arrive at the participant’s home, introduce themselves and verify they are speaking with the correct person. The examiner should use the Welcome script below to make
the introductions, obtain the signed consent form and obtain the EMSI examiner package (previously mailed to participant with collection kit).
i. Welcome Script
Hello. My name is __________ I am a medical technician with EMSI. I have an appointment with __________. I am here to complete the home visit part of the Community Health Survey Heart Follow-Up Study.

EMSI: Show your ID.

I need to confirm that I am speaking with the correct person. May I please see an ID?

Before we begin, I will need the package labeled “Do not open. Examiner use only.” that came in the box with your collection materials. I also need to collect your signed consent form, your study time log, and the 2 orange containers that you used to store your urine. I will need these supplies to complete the visit with you.

EMSI: When you get the package, remove the site contact report form and proceed with the visit.

Review the informed consent to make sure it is signed. If it is not signed, ask the participant to review and sign. Refer to the EMSI FAQ sheet to answer questions about the form or the study.

You cannot continue the visit without a signed consent form.

ii. Informed Consent Form
  o A signed informed consent form must be given to the examiner before the home visit can begin.
  o The EMSI FAQs (Appendix A) should be used to answer questions about the study when a participant has concerns that are preventing him or her from signing the consent form.

  o If the participant does not want to sign the consent form ask if he or she would like to speak with someone from the Health Department and give the participant the phone number from the informed consent form (Appendix B).
    ▪ If the participant would like to immediately call the Health Department and resolve the question, and decides to participate, proceed with the visit.
    ▪ If the participant wants to call the Health Department later, end the home visit. Abt/SRBI will contact EMSI so that a new home visit appointment can be scheduled.
    ▪ If the participant is waiting to hear back from the Health Department, refer to the “Rescheduling home visit appointments” section on page 4.
If the participant does not wish to speak with someone from the health department, thank them for their time and tell them they cannot continue with the study.

- An unsigned consent form would end the visit. This refusal needs to be documented on the site contact report form (Appendix A).

iii. EMSI examiner package

- This package includes the materials needed for collecting the urine samples as well as the forms that will be completed during the home visit (contents listed on page 6).
- These forms and collection tubes will be labeled with the participant’s study ID number.
- All these materials are packaged together and clearly marked “Do not open. Examiner use only.”

Once the examiner opens the package, he/she should remove the site contact report form and begin the data collection. The visit will begin with assessing the completeness of the urine collection. Then the examiner will take the participant’s blood pressure, pulse, height, weight, and waist circumference according to the protocol outlined below. Finally, the examiner will aliquot urine into two collection tubes and prepare them for shipment to the lab for analysis.

iv. Assessing Urine Collection Completeness

Using the site contact report form, the examiner will ask the participant a series of questions to determine if the sample is acceptable.

If any of the following apply we cannot use the urine sample. The examiner will need to ask the participant to redo the collection using the redo form (Appendix A). The examiner should flush all of the collected urine down the participant’s toilet.

- Total volume is less than 0.5 liters (500 cc)
- Urine collected during menstruation
- Initial (start of collection) void was included in the overall sample

The length of collection time is a different case. If the length of collection time deviates from 22-26 hours and is greater than 500cc, we can use these samples, but we would like the examiner to ask the participant to redo the collection using the redo form. If they refuse to redo the collection, proceed with the visit as usual.

- Determine the length of collection time using the start time and end time. Do not be concerned if collection time varies slightly from exactly 24-hours as long as the time is recorded in the data collection form and ranges from 22-26 hours.
  - If the length of collection is less than 22 hours or greater than 26 hours ask participant to redo the collection using the redo form.
• If the participant is willing to redo the collection, make arrangement for a new home visit appointment. Document that the participant will redo the urine collection on the **site contact report form**.
  • Pour the urine in the toilet and discuss with the participant how to redo the collection.
  • If the participant is unwilling to redo the collection, continue with the rest of the home visit.

Urine from participants who report spilling some or missing a void will be collected (as long as the total volume is greater than 500cc).

If the participant refuses to redo the collection, the blood pressure, height, weight and waist circumference measurements should be taken. The participant should also receive $90 incentive check. For those who agree to redo the collection, the visit should consist of an educational session on the proper way to collect the urine. No measurements should be taken and the $90 incentive check should be held until the second collection home visit is completed.

v. Redo’s (Second Collection)
The **redo form** should be easily accessible during the visit so there can be a smooth transition between the **site contact report form**, if needed. Below is a brief explanation for each of the four reasons for a redo.

• The urine volume is less than 500cc – This low volume indicates that the participant did not follow the directions and collected their urine every time he or she urinated. Dehydration nor any underlying biological reason would lead to a volume of less then 500cc. This urine sample cannot be used.
  o When discussing the second collection with the participant the examiner **should not** tell them that the volume needs to be at least 500cc.

• Female participant menstruating during the collection period – The urine can not be used for the study if a female participant is menstruating any time during the collection period. This urine sample cannot be used.
  o If the participant agrees to redo the collection, make sure to schedule the collection day and home visit appointment during a time period when she will not be menstruating.

• Including the start time void – In order to standardize the collection to cover the “next 24 hours” the void at the start time cannot be collected. For example, the first void of the day for person A may include urine from the last 12 hours, whereas for person B may include urine from the last 2 hours. To best ensure that we are collecting urine for the 24 hour period stated, the participant needs to “zero out” their bladder. Participants must begin with an empty bladder at their start time. This urine sample cannot be used.
• The length of collection time is <22 hours or >26 hours – In order for this to truly qualify as a 24 hour collection, the length of collection time should be 22-26 hours. Small deviation from that (e.g. 21 hour collection, 27 hour collection) will not affect the lab analysis but we prefer to ask the participant to redo the collection. This urine sample can be used, but it is preferable to get a new sample falling in the required timeframe.

The examiner will be responsible for scheduling a new urine collection period and home visit appointment

If the participant refuses to redo the collection, the $90 incentive check should be given.

vii. Blood Pressure and Pulse Measurement
Blood pressure and pulse will be measured according to the following standardized procedures.

• Measure on the right arm unless self-reported conditions prohibit the use of the right arm. If the measurement cannot be taken in the right arm, the left arm should be used.
  o The following are self-reported conditions that would prohibit use of the right arm:
    ▪ On any arm that has rashes, small gauze/adhesive dressings, casts, are withered, puffy, have tubes, open sores, bruises, wounds, arteriovenous (AV) shunt, or any other intravenous access device (e.g. fistula)
    ▪ Women who have had a unilateral radical mastectomy do not have their blood pressure measured in the arm on the same side as the mastectomy was performed.
    ▪ Right arm is missing.
    ▪ In all cases, if there is a problem with both arms, the blood pressure is not taken.
  o The arm that was used for the blood pressure measurement should be recorded on the site contact report form (Appendix A).

i. Prepare the Participant
  o Assess whether the participant smoked, had any caffeine, or did any vigorous exercise 30 minutes preceding the blood pressure measurement.
    ▪ If the participant reports doing any of the above activities, complete the rest of the visit and measure their blood pressure and pulse at the end of the appointment.
  o Locate a chair that will allow the participant to sit all the way back so that their spine is straight, their back and arm are supported and both feet are flat on the floor. It is suggested that a kitchen or other similar type chair be used instead of sofa or an oversized living room chair.
    ▪ The participant’s arm (on which the measurement will be taken) should be resting comfortably on a table. If this is not possible, pillows or books
can be used to prop up the arm at the proper level; the arm should be at heart level (refer to photograph).

- Ask the participant to remove any extra clothes (e.g. sweaters, cardigans etc.) so that the right arm is bare. If the participant is wearing long sleeves or a heavy garment, ask him or her to roll up their sleeve up to all allow room for the cuff. You can also ask the participant to change into a short-sleeved shirt. If the sleeve is tight on the arm, ask the participant to take their arm out of the sleeve for the measurements.

If a participant refuses this measurement, note this on the site contact report form and move on with the visit.

- Selecting the Appropriate Cuff Size
  - Determine the appropriate cuff size using the following procedure:
    - Using a measuring tape, determine the midpoint of the upper arm by measuring the length of the arm between the shoulder and the elbow.
    - Mark the midpoint of the bare arm with a cosmetic pencil.
    - Measure the circumference of the bare arm at the mid point.
  
Record the arm circumference on the site contact report form,
  - Find the correct cuff size based on the arm circumference
    - The sizing for each cuff is found on the front of the cuff.
    - If the participant’s arm circumference fits in the sizing range for two cuffs, use the larger of the two for the measurements.
- If the participant’s are circumference is greater than 20 inches, the blood pressure measurement should not be taken. The examiner should mark on the site contact report form that the measurement could not be completed due to “cuff could not be placed correctly/did not fit properly”.
- Record the cuff size used on the site contact report form,
  - NOTE: If the incorrect cuff size is used, this will result in an incorrect blood pressure measurement. The cuff size may be incorrect even if the cuff fits on the arm. Please be sure to use the correct cuff size.

- Procedure
  - Assembling the blood pressure monitor to the cuff
    - You will be provided with:
      - 4 cuffs in different sizes with attached cuff tube:

      | Cuff Size     | Arm Size       |
      |---------------|----------------|
      | Small (child) | 7” – 9”        |
      | Regular       | 9” – 13”       |
      | Large         | 13” – 17”      |
      | Extra Large   | 17” – 20”      |
  - Air tube
  - Blood pressure monitor

- The cuffs connect to the blood pressure monitor by connecting the cuff tube to the air tube. The air tube then connects to the blood pressure monitor. The exception is the largest cuff (17”-20”) which connects directly to the blood pressure monitor.
- Steps
  1. Connect the air tube securely to the blood pressure monitor.
  2. Securely connect the air tube and the cuff tube by rotating the connection ends in opposite directions.
o Locate the brachial artery and align the cuff’s Artery Position Mark (ART) with the artery.

o Wrap the cuff snugly around the bare arm.
  - The lower edge of the cuff must be placed ½ to 1 inch above the inner crease of the elbow joint.
  - Do not put the cuff on too tight. Wrap the cuff so that you can only insert one finger between the cuff and the arm.

o Position the participant so their elbow is slightly flexed and the midpoint of the upper arm is at the level of the heart and supported by a table or other suitably high surface. The participant should be seated in a comfortable position with the cuff applied, legs uncrossed and feet flat on the floor and back supported.

o Explain to the participant that he or she needs to sit quietly for five minutes. After the rest period, the blood pressure will be taken three times with a one minute rest between measurements. During the measurements the participants should not speak.
  - If the rest period is interrupted, the examiner will need to repeat any of the needed steps outlined above and have the participant rest again for the full 5 minutes
  - Any interruptions that would increase the participant’s blood pressure such as talking, continuous coughing, telephone ringing, getting up out of the chair or anything that would startle or scare the participant will require the medical service technician to start the rest period over again.

o While the participant is sitting quietly, it is a good time to check the ID number on all participant forms.
  - Use the ID on the participant contact sheet as the correct ID number.
  - During the blood pressure rest period, you need to check the site contact report form, the aliquot tubes, the lab requisition form, the consent form and the instruction booklet to make sure the ID numbers are all the same and match the ID on the participant contact sheet.
  - If ID numbers do not match the contact sheet you should correct the error by drawing a line through the label and writing the correct ID number (the ID number from the contact sheet) underneath for each instance.
  - If the participant has a redo form, make sure the ID number matches.
  - Contact your supervisor let them know your participant had an incorrect ID number.

2. How to Operate the Monitor

o Your monitor will come fully charged from DOHMH. Please be sure to check that your monitor is charged before going on home visit appointments. The blood pressure monitor cannot be used with the adaptor cord only. (the adaptor is only for charging the battery, which takes about 12 hours)
o Turn the monitor on by pushing the ON/OFF button. The READY TO MEASURE symbol will light up indicating that the machine is ready to start the measurements.

o Check to make sure that the MODE selector is set to “AVG” and the “P-SET” is set to “AUTO”
  ▪ The average mode will be preset to
    • Number of measurements: 3
    • Waiting time until first measurement: 5 minutes
    • Waiting time between measurements: 1 minute
      o If the monitor does not take the proper number of readings or the wait time is not correct then the average mode settings have been erased or changed. Follow the steps in the troubleshooting section to reset the correct average mode settings.
      o The participant will need to rest again for 5 minutes and redo the blood pressure readings
  ▪ With the cuff wrapped around the participant’s arm, press the START button. The monitor will begin the 5 minute countdown.
    • The participant should remain quiet and still during this time.
    • If the rest period is interrupted for any reason, press the STOP button on the monitor. Repeat any of the needed steps outlined
above and press the START button to begin the rest period and measurements.

- The blood pressure monitor will not beep to indicate that the blood pressure measurements are being taken. However, you will see on the display the incremental rise and fall of the cuff pressure. Also, the lower left corner of the display will show how many readings have been taken.

- Blood pressure will then be displayed on the monitor at one minute intervals. After each measurement, record the reading on the site contact report form. If any of the readings are missed, they can be recalled after the average blood pressure is displayed.
  - When the average reading is displayed, push the gray DEFLATION button. Each of the readings will display in order, including the average blood pressure and pulse.
  - The monitor will turn off after five minutes of inactivity and the measurements will disappear.

- After the three measurements are taken, the average value will display. Record the average blood pressure and pulse.

- If you receive an error message, try to address the issues based on the codes below in the troubleshooting section. Please also record on the site contact report form which error messages came up.
  - Try to repeat the measurement once. If you are still have problems, record that no blood pressure reading was obtained on the site contact report form and move on with the visit.
  - Remove the cuff, unscrew the cuff tube and air tube, and pack up the monitor.

3. Reporting Blood Pressure reading to Participant
   - The examiner will record the participant’s blood pressure and check off the appropriate blood pressure message check-box based on the participant’s average blood pressure reading on two Understanding Your Blood Pressure Today forms.
   - The following guidelines will be used.
     - A participant with a systolic blood pressure of less than 140 and a diastolic blood pressure of less than 90 will be given a message that says their blood pressure is in the normal range.
     - A participant with a systolic blood pressure of 140 to 179 or a diastolic blood pressure of 90 to 109 will be given a message that says their blood pressure is above the normal range and that the NYC Health Department suggests he or she sees or calls their doctor as soon as possible.
     - Those with a systolic blood pressure of 180 and higher or a diastolic blood pressure of 110 and higher will be giving a message that says their
average blood pressure is very high and that the NYC Health Department suggests that he or she get medical care that day.

- The examiner will ask the participant to sign one of the forms indicating that he or she was given their blood pressure readings and the examiner will fax the signed form and mail the original form to Abt SRBI.
- The other form will be given to the participant to share with their doctor.

4. Troubleshooting Monitor Problems
   - Error Readings

If you receive an error message the following will assist you with fixing the problem. The error messages will appear on the display:

<table>
<thead>
<tr>
<th>Error</th>
<th>How to Correct</th>
</tr>
</thead>
</table>
| Er1, Er2 | • Check to make sure that the tube is inserted all the way in the unit and that the tube is not bent.  
          • Make sure that the cuff is wrapped correctly  
          • Repeat measurement |
| Er3    | • Check to make sure that the tube connecting the cuff to the monitor is not bent  
          • Repeat measurement |
| Er4    | • This error could be caused by motion. Ask the respondent to sit as still as possible and take the measurement again.  
          • If you still get an Er4 error it could be because the participant has very high blood pressure. Set the P-SET to 260  
          • Repeat the measurement. |
| Er5, Er6 | • Check to make sure the cuff is wrapped correctly  
           • Repeat measurement |

If any of the above errors cannot be resolved record that it was not possible to take the blood pressure and explain to the respondent that this sometimes happens. Then contact your supervisor and inform him or her that there is a problem with the monitor.

| Er7,Er8 | • Ask the respondent to sit as still as possible and take the measurement again.  
          • If you still get an error reading the pulse maybe irregular. Do not palpate the pulse. Record that it was not possible to get a blood pressure reading and explain that it sometimes happens. |
| Er9    | • Unit malfunction. Contact your supervisor and inform him or her that there is a problem with the monitor. Arrange to pick up another monitor. |
o Average (AVG) Function Setting
  - The average (AVG) function settings will be preset for you. These settings will automatically time the 5 minute wait period, the measurement interval and the number measurements. If these settings happen to get erased or changed the following procedure should be followed to reset them.

<table>
<thead>
<tr>
<th>Function #</th>
<th>Item to Set</th>
<th>Setting Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>Number of Measurements</td>
<td>3 times</td>
</tr>
<tr>
<td>F2</td>
<td>Waiting time until the start of 1st Measurement</td>
<td>5 Minutes</td>
</tr>
<tr>
<td>F3</td>
<td>Measurement interval</td>
<td>1 minute</td>
</tr>
</tbody>
</table>

1. When the power is OFF, push the ON/OFF button and the START button at the same time for three seconds. F1 will display.
2. Push the START button to select the function to set. Each time you push the START button the functions will change in order from F1-F3.
3. Push the DEFLATION (deflation control) to select the correct setting.
4. When the setting is finished, push the ON/OFF button to turn the power off. The setting has been changed.
5. Repeat the steps to correct the other function settings.

o Charging the battery of the blood pressure monitor
  - The blood pressure monitors will arrive to EMSI examiners fully charged.
  - The blood pressure monitor cannot be used with the adaptor power source. The adaptor is only used for charging the battery.
  - The blood pressure monitor can be used for approximately 300 measurements with one charge.
  - When the battery icon starts blinking about 20 measurements remain on the battery.
    - The examiner should charge the blood pressure monitor that evening by plugging it into an electrical outlet using the adaptor cord.
      - It takes about 12 hours to fully charge the battery.
      - When the battery is charging the battery icon will appear on the display.

The next step in the protocol is to take anthropometric measurements following the instructions below.
viii. **Weight**
The weight measurement protocol is the EMSI’s Standard Operating Procedures and Guidelines. The examiner will do the following:

- Before the participant is weighed, ensure that the scale is balanced so that the indicator is at zero when no weight is on the scale.
- Make sure the scale is level and on a firm surface (not a carpet).
- Instruct the participant to stand in the middle of the platform of the scale without shoes, head erect and eyes looking straight ahead.
- Record the results to the nearest pound using the rounding method.
- Always assist the participant on and off the scale.
- Only use examiner scales to obtain all weight measurements.

If a participant refuses this measurement, make note on the **site contact report form** and move on with the visit.

tax. **Height**
The height measurement is also the EMSI’s Standard Operating Procedures and Guidelines. The examiner will do the following:

- Have the participant stand erect on the floor or horizontal platform with his/her back against a wall, without shoes, heels together, looking straight ahead.
- If the examiner is shorter then the participant, a foot stool may be used. The examiner’s view should be level with the point of measurement on the head of the participant.
- Record the participant’s height to the nearest hundredth of an inch using rounding rules.
- Instruct the participant to stand as straight as possible but with feet flat on the floor.

If a participant refuses this measurement, make note of it on the **site contact report form** and move on with the visit.

x. **Waist Circumference**
The following protocol will be used to measure the waist circumference.

- Ask the participant to lower their pants and underclothing slightly and hold their shirt above their waist.
- If the participant is wearing a dress, ask if they can change into pants or a skirt.
- Stand behind and to the right of the participant and feel for the top of the lateral (side) border of the right ilium (hip bone). Place the end of the measuring tape on the spot and wrap it around the participant’s waist keeping a level horizontal plane.
- Record the measurement to the nearest hundredth of an inch using rounding rules.
If a participant refuses this measurement, make note of it on the site contact report form and move on with the visit.

xi. **Aliquotting the Urine Sample**

Two small samples of urine will need to be taken and sent to a lab for analysis. The following is the procedure for collecting the sample urine.

- Ask the participant where he or she would like you to take the sample of the urine.
  - Explain that you will need to mix the urine in the orange storage container, pour some out into a little cup, and then fill the two tubes.
  - Suggest that you do the procedure in their bathroom in the bathtub or on the floor.
    - If the participant does not want you to use the bathroom, you can use any flat surface such as a table or hard wood floor. Do not aliquot on carpet.
• If you have not already, ask the participant for the EMSI examiner package.

• Assemble the following materials on an absorbent mat.
  o 2 aliquot tubes, labeled with participant ID number
  o 1 Vacutainer urine transfer unit
  o 1 Small beaker
  o Pair of gloves

• Assemble the packing materials
  o 1 frozen icepack from the participant collection kit
  o Small biohazard bag
  o Small absorbent pad
  o mini thermal bag
  o Lab requisition form labeled with participant ID number
  o Shipping box – labeled “Exempt – Human Specimens”
  o Fed Ex shipping label

1. Procedure
   o Put on gloves and face mask.
   o Make sure all of the urine collected from all containers is in the orange storage containers (i.e. if there is urine in the urine hat or collection cup, add it to the orange storage container).
     ▪ If the volume is >3L and is in both orange storage containers:
       • Record the volumes on each orange storage container and add to get the total volume,
       • Then use one of the provided 5L containers to combine all the urine.
   o Record the total volume of urine collected on the site contact report form and on the lab requisition form.
   o Invert the collection container with the total volume of urine at least 8 times to ensure a uniform urine sample
   o Pour enough urine into the beaker to fill it about ¾ of the way full.
   o Using the Vacutainer transfer unit and tube, extract urine into each of the two 8 ml tubes.
     ▪ Submerge the tip of the transfer unit in the beaker of urine
     ▪ Holding the transfer unit straight up, push the tube all the way into the transfer unit. Urine will begin to fill the tube. Keep in position until the urine flow stops.
     ▪ Remove the tube, leaving the transfer unit in the beaker.
     ▪ Repeat the steps for the second tube.
     ▪ Set the tubes aside for shipping to the lab.
   o Discard the remaining urine in the participant’s toilet and flush.
   o All collection materials need to be gathered and taken with the examiner when the home visit is completed
     ▪ The materials include
• 2 3-L orange storage containers
• Collection cup
• Urine hat (females)
• Large biohazard bag
• Funnel and resealable bag for funnel
• 1 Vacutainer urine transfer unit
• 1 Small beaker
• Pair of gloves

  o The participant can keep the cooler bags, safety pins, and remaining ice packs
  that are not being used for shipment, if desired.

2. Preparing the samples for shipping
  o Place the absorbent sheet and the 2 tubes in the small biohazard bag. Seal the
    bag and put in the small thermal bag with the frozen icepack. Seal the thermal
    bag.
  o Place in the shipping box with the lab requisition form on top. Seal the shipping
    box.
  o Place the pre-printed Fed Ex shipping label on the box so it covers the label
    marked “Do not open. Examiner use only.”

xii. Incentive Payment
At the end the visit, give the participant their $90 check for participating in the study.

xiii. Shipping Samples to Lab
  • All samples will be sent to the lab by Fed Ex overnight delivery for visits completed
    Monday through Thursday.
    o The samples will need to be prepared as described above under “Preparing
      the samples for shipping”
    o Drop off package at Fed Ex drop off location the same day as appointment
      for next day delivery to the lab.
  • Samples from Friday and weekend visits will be stored by EMSI examiners at a
    refrigerated temperature and will be shipped to the lab on Monday.
    o These samples should be placed in the biohazard bag and put in the thermal
      bag with the frozen icepack. Both bags should remain unsealed until
      preparation for shipment to the lab.
    o The samples in the unsealed bags should be placed in the shipment box with
      the lab requisition form.
    o As soon as possible, the samples should be placed in the refrigerator and the
      ice pack in the freezer until Monday.
      ▪ On Monday morning, the samples should be prepared a described
        above under “Preparing samples for shipment” and arrangements
        made for next day Fed Ex delivery.
D. References

E. Key Personnel & Contact Information

With questions, please contact:
Stella Yi, PhD, MPH
New York City Department of Health & Mental Hygiene
42-09 28th Street, 9th Floor
Long Island City, NY 11101
Email: syi@health.nyc.gov

Other key personnel:
Cardiovascular Disease Prevention and Control Program:
Sonia Angell, MD, MPH

Kristin Quitoni, MPH

Epidemiology Services:
Donna Eisenhower, PhD

Michael Sanderson, MS

Kinjia Hinterland, MPH
Appendix A- Materials for Subcontractor

1) Home Visit Scheduling Call Script  
2) Home Visit Reminder Call Script (Answering Machine Script at end)  
3) EMSI Site Contact Report Form  
4) Redo form  
5) EMSI FAQs  
6) Understanding Your Blood Pressure Today form

Appendix B- Materials for Participant Urine Collection Kit

1) Kit Letter  
2) Informed Consent form  
3) Instruction Booklet  
4) Participant FAQs  
5) Study Time Log
Home Visit Scheduling Call Script

General Introduction
Hello. May I please speak to_______________?
IF NECESSARY: This is ______________ from EMSI, and I’m calling to follow-up on a telephone survey that [name] recently completed.

Participant Introduction
My name is ______________ from EMSI, and I am calling you on behalf of the NYC Health Department. You recently completed a health survey on the phone called the Community Health Survey. At the end of the survey you said that you would be willing to participate in a study that includes collecting your urine. I am calling you today to provide information about your participation in the Community Health Survey, Heart Follow-up Study, and to schedule a day for you to collect all of your urine over a 24-hour period.

I would like to briefly review what’s involved in the study, confirm your address, and schedule a time for you to participate.

_______  Continue
_______  Call back another time
_______  I don’t want to participate anymore [DISPO – REFUSED – GO TO [IF REFUSED]]

[IF REFUSED:] Can you tell me why you do not want to participate anymore?

The NYC Health Department is asking New Yorkers to provide a sample of all of their urine collected over a 24-hour period. A total of $100 is being offered for completing all portions of the study; which includes $10 for completing the interview which you have already done, and $90 for completing the urine collection.

RECEIVED - Have you received the first check for $10?

1 YES
2 NO – READ: The check for $10 should be arriving in the next few days.

I will send you a kit with all of the materials you will need to collect all your urine over a 24 hour period, including detailed instructions. This kit will be sent through the US postal service.
The kit will include:

- An informed consent form which describes the study in detail. This will need to be signed in order to continue in the study.
- Containers will be provided for storing your urine, with ice packs and cooler bags for keeping your urine cool.
- The kit will also include a detailed written instruction booklet so you can read about how to collect your urine.
- A Study Time Log will also be included in the kit. You will need to write down the time you start and stop your urine collection in the Study Time Log.

**PREVISIT1** - Someone from EMSI can also come to your home the day before your scheduled urine “collection day” to go over the written instruction booklet in person. Is this something that you would like to schedule?

1. Yes
2. No

**IF THE PARTICIPANT WOULD LIKE A PRE-COLLECTION VISIT TO WALK THROUGH THE MATERIALS AND INSTRUCTION BOOKLET, SCHEDULE THE PRE-COLLECTION VISIT THE DAY BEFORE THE COLLECTION STARTS, AT THE END OF THIS CALL.**

- The kit will also include a telephone number you can call if you have additional questions.

Your “collection day” will start when you wake up on the day you choose. When you wake up, you should go to the bathroom as usual in the toilet. For the rest of the day, you will need to collect ALL of your urine until the following day when you wake up. The storage container where you will keep your urine needs to be kept cool using the silver cooler bag and ice packs provided, or by keeping it in the refrigerator.

Next, I need to set up an appointment for a medical technician to come to your home the day you finish your collection. The technician will pick up the urine and measure your blood pressure, height, weight, and waist.

Before I do that, do you have any questions?

**EMSI NOTE: REFER TO THE EMSI FAQ SHEET TO ANSWER QUESTIONS ABOUT THE PROJECT. IF YOU ARE UNABLE TO ANSWER THE QUESTIONS OR THE PARTICIPANT WANTS TO VERIFY THE STUDY PLEASE HAVE HIM OR HER CALL [MICHAEL SANDERSON] AT THE NYC HEALTH DEPARTMENT AT 212-788-9310.**

**IF THE PARTICIPANT WANTS TO CALL NYC HEALTH DEPARTMENT: EMSI SHOULD NOT CALL THE PARTICIPANT BACK UNTIL ABT/SRBI CONFIRMS THAT THE PARTICIPANT WANTS TO CONTINUE WITH THE STUDY.**
Let’s pick a good day for your urine “collection day” and for the home visit. Please think about what responsibilities or plans you have that may make the urine collection difficult. You should pick a day to collect your urine when you are less busy.

**For Women Only:** Also, you should pick a day when you will not have your period. Urine collected while you have your period can not be used. If you happen to get your period, you can reschedule your urine collection and home visit.

You will need to be available the day you finish your urine collection for a medical technician to come to your home to pick up your urine and to complete the blood pressure, height, weight, and waist measurements. This appointment will take no more than half an hour.

Earlier you said you would be able to do your collection on a [weekday/weekend day]. Thinking about the next week and the week after, what day would you like to start the urine collection?

**EMSI:** IF PARTICIPANT SAYS THEY ARE UNABLE TO DO THE COLLECTION ON THE PREVIOUSLY ASSIGNED WEEKDAY/WEEEKEND, SCHEDULE THE URINE COLLECTION ON THE DAY THE PARTICIPANT REQUESTS.

[RECORD COLLECTION DATE]

**EMSI NOTE:** THE URINE COLLECTION PERIOD MUST BE AT LEAST 7 DAYS AFTER THE SCHEDULING CALL

Ok. So if you start the morning of [DATE] you will finish the morning of [DATE+1]. What time on [DATE+1] would be most convenient for the medical technician to visit your home?

So I have you scheduled for a home visit on [DAY DATE] at [TIME]. Thank you for participating in this important study. I will send you the urine collection kit. It will arrive in about 3 days by US postal service. I just need to confirm the mailing address where you would like the kit sent. This can be either a home, work or some other address, wherever you think you will be able to receive it. The package is too large to fit in your mailbox.

**IF ASKED:** The size of the package is 12 inches tall, 12 inches wide and 12 inches deep and weighs just over 6 pounds.

[CONFIRM MAILING ADDRESS]

I also need to confirm your home address where the medical technician will go for your home visit. I have your address as [ADDRESS]. Is this correct?
**EMSI NOTE: IF THE ADDRESS IS NOT CORRECT:** Can you tell me what your address is?

Everything I have told you today about how to collect your urine will be outlined in the kit you receive. There will also be a phone number you can call if you have more questions once you receive the kit.

The technician that will be coming to your home will call you at least 48 hours in advance to confirm your home visit appointment. Please read the instructions and if you have any questions, please call 1-800-351-4321.

**EMSI NOTE: IF PREVISIT1 = 1 [IF PARTICIPANT WOULD LIKE A PRE-COLLECTION VISIT, CONFIRM THAT NOW.]**

You indicated that you would also like someone to go over the instruction booklet in person before you start collecting your urine. I just want to confirm that you will be available on [DATE – 1 day] at your home for this visit before your collection starts. Is this okay?

*If yes – Thank you [End Call]*

*If no – We will have to change your collection day to a day when you are available the day before and the day after. What day would you like to start your urine collection?*

Thank you again for your participation in this study. Your urine collection kit should be delivered to your home in about 3 days.

[End Call]
Home Visit Reminder Call Script

General Introduction
Hello. May I please speak to________________?  
IF NECESSARY: This is ______________ from EMSI, and I’m calling to remind [name] of his/her appointment.

Participant Introduction
My name is ______________ from EMSI, and I am calling on behalf of the NYC Health Department about the Community Health Survey Heart Follow-Up Study. You are scheduled for a home visit appointment on [day] [date] at [time]. During this visit I will pick up the urine you collected, and measure your blood pressure, height, weight and waist size. This appointment will take less than 30 minutes.

KITRCVD1 - I want to confirm that you received the urine collection kit in the mail. Did you receive the collection kit?

1 YES – CONTINUE WITH CALL [GO TO IF KIT WAS RECEIVED]  
2 NO – [GO TO NOKIT1]

NOKIT1 - Did you receive a paper notification that the kit is at the post office?

1 YES [GO TO NOKIT2]  
2 NO [GO TO NOKIT3]

IF NO: PROBE WHETHER RESPONDENT MAY HAVE HAD IT DELIVERED TO THEIR WORK Place OR SOME OTHER LOCATION.

NOKIT2 – Are you able to pick up the kit from your post office or call the post office and ask them to redeliver the kit in time to start your 24-hour urine collection on [DATE]?

1 YES – WILL PICK UP – [GO TO NOKIT4]  
2 NO – READ: I will need to reschedule your collection day and home visit for when you have the kit. [RESCHEDULE HOME VISIT]

NOKIT3 - I will look into why the kit was not received and someone from EMSI will call you back and resend the kit if needed. When is the best time to reach you by phone?

Thank you. 
[END CALL]
IF PARTICIPANT STATES THEY NO LONGER WANT TO PARTICIPATE THEN DISPO – [REFUSE - AT REMINDER] AND ASK:

Can you tell me why you are no longer interested in participating in this study?

IF KIT WAS RECEIVED

KITRCVD - On the first page of the participant instruction booklet, there are pictures of items included in the kit. Did you check to see that all of the items were there?

IF YES- Was everything there?
   IF YES- CONTINUE WITH CALL
   IF NO- What is missing?

RESCHEDULE HOME VISIT AND REPORT THE NEW HOME VISIT AND THE MISSING PART OF KIT. CONTACT CLINICAL SERVICES IMMEDIATELY BY CALLING 1-866-202-5310. SO A REPLACEMENT CAN BE SENT TO PARTICIPANT

IF NO- Please check to see if all of the items are in the kit and call 1-800-351-4321 if anything is missing.

IF KIT IS AT POSTOFFICE, BUT PARTICIPANT SAYS THEY WILL PICK IT UP IN TIME FOR THE URINE COLLECTION

NOKIT4 – Once you have picked up/or received the kit, please read the participant instruction booklet. This booklet has pictures of all the items included in the kit. Please check to see if all of the items are in the kit and call 1-800-351-4321 if anything is missing.

OK. Let’s review the instructions.

• When you wake up on your collection day, urinate (pee) as usual into the toilet but do not collect this urine in the orange storage container. Write down the date and time of your first urine on the Study Time Log form that is provided.
• Begin collecting your urine the second time you need to urinate. Collect all of your urine over the next 24 hours and store it in one of the orange storage containers.
• Make sure to keep your collected urine cool either in a cooler bag with icepacks or in the biohazard bag in the refrigerator.
• When you wake up the next day collect your first urine and write down the date and time in the Study Time Log.
• On the day of your urine collection, you should continue taking any prescribed medications that you usually take.
• Before your home visit, please do not smoke, have a drink with caffeine [Ex: coffee, tea, colas], or exercise 30 minutes beforehand.
• Please wear a short sleeve shirt or a shirt that you are able to roll up the sleeve, to help make taking your blood pressure easier. Also, please wear pants or a skirt so we can measure your waist circumference.
  o **IF FEMALE:** Don’t wear a dress during the home visit, as this will make it hard to measure your waist circumference.

**Q1** - Do you have any questions about the urine collection or the home visit appointment?

**YES** → **READ:** I can answer your questions. I can also schedule a time for me to come to your home to go over how to collect your urine. [GO TO PREVISIT2]

**NO** → **CONTINUE WITH CALL (GO TO INFCONSENT)**

**IF Q1 = 1 [YES]**

**PREVISIT2** - Would you like to schedule a time for me to come to your home to go over the urine collection instructions before your collection day or do you think you can figure it out on your own?

**YES** → **SCHEDULE A PRE-COLLECTION VISIT. CONTACT EMSI SCHEDULING TO ADD THE VISIT TO YOUR SCHEDULE**

**NO** → **READ:** What questions do you have?

**EMSI NOTE:** Refer to the EMSI FAQ sheet to answer questions about the project. If you are unable to answer the questions or the participant wants to verify the study please have him or her call [Michael Sanderson] at the NYC Health Department at 212-788-9310.

**IF THE PARTICIPANT WANTS TO CALL NYC HEALTH DEPARTMENT:** EMSI should NOT call the participant back until Abt/SRBI confirms that the participant wants to continue with the study.

**IF THE PARTICIPANT WOULD LIKE A PRE-COLLECTION VISIT TO WALK THROUGH THE MATERIALS AND INSTRUCTION BOOKLET, SCHEDULE THE PRE-COLLECTION VISIT FOR THE ORIGINAL HOME VISIT TIME AND BUMP BACK THE COLLECTION DAY TO THE DAY AFTER.**

**INFCONSENT** - Do you have any questions about the informed consent? I cannot come to your home if this is not signed.

**IF YES** –

**EMSI NOTE:** Refer to the EMSI FAQ sheet to answer questions about the project. If you are unable to answer the questions or the participant wants to verify the study please have him or her call [Michael Sanderson] at the NYC Health Department at 212-788-9310.
IF THE PARTICIPANT IS WAITING TO HEAR FROM THE NYC HEALTH DEPARTMENT: EMSI SHOULD NOT CALL THE PARTICIPANT BACK UNTIL ABT/SRBI CONFIRMS THAT THE PARTICIPANT WANTS TO CONTINUE WITH THE STUDY.

IF NO — continue with call

Thank you for your time. I will see you on [DAY] [DATE] at [TIME]. Be sure to put the icepacks in the freezer the night before your collection day. Please be sure to keep an icepack in the freezer for me to use at your home visit. In the meantime if you have any questions about the instructions or the study, please call 1-800-351-4321. This toll free number can also be found on your instruction booklet.

[END CALL]
**Answering Machine Script**

Hello. My name is ______________ from EMSI for the Community Health Survey, Heart Follow-up Study. I am calling to remind [name] of [his/her] home visit appointment on [DAY] [DATE] at [TIME]. Please review the materials that were sent to you before [DATE – 2]. Also, please be sure to put the ice packs in the freezer the night before you start you collection and keep an icepack in the freezer for me to use at your home visit. If you have any questions about the instructions, have not received your collection kit yet, or are unable to keep this appointment please call the helpline as soon as possible at 1-800-351-4321 Thank you.
EXAMINATION MANAGEMENT SERVICES, INC.
Health Services Division

EMSI Field Office Site Contact Report Form [SCRF]
Fax same day of collection to 866-603-4174 and to SRBI at 301-576-5320

Client Name: SRBI
Study Name: NYC Project
EMSI Account #: 180770000

Appointment Information

Appointment Date: __________ / __________ / 2010
Appointment Time: _______ : ________ am / pm

Subject Information

Subject ID #: ____________________
Subject Printed Initials: ____________________

COLLECTION VISIT QUESTIONS (EXAMINER: read questions in *italics* verbatim to subject)

1. EXAMINER: Signed Consent Form Collected?
   - Yes
   - No → STOP. Do not continue w/o consent

2. EXAMINER: Indicate if Total Urine Volume is >500 cc (if volume is close to 500cc, measure carefully)
   - Yes
   - No → STOP. ADMINISTER REDO FORM

3. Were you menstruating, that is having your period, at any time during your collection?
   - Yes → STOP. ADMINISTER REDO FORM
   - No, Female
   - Male/NA

4. Did you urinate directly into the toilet for your first urination at your start time?
   - Yes, Urinated directly into toilet
   - No, Collected → STOP. ADMINISTER REDO FORM

5. EXAMINER: Record Start Time from Study Time Log
   IF TIME LOG NOT FILLED: What day and time did you start your collection? That is the first time you urinated on your collection day.
   - a. Date: ___ ___ / ___ ___ / 2010 (mm/dd/yyyy)
   - b. Time: _____ : _____ (AM / PM)

6. EXAMINER: Record End Time from Study Time Log
   IF TIME LOG NOT FILLED: What day and time did you end your collection? That is the last time you collected your urine.
   - a. Date: ___ ___ / ___ ___ / 2010 (mm/dd/yyyy)
   - b. Time: _____ : _____ (AM / PM)

7. EXAMINER: Calculate the total collection period:
   What is the number of hours between the time listed in Q5 and the time listed in Q6?
   - a. _________ hours.
   - b. Is it 22-26 hours? Yes → STOP. ASK TO REDO
   - c. Participant unwilling to redo collection → Proceed with visit and collect sample per protocol

8. During your collection period, did you collect your urine every time you used the bathroom to urinate?
   - Yes
   - No → b. How many times did you miss? ______

9. Is there any urine missing from the orange storage container for any other reason such as spilling?
   - Yes → b. Was the urine lost more than a few drops?
     - Yes
     - No

10. Were you able to keep the orange storage container cold in the cooler with ice packs or in the refrigerator until this appointment?
    - Yes
    - No → b. How long was the sample not kept cold?
      - _________ min / hr (circle min or hr)

11. Did you perform this collection on a day that you also went to work?
    - Yes
    - No
    - Do not work

12. Did you have any alcoholic drinks during your urine collection period?
    - Yes → b. About how many drinks did you drink?
      - _________ drinks (Round up. Code ½ drink as 1 drink.)
    - No
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
</table>
| 13. Have you had any caffeine, smoked or exercised in the past 30 minutes? | Yes → Complete rest of visit and do blood pressure measurements at end  
No → Continue with BP & pulse measurements |
| Blood Pressure & Pulse Measurement: Make sure the participant is sitting with feet flat on the floor with their back supported and their arm is at heart level. |        |
| 14. EXAMINER: Record measured arm size | Measured arm size → __________ inches |
| 15. EXAMINER: Record cuff size used (check one): | a. 7”–9”  
b. 9”–13”  
c. 13”–17”  
d. 17”–20” |
| 16. EXAMINER: Record arm used for BP measurement: | Right (preferred)  
Left  
REFUSED BP → SKIP TO 20. WEIGHT/HEIGHT/WAIST |
| 17. EXAMINER: Record blood pressure and pulse. Participant must rest quietly for 5 minutes with the cuff on. |        |
| A. SITTING BLOOD PRESSURE, (1) | / mm/hg |
| B. SITTING BLOOD PRESSURE, (2) | / mm/hg |
| C. SITTING BLOOD PRESSURE, (3) | / mm/hg |
| D. AVERAGE of 3 BP READINGS (A–C) | / mm/hg |
| E. PULSE (AVERAGE) | beats/ min |
| 18. a. EXAMINER: Did you have to retake the blood pressure measurement? | Yes  
No |
| INDICATE PROBLEM(S) w/ BP MEASUREMENT: | b. Error messages. Record the error message/code here:  
c. Participant had difficulty resting quietly for 5 minutes.  
d. Participant was upset/anxious/nervous.  
e. Cuff could not be placed correctly/did not fit properly.  
f. Other problems with equipment (not error messages).  
Explain: |
| 19. EXAMINER: Complete Understanding your Blood Pressure Today form. Fill in average BP on two forms. Check appropriate box, read message, and ask participant to sign one form. Take signed copy. Leave the other copy with participant. | Average blood pressure was reported to participant |
| 20. EXAMINER: Measure height, weight, and waist circumference. |        |
| A. WEIGHT | lbs. | (ex: 154 lbs)  
Refused |
| B. HEIGHT | ft’ in” | (ex: 5’ 6.25”)  
Refused |
| C. WAIST | in” | (ex: 32.75”)  
Refused |
| 21. EXAMINER: Record Total Urine Volume | __________ cc |
| 22. EXAMINER: Aliquot well-mixed urine into each of two vials. Prepare vials for shipment per protocol. Discard the remaining urine in the participant’s toilet. Were two vials of urine obtained? | Two vials obtained  
No sample obtained (collection not done correctly) |
<p>| 23. Examiner comments (optional): |        |
| Shipping Information: |        |
| 24. a. Date Shipped: |  b. FedEx, Air Bill Number: |        |
| Phlebotomist Information |        |
| EMSI Branch Name/Number: | NYContract/938 |
| 25. Date: |        |</p>
<table>
<thead>
<tr>
<th>Client Name:</th>
<th>SRBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Name:</td>
<td>NYC Project</td>
</tr>
<tr>
<td>EMSI Account #:</td>
<td>180770000</td>
</tr>
</tbody>
</table>

26. Printed Name: ___________________________
27. Phlebotomist Signature: ___________________________
EXAMINATION MANAGEMENT SERVICES, INC.  
Health Services Division

EMSI Field Office – Redo Form

Fax same day of collection to 866-603-4174 and to SRBI at 301-576-5320

Client Name: SRBI
Study Name: NYC Project  
EMSI Account #: TBA

Appointment Information
Appointment Date: ___________ / ___________ / 2010

Subject Information
Subject ID #: ___________________________________________

Appointment Time: ___________:___________ am / pm

Subject Printed Initials: ___________________________________

Phlebotomist Information
EMSI Branch Name/Number: NYContract/938

Phlebotomist Printed Name: ________________________________

Phlebotomist Signature: __________________________________

1. EXAMINER: Indicate reason for administering Redo Form (check one)
   □ Volume < 500 cc
   □ Urine collected during menstruation
   □ Initial (start of collection) void was included
   □ Length of collection time < 22 hours
   □ Length of collection time > 26 hours

2. We appreciate the time you spent collecting your urine, but your urine sample does not meet certain criteria I was given. I need to ask you to redo your collection. Would you be willing to redo the collection?
   □ Yes (follow instructions below)
   □ No (follow instructions below)

EXAMINER:
• Review collection instructions with participant
• Refer to scheduling (1-800-351-4321, option 1)
• Discard urine & remove materials as instructed
• Do NOT give $90 check – hold for redo appt.

IF REDO FOR VOLUME <500cc, MENSTRUATION, OR INITIAL VOID INCLUDED:
• 2a. Ask: Could you please explain why you do not want to redo the collection? (record answer below)
   ____________________________________________
   ____________________________________________
   ____________________________________________
• Discard urine & remove materials as instructed.
• Thank participant and give $90 check.

IF REDO FOR COLLECTION TIME <22 OR >26 HOURS:
• Proceed with visit and indicate on SCRF 7c participant would not redo collection.

RESCHEDULE SECTION (EXAMINER - USE DURING REMINDER CALL)  Date: _____________

If appointment scheduling changes, indicate reason(s):
  □ Change collection date/reschedule appointment
  □ Collection appt changed to education appt (new collection appt needed)
  □ Missing kit pieces – need to reschedule
  □ Refusal/cancel appt (no longer wants to participate)

Notify Clinical Services of Redo form or scheduling changes by calling 866.202.5310

Version 1.1 FEB 1 2010
EMSI Frequently Asked Questions

General Information

*Why is this study being conducted?*
The New York City Health Department conducts the Community Health Survey to learn about health and health care needs in our city and in your specific community. The Heart Follow-Up Study, which you are being asked to participate in, will study things like sodium, potassium and blood pressure.

*What exactly will be done with my urine? What is being measured in my urine?*
Your urine will be sent to a laboratory where it will be analyzed for sodium, potassium, creatinine and albumin. After your urine is analyzed, all of the remaining urine will be discarded immediately at the lab.

*What specific nutrients are you looking at?*
Sodium and potassium.

*What happens to my urine after the sample is collected in my home?*
When the EMSI technician comes to your home, they will examine your full urine collection and take a sample of your urine to send to the lab for analysis. The technician will flush the remainder of the urine you collected down the toilet during the appointment. Even though they will not take all of your urine to the lab, you must have collected all of your urine for 24 hours for us to be able to use a sample.

*What happens to my urine after the sample is analyzed?*
After the lab analyzes your urine, the sample will not be stored, it will be discarded.

*Will you be collecting any of my blood?*
No, for this study we are only collecting your urine and won’t be asking for a blood sample or any other type of body fluid.

*Is anyone collecting my DNA?*
No. DNA will not be collected from your urine sample. Urine is only being analyzed to measure specific nutrients such as sodium and potassium. We will also measure levels of creatinine and albumin, which are both related to kidney function.

*What are creatinine and albumin?*
Creatinine and albumin are both naturally occurring substances excreted in your urine and are both related to kidney function.
**Why do you need urine to measure sodium and potassium? Can’t I just tell you about my diet?**
Self reported diet information is not very accurate. A 24 hour urine collection is the most accurate way to measure sodium and potassium intake.

**How will results be used?**
Your results will be combined with results of other participants to calculate overall levels of specific nutrients. Your answers to the survey will be linked to the results of your urine analysis to provide the City with additional information about how health practices are linked to different nutrient levels in New Yorkers. We will study how consumption of these nutrients affects blood pressure. None of your identifying information will be linked to your survey answers or test results.

**Informed Consent Issues**
**What is the informed consent? Why do I need to sign it?**
The informed consent explains what the study is about and what is expected of participants in the study. By signing the form, it says that you understand what is involved in the study and agree to participate. Even after you sign the consent, you can stop participating in the study at any time. We cannot complete the urine collection without the signed informed consent form.

**I have questions about the study and would like to have them answered before I sign the consent form. Who can I speak to?**
Please ask me your questions. If I am unable to answer them, I will provide you with the phone number of the project coordinator at the New York City Health Department.

**If unable to answer question or participant requests to speak the NYC Health Department:**
Please contact Michael Sanderson at 212-788-9310.

**Privacy Concerns**
**Will my identity be confidential?**
ABSOLUTELY! Your identity is protected and will not be paired with the results of your urine analysis or your survey answers, except to inform you of an abnormal test result. No one outside of EMSI or Abt/SRBI, the company you completed the telephone survey with, will even know that you have participated. Both of these companies are required to keep your personal identity private and confidential.

**Who will have access to the results?**
Your responses will be combined with all of the results from everyone else who participates in the Community Health Survey Heart Follow-up Study. There will be nothing in the combined data that can identify you or anyone else at an individual level. The Health Department does not have access to your name or your address. The combined results will be used by different programs in the Health Department to develop programs to better meet the health needs of New Yorkers. No one outside EMSI or Abt-SRBI, the company you completed the telephone
survey with, will even know that you have participated. Both of these companies are required to keep your personal identity private and confidential.

**Why do you need my mailing address and my physical address?**
We need your mailing address to send you the materials to collect your urine. If it is different from your mailing address, we will also need your home address for one of our EMSI examiners to come to your home to collect your urine and basic physical measurements. Any personal identifying information, such as your address or phone number will only be used by EMSI or Abt-SRBI for the purposes of this study. The Health Department will not have access to this information. Your name, phone number and mailing address will be used to:

- Send you a kit with materials you need to collect your urine
- Send you a $10 check
- Contact you to schedule an in-home appointment to collect your urine
- Send you a letter to inform you of an abnormal test result

Your personal information will not be used for any other purpose other than what I just told you.

**What will I be sent?**
We will send you a box through the US postal service that contains all of the materials you will need to collect your urine over a 24-hour period.

**Procedure and Kit Materials**

**What exactly am I being asked to do? / What materials will be provided?**
You are being asked to collect ALL of your urine over a 24-hour period and store it in a container that we will provide. We will send you a collection kit with an instruction booklet and a phone number to call at any time if you have any questions. The necessary materials for collecting and storing the urine and keeping it cool will be included in this kit.

Some of these materials include: two orange storage containers, one to use to store your urine at home and one to use if you leave your home, a urine collection cup and a urine hat for women to urinate directly into. We will also provide a travel cooler bag so that you can easily collect your urine when not at home during the 24-hour period.

**What if I read the instructions and they are not clear?**
The collection kit includes a detailed instruction booklet on how to collect your urine. However, if you do not understand the instructions or have any other questions, please call the toll-free helpline at 1-800-351-4321. Someone from EMSI can answer your questions or an EMSI technician can come to your home and explain the contents of the kit and provide more instruction on how to collect your urine.

**What will the package labeled “Do not open. Examiner use only.” be used for?**
These materials will be used by the technician during your home visit appointment. The materials in the package include data collection forms and equipment to prepare your urine to be sent to the lab for analysis.
**Why shouldn’t I include urine from my first urination of the day?**

It is very important that you **do not** collect your urine the first time you urinate (pee) at the start of your collection day. Otherwise, your collection will not be correct. When you wake up on your start day, you should go to the bathroom as usual in the toilet. You will need to write down the date and time of your first urination on the Study Time Log included in the kit, but do not put this first urine in the storage container. Begin your collection the next time you use the bathroom, and collect all your urine for the next 24 hours.

**Do I have to stay home the entire day that I do this? What if I work, or need to go out for some reason?**

You do not need to stay at home during the collection. The kit will include two orange storage containers for your urine, one to use at home and another one to use if you need to go outside of your home. If you need to go out of your home for work or errands, use the second orange container that is not being used to store your urine at home. The kit will also include an extra cooler bag for storing the collection container outside of your house, and ice packs to keep your urine cool while you are outside of your home.

**Do I have to start the collection in the morning?**

No, you do not have to start the collection in the morning. We recommend that you start the collection when you wake up for the day, whether this is in the morning, afternoon or evening. This is the simplest way to ensure a complete and accurate collection.

**Is there a difference between the two orange storage containers or between the ice packs?**

No, the two orange containers are identical. Use one container to store your urine at home and use the other container to store urine if you go outside of your home. Both of the orange storage containers have the boric acid tablets in them. All of the ice packs are the same thing.

**Can I use the travel cooler bag in my home/silver cooler bag for travel?**

Yes, you can swap the bags. Use one bag to hold an orange container at home and use the other one if you need to go out. Just remember to always keep your collected urine in the orange storage containers cold using the ice packs in the cooler bags (using two packs in a cooler bag at a time).

**Is there anything dangerous included in the collection kit?**

A small amount of boric acid is being included in the orange storage containers to slow bacteria growth in the urine. It is not dangerous to adults but can cause skin or eye irritation by contact or could cause an upset stomach if swallowed. It can be dangerous to young children and pets. Make sure to keep the two orange storage containers out of the reach of children, pets, and people with sight or mental impairments.
**Should I urinate directly into the orange container I will be using to store my urine?**

No. You should not urinate directly into the orange container, rather use the collection cup or the urine hat (women only). The orange storage container has a preservative (boric acid) that prevents bacteria growth.

We will provide a special collection cup for you to urinate directly into. You will then need to pour your urine from the collection cup into the orange storage container. We will also provide a special funnel that will make it easier to pour the urine from the collection cup into the orange storage container. Always be sure to remove the funnel and put the lid back on the orange storage container tightly after you have poured urine in.

*(For women only)*: We will also provide a ‘urine hat’ which is a collection cup that sits in the front of any toilet to make it easier for you to collect your urine. You will then need to pour your urine from the ‘urine hat’ into the orange storage container. We will also provide a special funnel that will make it easier to pour the urine from the urine hat into the [orange] storage container. Always be sure to remove the funnel and put the lid back on the orange storage container tightly after you have poured urine in.

*(For women only) How do I use the urine hat?*

The urine hat fits on the front of the toilet. You should lift up the toilet seat and place the urine hat on the front then lower the seat. The rounded end fits in the front of the toilet. Sit on the toilet as usual to urinate, making sure the urine hat is collecting your urine. When you are finished, place the orange storage container on the floor by the toilet, insert the funnel in the container, remove the urine hat from the toilet and then pour the urine from the urine hat into the funnel.

*(For women only) I don’t want to use the urine hat.*

If you do not want to use the urine hat, you don’t have to. You can also use the collection cup to urinate directly into.

**How do I transfer my urine from the collection cup/urine hat without spilling it?**

There is a funnel included in your materials. Place the funnel in the orange storage container and pour the urine slowly into the funnel so it goes into the storage container. Always be sure to put the lid back on the storage container tightly after you have poured urine in.

**How do I keep the urine cold?**

You should keep your urine cold at all times. The collection kit that is sent to you also includes 6 ice packs. You will need to put these ice packs in your freezer the night before you begin the collection and these ice packs can be used to keep the urine cold.

To keep your urine cold whether at home or if you leave your home, you can put an [orange] storage container in a cooler bag with 2 frozen ice packs. You should rotate the ice packs every 12 hours, by replacing the ones in the cooler bag with ones from the freezer.
If you are at home, you can also put the storage container in the provided biohazard bag and place it in your refrigerator. Make sure to keep any urine that is in an orange storage container cold.

**Why do I need to keep the [orange] storage container cold?**
In order for the tests that we do to be accurate, it is important to keep your urine cold.

**How do I collect my urine when I am away from home/at work?**
A travel cooler bag is included in your kit so you can carry everything you will need to collect your urine if you are away from home. You will need to carry one of the storage containers, urine hat/collection cup, funnel, and 2 frozen ice packs in the travel cooler bag. You should also bring the instruction booklet with you. Bring the travel cooler bag with you each time you visit the bathroom. The urine should always be collected according to the instructions.

**Troubleshooting**

**I spilled some urine while I was transferring the urine into the orange storage container. What should I do?**
Please continue to collect your urine for the remainder of the collection period. Clean up the spilled urine but do not include it in the storage container. When you put your urine into the storage container, please remember to place the container on a flat surface, and pour the urine slowly into the funnel so it goes into the container.

Also, after you have poured the urine into the storage container, remove the funnel and make sure to tighten the lid all the way.

**I forgot to collect my urine one/two time(s). What should I do?**
Please continue to collect your urine for the rest of the collection period. You will need to make sure to collect your urine every time you use the bathroom for the rest of the collection period. You can try some of the following techniques to help you remember:

1. Pin your clothes and your underwear together using one of the safety pins.
2. Put notes on the door of the bathroom on the toilet or anywhere that will help you remember to collect your urine.
3. Place the collection cup/urine hat on top of the closed toilet lid.

**I forgot to collect my urine three/four/five times. What should I do?**
You will need to redo your urine collection. Let’s reschedule your urine collection and home visit appointment. I will also send you a new collection kit. Please flush any urine already collected down the toilet. At your home visit appointment, the medical technician will take all the kit materials with them.

**EMSI:** Schedule the new 24-hour urine collection and home visit. Make sure the start of the 24-hour urine collection is at least 7 days after this call. The participant will need a new kit mailed to them.

(For women only) **I got my period while I am collecting my urine. What should I do?**
Urine collected while you have your period cannot be used. Let’s reschedule your urine collection and home visit appointment. I will also send you a new collection Kit. Please flush any urine already collected down the toilet. At your home visit appointment, the medical technician will take all the kit materials with them.

**EMS1: Schedule the new 24 –hour urine collection and home visit. Make sure the start of the 24-hour urine collection is at least 7 days after this call. The participant will need a new kit mailed to them.**

**What if the urine I collect is more than what fits in one orange storage container?**
If the volume of your urine is greater than the volume that one storage container can hold, you can store the rest of your urine in the other container. Just make sure to keep both storage containers cold with either provided ice packs or the refrigerator.
Understanding Your Blood Pressure Today

Thank you for participating in the Community Health Survey Heart Follow-Up Study being conducted by the New York City Health Department.

Your average blood pressure today is ______________.

☐ Your blood pressure today falls within the normal range. For most people, blood pressure below 140/90 is within the normal range according to national guidelines.

☐ For most people, blood pressure of 140/90 to 179/109 is above the normal range according to national guidelines. The New York City Health Department suggests that you see or call your doctor as soon as possible to discuss this blood pressure reading.

☐ Blood pressure of 180/110 or greater is above the normal range and is very high according to national guidelines. The New York City Health Department suggests that you see your doctor or get medical care today.

These findings do not represent a medical diagnosis. Only your doctor can determine if these results indicate illness. We advise you to review this letter with your doctor, who can help you better understand what these results mean for you. If you do not have access to a doctor or do not have health insurance please call 311 for more information on how to get a doctor. If you have other questions about this form, you can reach the New York City Health Department at 212-513-0525, between 9 AM and 5 PM Eastern Time, Monday through Friday.

If this blood pressure is not normal for you or if for any reason you are not feeling well, please contact your doctor.

__________________________   ____________
Participant signature     Date
Dear Study Participant,

Thank you for taking part in the Community Health Survey Heart Follow-Up Study and agreeing to collect your urine for 24 hours. You are scheduled to begin your urine collection on ________________ and have a home visit appointment on ________________ at __________am/pm. During the home visit a medical technician will pick up the urine you collected and measure your blood pressure, height, weight, and waist. The appointment will take less than 30 minutes.

In preparation for the home visit, please remember the following:

1) Do not smoke, have a drink with caffeine (coffee, tea, soda), or exercise 30 minutes before your scheduled home visit appointment.
2) Wear a short sleeve shirt or one with sleeves that can be rolled up easily to help make taking your blood pressure easier.
3) Do not wear a dress. Wear a comfortable and loose fitting skirt or pants so that the EMSI technician can measure your waist.
4) Leave one ice pack in the freezer for the medical technician’s use.

This package includes everything you will need to collect your urine. Please read the instructions and look at all the materials the night before the start of your urine collection. If you have any questions about how to collect your urine or the study, if you need to reschedule your home visit, please call the toll free study helpline at 1-800-351-4321.

If you’d like more information on the Community Health Survey Heart Follow-Up Study, please visit our website at: http://www.nyc.gov/health/heartfollowup.

We appreciate your willingness to participate.

Sincerely,

Sonia Angell, MD, MPH
Director, Cardiovascular Disease Prevention and Control
New York City Department of Health and Mental Hygiene
Consent to Participate in a Research Study

Study: The Community Health Survey Heart Follow-Up Study

You are being invited to take part in a research study about heart health called the Community Health Survey Heart Follow-Up Study. This study is being conducted by the New York City Health Department. Please sign the last page after reading this information.

What is the study is about?

The Community Health Survey Heart Follow-Up Study is being conducted by the NYC Health Department in an effort to learn more about the heart health of New Yorkers and how sodium and potassium affect blood pressure. About 1,800 other New Yorkers are also taking part in this study.

By agreeing to participate in the Heart Follow-Up Study you agree to:

• Collect all of your urine over a 24-hour period, using materials sent to you in the mail by EMSI, the company that is contracted by the Health Department to assist with this study.
• Allow a medical technician from EMSI to come to your home the day you complete your urine collection. The medical technician will measure and take your urine and ship it to a laboratory to be analyzed. Any additional urine, after it has been analyzed at the lab, will be disposed of. At the home visit, the medical technician will also measure your blood pressure, height, weight, and waist size.

What do I gain by taking part in this study?

• By participating in this study you will help the NYC Health Department learn more about the health of New Yorkers.
• You will be notified if your blood pressure falls outside of the normal range or laboratory tests indicate problems with your kidneys.
• In appreciation for your participation you will receive $100 in compensation. You should have received a check for $10 in the mail for completing the interview part of this study. The remaining $90 check will be hand delivered by the medical technician on the day of your home appointment.

Are there any risks to participating in this study?

A small amount of boric acid has been included in the orange urine storage containers to inhibit bacteria growth in the urine. It is not dangerous but can cause skin or eye irritation by contact or cause an upset stomach if swallowed. To avoid contact with skin, follow the urine collection instructions. If you happen to get some on your skin, simply wash it off with soap and water. You can also call the toll free EMSI helpline telephone number at 1-800-351-4321.
Will my information be kept confidential?

We respect your privacy. Public laws keep all information you give confidential. No one outside of EMSI, the home visit examination service, and Abt/SRBI, the company you completed the telephone survey with, will know that you participated. Both of these companies are required to keep your personal identity private and confidential. All research records will be kept secure and your individual results will not be connected to your name, address or other identifying information in any way other than to inform you of any abnormal test results.

Do I have to participate in this study?

No, participation is completely voluntary. It is up to you to decide. You will not lose any benefits or rights you would normally have if you choose not to participate. Even after signing this form, you can decide not to participate at any point.

What if I have questions?

You can discuss them with the medical technician at your home visit or call the Health Department at 212-788-9310. Or if you have any questions about your rights as a volunteer in this research, you can contact the NYC Department of Health and Mental Hygiene’s Institutional Review Board (IRB) at 212-788-4483. An IRB is a group that watches over the rights and safety of people that are in research studies.

Statement of Consent:

I have read the consent form or have had it read to me. I have had the opportunity to ask questions and my questions have been answered. I consent to participate in the Community Health Survey, Heart Follow-Up Study.

Your Signature _________________________________      Date ________________________

Your Name (printed) ____________________________________________________________

This consent form will be kept by the researcher for at least two years beyond the end of the study and was approved by the IRB on [March 2, 2010].

Contact information used to send collection kit supplies for the CHS Heart Follow-Up Study will be securely stored for at least two years beyond the end of the study by Abt/SRBI. Contact information will NOT be given to the Health Department or any other private or governmental agency.
Thank you for participating in the Heart Follow-up Study. Please be sure to read all of these instructions. The study results will only be accurate if you follow the instructions and collect all your urine for 24 hours.

If you need to reschedule or cancel your home visit appointment, call the helpline at 1-800-351-4321.
Please be sure to read all of the instructions in this booklet. The study results will only be accurate if you follow these instructions closely.

**Step 1:** Review the contents of the kit  
**Step 2:** Review how to use the pieces of the kit  
**Step 3:** Get ready to collect your urine  
**Step 4:** Record your START time  
**Step 5:** Collect your urine  
**Step 6:** END your collection  
**Step 7:** Get ready for the home visit

**Study Basics**

- The study period is 24 hours long, beginning when you wake up on the start day.
- When you wake up on the start day, urinate (pee) in the toilet as usual. DO NOT collect this first urine of the day, but BE SURE TO write down the date and time of your first urine in the Time Log.
- Begin to collect your urine the second time you urinate; store it in the orange storage container.
- Continue to collect and store all your urine each time you urinate during the 24-hour study period. Keep your collected urine cold either by storing the orange storage container in the cooler bag with frozen ice packs or by keeping it in the biohazard bag in the refrigerator.
- Wake up the next day at about the same time you did on the start day. Collect all the urine from the first time you urinate on the second day. This is the last urine you will collect. Write down the date and time of this last urine in the Time Log.
- Keep your orange storage container cold until your home visit appointment.

Call the helpline at 1-800-351-4321 if you have any questions. Mon through Fri: 8am–8pm; Sat: 11am–3pm.
STEP 1: REVIEW THE CONTENTS OF THE KIT

Make sure you have all the kit pieces pictured below. If any are missing, call the helpline at 1-800-351-4321.

- Urine hat (For women only)
- Urine collection cup
- Funnel with resealable bag
- Orange storage containers that contain a preservative (2)
- Biohazard bag
- Home cooler bag
- Ice packs (6)
- Safety pins (2)
- Travel cooler bag either blue, red or black
- Home visit package Do not open; for medical technician only

Your kit also includes the following materials:
- Welcome letter
- Consent form
- This instruction booklet
- Study Time Log
- Frequently Asked Questions (FAQ) sheet

Call the helpline at 1-800-351-4321 if you have any questions. Mon through Fri: 8am–8pm; Sat: 11am–3pm.
STEP 2: REVIEW HOW TO USE THE PIECES OF THE KIT

<table>
<thead>
<tr>
<th>Item</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urine Hat (for women only)</strong></td>
<td>Women can use the urine hat to collect their urine. The urine hat sits under the toilet seat.</td>
</tr>
<tr>
<td><strong>Urine Collection Cup (for men and women)</strong></td>
<td>Both men and women can use this cup to collect their urine.</td>
</tr>
<tr>
<td><strong>Orange Storage Containers</strong></td>
<td>The urine collected in the urine hat or the collection cup will be poured into and stored in an orange container. Two containers are provided; one is for home use and the second is for using when away from home. DO NOT urinate directly into the orange storage container.</td>
</tr>
<tr>
<td><strong>Funnel with Resealable Bag</strong></td>
<td>The funnel should be used to help transfer your urine from the collection cup or urine hat into the orange storage container to avoid spilling.</td>
</tr>
<tr>
<td><strong>Biohazard Bag</strong></td>
<td>Use the biohazard bag when you store the orange container in the refrigerator.</td>
</tr>
<tr>
<td><strong>Cooler Bags and Ice Packs</strong></td>
<td>The home cooler bag (silver) is to be used to store urine in the orange container <strong>at home.</strong></td>
</tr>
<tr>
<td></td>
<td>The travel cooler bag (either blue, red or black) is to store urine in the orange container when you are <strong>away from home.</strong></td>
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<td></td>
<td>Keep two frozen ice packs in the bag with the collected urine at all times.</td>
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<tr>
<td><strong>Safety Pins</strong></td>
<td>Use the pins to help you remember to collect your urine. For example, you can pin your underwear to your shirt so you will be reminded every time you use the bathroom.</td>
</tr>
<tr>
<td><strong>Home Visit Package</strong></td>
<td>You will <strong>not</strong> need to use this to collect your urine. Please set aside until the medical technician comes to pick up your urine.</td>
</tr>
<tr>
<td><strong>Consent Form, Instruction Booklet, Study Time Log and FAQ Sheet</strong></td>
<td>Read and sign the consent form. Set aside to give to the medical technician.</td>
</tr>
<tr>
<td></td>
<td>Carefully read both this instruction booklet and the FAQ sheet.</td>
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<td></td>
<td>The Study Time Log is where you will write down your START and END times.</td>
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<tr>
<td></td>
<td>Any questions about these documents, call the help line at 1-800-351-4321.</td>
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</tbody>
</table>

Call the helpline at 1-800-351-4321 if you have any questions. Mon through Fri: 8am–8pm; Sat: 11am–3pm.
STEP 3: GET READY TO COLLECT YOUR URINE

The night before your collection begins:

- Put all six ice packs in the freezer (as shown).
- Put in the bathroom:
  - Instruction Booklet
  - Study Time Log
  - Pen (not included in the kit materials)
  - **One of the two** Orange Storage Containers. The containers are exactly alike. We have given you one for home use and one you can use away from home.
- Collection Device:
  - Urine Hat (for use by women)
  - Urine Collection Cup (for use by either men or women)
- Funnel with Resealable Bag
- Home Cooler Bag

STEP 4: RECORD YOUR START TIME

- **On the day you are scheduled to collect your urine,** wake up and urinate in the toilet as usual. **DO NOT** put this urine in the orange storage container.
- Write down the time of this first urine of the day on the Study Time Log. This is your **START** time.

STEP 5: COLLECT YOUR URINE

- You will collect your urine and place it in the orange storage container the SECOND time you urinate and every time you go to the bathroom for the rest of the 24-hour study period, whether you are at home or away from home.

**Before you begin:**

- Open one of the orange storage containers and place it on the floor (or another flat surface).
- Place the funnel in the opening of the orange storage container.

**Please note:** If you need to pass stool (poop), urinate and collect your urine first.
How to collect your urine

Women can use either the urine hat or the urine collection cup to collect urine. Men should use the urine collection cup.

**Do not urinate directly into the orange storage container.**

Because the orange storage container contains the preservative boric acid, keep the cooler out of reach of children, pets and people with sight or mental impairments. Do not swallow. If boric acid comes into contact with your skin or eyes, rinse with water.

**Women: Collecting urine using the urine hat**

- Lift up the toilet seat and place the urine hat on the front half of the toilet (as shown) and then lower the seat.
- Sit on the toilet and urinate as usual, making sure the urine hat is collecting your urine.

- After you’ve finished urinating, lift the seat and carefully remove the urine hat. Pour the urine from the urine hat through the funnel into the orange storage container (as shown).
- **DO NOT** urinate directly into the orange storage container.

**Men and Women: Collecting urine using the urine collection cup**

- Urinate directly into the urine collection cup.
- After you’ve finished urinating, pour the urine from the collection cup through the funnel into the orange storage container (as shown).
- **DO NOT** urinate directly into the orange storage container.

After you have poured the urine into the orange storage container:

- Remove the funnel from the opening of the orange storage container.
- Screw on the lid tightly and swirl the orange storage container around a few times. There is a preservative – boric acid – in the container that prevents bacteria from growing in the urine. Swirling the container helps mix the urine with the preservative.
- Put the orange storage container in the home cooler bag containing two frozen ice packs. Close the bag. **OR**, if you prefer, put the orange storage container in the plastic biohazard bag and place in the refrigerator.

Repeat this process **every time** you urinate in the 24-hour period. **When the ice packs melt (usually within 12 hours), replace them with two frozen packs taken from the freezer. Place the melted packs back in the freezer.**

Call the helpline at 1-800-351-4321 if you have any questions. Mon through Fri: 8am–8pm; Sat: 11am–3pm.
Collecting urine when away from home:

- A travel cooler bag is included in your kit. Before leaving your home, pack the following materials in the cooler bag: 1. instruction booklet, 2. the other (empty) orange storage container, 3. urine hat (women) or collection cup (men or women), 4. funnel and 5. two frozen ice packs.

- Each time you use the bathroom, bring the cooler bag with you and collect your urine, following the same instructions for collection as when you are at home.

- When you get home, transfer the urine from the “away” orange storage container to the “home” orange storage container, using the funnel. Swirl the container to mix urine with the preservative. Put the orange storage container in the home cooler bag containing two frozen ice packs. OR, if you prefer, put the orange storage container in the plastic biohazard bag and place in the refrigerator.

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**STEP 6: END YOUR COLLECTION**

- The next day, wake up and collect your urine the first time you urinate. Add it to the orange storage container.

- The total study period equals about 24 hours. So, try to wake up about the same time you did the day before.

- Write down the date and time of this final urine collection in the Study Time Log. This is your END time.

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**STEP 7: GET READY FOR THE HOME VISIT**

*During the home visit, a medical technician will collect your urine, take your blood pressure, and measure your height, weight and waistline. Before this visit:*

- Keep the urine in the orange storage container cold until your home visit appointment. Put it in either of the cooler bags with frozen ice packs OR put it in the biohazard bag and place it in the refrigerator.

- Make sure that you have signed the consent form.

- Do not smoke, drink anything with caffeine (coffee, tea, soda), or exercise 30 minutes before your appointment.

- Wear a short-sleeved shirt to help make taking your blood pressure easier.

- Wear a skirt (but not a dress) or pants to help make measuring your waist easier.

- Leave one ice pack in the freezer for the medical technician to use.
**Tips for Remembering to Collect Your Urine**

*While at home:*
- Pin your clothes and your underwear together using one of the safety pins.
- Put notes on the bathroom door, the toilet or anywhere else that will help you remember to collect your urine.
- Leave the collection cup/urine hat on top of the closed toilet lid or on the back of the toilet tank.

*While away from home:*
- Place the safety pin on your clothing.
- Put a note on your desk.
- Place the travel cooler bag by your workspace.

We hope that this instruction booklet and the Frequently Asked Questions sheet answer any questions you may have. If you have any other questions, please call the helpline at 1-800-351-4321. You are free to withdraw from this study at any time.

*Thank you! Your cooperation is very much appreciated.*
Frequently Asked Questions
Community Health Survey – Heart Follow-Up Study

General questions about the study

What is the purpose of this study?
The purpose of this study is to learn more about the nutrition of New Yorkers by analyzing the urine of study participants.

How can I verify that this study is valid? No one came to pick up my urine sample. I did not receive my $90 check at the end of the home visit.
If you would like to speak to someone at the health department to verify that this study is valid or to ask other questions, please call 212-788-9310.

If you have collected your urine and the technician from EMSI did not come to your home to pick it up, or if you did not receive your $90 check for participating at the end of the home visit you can also call 212-788-9310.

Will you be collecting any of my blood or DNA?
No, we will not be collecting blood samples – only urine. DNA will not be collected from your urine sample.

As a participant, what am I being asked to do?
For a 24-hour period, we are asking you to collect and properly store your urine. At the end of the collection period, a medical technician from EMSI will visit you in your home.

What will happen at the home visit?
When you have finished collecting your urine for 24 hours, a medical technician will visit you in your home. The visit will last about 30 minutes. During this visit, your urine will be collected. The technician will also take your blood pressure and measure your height, weight and waist. These are standard measurements for this type of study. Finally, for participating in this portion of the study, you will be given a check for $90.

What exactly will be done with my urine? What is being measured in my urine?
Your urine will be sent to a laboratory where it will be analyzed for sodium, potassium, creatinine and albumin. After your urine is analyzed, all of the remaining urine will be discarded immediately at the lab. Your urine will not be tested for anything else, including drugs.

Do I have to change what I eat (or don’t eat) while collecting my urine?
No. In fact, you should eat and drink just as you normally do. We are interested in knowing what New Yorkers eat and drink on a typical day.

I take prescription medications / vitamins. Can I still take those while collecting my urine?
Yes. You should continue taking any medications prescribed to you by a doctor. Likewise, you can continue to take any vitamins or supplements that you normally do.

Questions about the contents of the collection kit mailed to you

What is the informed consent form? Why do I need to sign it?
The informed consent form explains what the study is about and what is expected of you as a participant in the study. By signing the form, it says that you understand what is involved in the study and agree to participate. Even after you sign the consent form, you can stop participating in the study at any time. The consent form needs to be signed and given to the medical technician at the time of your scheduled visit.

What will the package labeled “Do not open. Examiner use only.” be used for?
This package contains supplies needed to prepare your collected urine for the lab. During the home visit, the medical technician will ask you for this package.

Why is there boric acid in the orange storage containers? Is it dangerous?
There are boric acid tablets in the orange storage containers in order to slow the growth of bacteria in the urine. While the boric acid is not dangerous to adults, it could cause skin or eye irritation upon contact or an upset stomach if swallowed. To avoid contact with your skin, do not urinate directly into the orange storage containers. Instead, urinate into the
collection cup/urine hat that is provided. If you do get some acid on your skin, simply wash it off with soap and water.

Boric acid can be dangerous to young children and pets. Make sure to keep the two orange storage containers out of the reach of children, pets, and people with sight or mental impairments.
Questions about collecting and storing your urine

The instructions say that I shouldn’t I collect my urine the first time I urinate on my collection day. Why?
We want everyone who participates in this study to do it the same way. So, it is very important that you do not collect your urine the first time you urinate on your collection day. Your collection day will start when you wake up on the day you have chosen. When you wake up, you should go to the bathroom as usual in the toilet. Write down the date and time of this first urination in the Health Follow-up Study Time Log. After the first urination, collect all of your urine for the next 24 hours in the orange storage containers.

Do I have to start the collection in the morning?
No. The 24-hour collection period needs to begin when you wake up for the day. However, if you do not start the collection in the morning, please call 1-800-351-4321 so we can explain exactly how to start and stop your collection.

Can I rinse the urine hat/collection cup after each use?
Yes, it’s OK to rinse the hat or cup with water after each use.

Why do I need to keep the orange storage container that has my urine in it cold?
In order for the laboratory test results to be accurate, it is important that your urine is kept cold. If you’d like, you can put the orange storage container with urine in your refrigerator. However, do not put it in the freezer.

Do I have to stay home the entire day that I collect my urine? What if I work, or need to go out for some reason?
You do not need to stay at home during the collection. When leaving your home, put everything you need – an orange storage container, the urine hat/collection cup, funnel and 2 frozen ice packs – into a cooler bag and take that with you. Also, you should take the instruction booklet to remind you how the urine should be collected and stored. Every time you visit the bathroom, bring the cooler bag with you.
**I spilled some urine while I was transferring it into the orange storage container. What should I do?**
Clean up the spilled urine but do not include this in the storage container. Please continue to collect your urine for the remainder of the collection period.

When transferring urine to the storage container, please remember to place the container on a flat surface, and pour the urine slowly into the funnel so that it all goes into the container. Also, after you have poured the urine into the storage container, remove the funnel and make sure to tighten the lid.

**I forgot to collect my urine one time. What should I do?**
Please continue to collect your urine for the rest of the collection period. Here are some tips to help you remember:
1. Put notes on the door of the bathroom, on the toilet or anywhere else that will help you remember to collect your urine.
2. Place the collection cup/urine hat on top of the closed toilet lid.
3. Pin your underwear and clothing together with one of the safety pins provided.

**I got my period while I am collecting my urine. What should I do?**
Urine collected while you have your period (while menstruating) cannot be used. You should stop collecting your urine and call the helpline to reschedule your urine collection and home visit appointment at 1-800-351-4321.

**What if the urine I collect is more than what fits in one orange storage container?**
If you collect more urine than one storage container can hold, store the rest of your urine in the second storage container. Just make sure to keep both containers cold by using the ice packs provided or by putting them in the refrigerator.
Study Time Log

1. The study period is 24 hours long, beginning when you awake on your collection day.

2. When you wake up on your collection day, urinate (pee) in the toilet as usual. DO NOT collect urine from this first time you use the bathroom, BUT write down the date and time of your first urination in the Time Log below.

   Example: On your collection day, if you wake up at 7:00am to use the bathroom, you should urinate in the toilet as you normally would. Your start time is 7:00am.

3. Begin to collect your urine the second time you use the bathroom; store it in an orange storage container.

4. Continue to collect and store your urine each time you use the bathroom during the 24-hour study period.

5. Wake up the next day at about the same time you did the day before. Collect the urine the first time you urinate on the second day, and write down the date and time of your last urine in the Time Log.

   Example:
   If your start time for the 24 hour collection was at 7:00AM on Thursday, your end time should be around 7:00AM on Friday.

6. Keep your orange storage container cold until your home visit appointment.

Remember: The orange collection container contains a preservative boric acid. Keep container away from children, pets, and people with sight or mental impairments. Do not swallow. If boric acid comes in contact with your skin or eyes rinse with water.

If you’d like more information on the Community Health Survey Heart Follow-Up Study, please visit our website at: http://www.nyc.gov/health/heartfollowup

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<tr>
<th>Date (MM / DD / YY)</th>
<th>Time of Day (circle AM or PM)</th>
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<tr>
<td>Example: Start Time</td>
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<tr>
<td>Start Time</td>
<td>_____ / _____ / _____</td>
</tr>
<tr>
<td>End Time</td>
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If you have questions about the collection, please refer to the instruction booklet or call the helpline at 1-800-351-4321.

NOTES (if needed):
Example: I missed my urine collection at 11:15 AM. I spilled about half of urine collection at 3:00am.