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INTRODUCTION

This Manual of Operations addresses the SHOW standards applied to the survey methods of Recruitment planning, Recruitment and Screening, Time 1 (including Informed Consent and In-Home Questionnaire) and Time 2 (Self-Administered Questionnaire) data collection from Survey Participants (SPs).
A. RECRUITMENT PLANNING (1)

1. BLOCK GROUP - SCOUTING ACTIVITIES

Following Block Group (BG) selection (see Sampling Design Manual of Operating Procedures), the Field Team Manager and SHOW Program manager assign SHOW staff members to visit local authorities and “scout” the area in the month preceding recruitment in that BG in preparation for recruitment activities. A SHOW Scouting Checklist has been developed to support the scouting efforts. Materials needed prior to visiting a block group include block group maps and list of potential survey sites/hotels provided by administrative staff at SHOW headquarters.

Related documents
- SHOW Scouting Checklist

a. Supplies
- Block group map(s)
- List of potential Survey Sites/Hotels

b. Procedures for completing the Scouting Checklist:
- Complete identifying information and:
  - Block Group #
  - County
  - City/Town
  - Person and Date Scouted
  - Target Recruitment Weeks
  - Target Time 3 Dates at Survey Site/Mobile Examination Center

- Driving/walking through the area, make note of the following:
  - Whether area is rural, suburban or urban
  - Many vacancies in residences
  - New construction/anticipate missed dwelling units (MDUs)
  - Whether dwellings include the following (note addresses for checking against selected household addresses):
    - Apartment buildings
    - Assisted living/group homes
    - Nursing homes
    - Shelters/half-way houses
    - Huber centers
    - Dormitories/student housing
    - Vacation homes
    - Other dwellings with potential obstacles
  - Other characteristics of the BG, again noting addresses of potential obstacles (gated communities, private/long drives, etc.)
• Visit possible Survey Sites (Hotels/Other) noting:
  Address and contact name/information for follow-up
  Accommodations
    Conference room
    2 rooms/suites
    Lighting/Windows/Shades
    Restroom location(s)
    Counter space/tables and outlets
  Contract required
  Government rate available
  Availability of site for designated Time 3 dates
A. RECRUITMENT PLANNING (2)

2. ARRIVING AT THE BLOCK GROUP

Prior to arriving at the block group, officials will be contacted that SHOW staff will be working in the community. During the first week of actual household recruitment some communities request that SHOW field staff introduce themselves to municipal officials. Often, such a request will come from police officials in communities where our presence may cause suspicion among residents of the neighborhood we are visiting. If a visit is requested, it is a good idea to make this visit prior to beginning any data collection in the block group. Field staff should wear their SHOW uniform and ID badge when making this visit. Generally, it is only necessary to introduce yourself at the reception desk and explain what you will be doing in the block group. Occasionally, you may be asked for the make, model and license plate number of the vehicle you are driving.
B. RECRUITMENT (1)

1. MISSED DWELLING UNIT PROCEDURE

While we make every effort to identify all possible households prior to recruitment, there is a small possibility that there are errors in our sampling frame and we have missed potentially eligible households. If this is the case, in order to make data truly random and representative, these missed households need to be added to the sampling frame and provided equal opportunity to be recruited into the SHOW sample.

Related documents
- Missed Dwelling Unit segment of SHOW Screener (electronic)

a. Supplies
- Block group map(s)
- Laptop computers

b. Procedures for completing the Missed Dwelling Unit (MDU) procedure

- MDU Procedure
  - Locate a selected dwelling unit (SDU).
  - Face SDU from the street and move to the left around the block to the next residential unit
  - Check to see if the next residential address is on the full block group list.
  - If the address is on the full block group list, then the MDU procedure is complete.
  - Go to the end of the screener page, indicate that the MDU procedure has been completed and enter 0 as the number of MDU’s found.
  - If the next residential address is not on the full block group list but you suspect it is outside the boundaries of the block group, check your block group map.
  - If the next residential address is inside the block group and not on the full block group list it is an MDU. Record the address and repeat the process until the next residential address is on the full block group list or is located outside the boundaries of the block group. In the screener page, indicate that the MDU procedure is complete and record the number of MDU’s.
  - In apartment complexes, look for the next highest unit number and see if it is included on the full block group list.
  - If 4 or less MDU’s are found for one SDU, a new household is added for each.
  - If 5 or more MDU’s are found for one SDU, contact Andy Bersch (608 821-1255) and he will select which MDU’s will be added.

- If an MDU is found, create a new household on the computer.

To add a new household:
  - Bring up the screener page
  - Click on SURVEY>DATA
  - Highlight the SDU on your list
  - Click on the NEW HOUSEHOLD button at the top of the screener page
  - Type in the address of the MDU found and click to create the household
The MDU will now appear on the household list

- If additional MDU’s are to be added, highlight the newly created MDU and repeat the process.

The MDU procedure is often done prior to attempting contact at the SDU’s. In that case use the screener Code 16.3 Non-contact. Check sampling frame for MDU’s when recording the visit. If the MDU procedure is performed while attempting contact at the SDU, use the screener code appropriate for the visit and fill out the MDU information at the bottom of the screener page.

- **Obstacles to finding households**
  - In visiting households for the first time field staff may have difficulties accessing selected households. Among the problems they may encounter:
    - **Locked apartment buildings**
      - Some apartment buildings will be locked. In that case, field staff may need to use the intercom to contact the selected household. When no intercom is available, field staff have several options. They may leave a red bag and/or a ‘Sorry I missed you’ note in the vestibule if they have access to it. The unit number of the selected household should be written on the outside of the red bag or envelope. If field staff can’t access the inside of the building, they may leave a red bag on the entry door, again with unit number on the outside of the bag. Field staff may also utilize the building’s management office to assist in the distribution of red bags. They may also have a postcard sent to the address to inform residents of SHOW’s attempt to contact them.
    - **Senior Care Centers**
      - If the selected household is in a senior care center field staff should check with the front desk to find out about the building’s policy toward visiting residents.
    - **No Trespassing**
      - Field staff may encounter homes with “No Trespassing” signs on the driveway. In these cases field staff should check with local law enforcement before visiting the home. It is our experience that the advance letter, which states that a member of our staff will be visiting, gives us grounds to visit these homes. Field staff should leave promptly if requested by the resident.
    - **Unable to Enter**
      - There are some situations where field staff may not be able to access a household, such as locked gates, snow or mud covered driveways or dogs loose in the yard. In these cases, field staff should use the Unable to Enter screener code and try again at another time. Field staff may also encounter households where they feel unsafe visiting alone. They should arrange to have another field staff member accompany them when they visit the household the next time.
    - **Vacant or Commercial Property**
      - Field staff may encounter addresses that are empty land, vacant or abandoned homes or apartments, or commercial buildings. In the case of commercial buildings, field staff should try to verify that the property does not contain a dwelling unit. If field staff suspects that a home or apartment is vacant, they should attempt to verify with a
building manager or neighbor. In all cases, field staff should use the code appropriate for the situation.
B. RECRUITMENT (2)

2. RECRUITMENT PROCEDURES
Following Scouting and MDU procedures and the advanced mailing sent to selected households (see Public Relations Manual of Operations), recruitment on-site proceeds over a two-week period and includes the introduction of field staff (self), the research study, and the invitation to participate. These steps are completed by respectfully presenting oneself at the door of the household, asking for time in order to explain the study and posing the benefits of participation, and obtaining consent. Successful recruitment includes this step of thoughtful, respectful presentation of the research study following study protocols outlined in this Manual of Operations.

a. Related documents
Recruitment materials checklist
SP file folder checklist
- Red bags with information for participants:
  - “We are Sorry we missed you” card
  - Confidentiality card
  - Most recent Newsletter
  - WSJ article from June 2008
  - Rack card “SHOW is coming soon to your community”

Paper copies of Screeners
Paper copies of T1 questionnaires
Paper copies of T3 questionnaires
Advance letters and magnets
Preprinted thank you notes with envelopes
Blank thank you notes (IHQ appt) with envelopes
Preprinted Sorry we missed you cards with envelopes
Blank Sorry we missed you cards with envelopes
Participant Selection brochure -- for field to use as needed

b. Equipment and supplies
(As listed in recruitment materials checklist & Related documents list)

Equipment/hardware
- Computer, modem & charger
- Cellphone, car & wall chargers
- Tape recorder & batteries
- Flash-Drive

Recruitment materials
- Maps: Maps of the general block group area and with specific household locations are created for each block group.
- Sample dwelling unit / Household lists: A list with the address, household ID number and city for each selected household is created for each block group. This form also has room for notes, MDU’s and disability needs. It is a useful place for notes or to keep track of your visits to the various households.
- Time 1 – In-Home Questionnaires (IHQ) packets

Block group information
SHOW SURVEY METHODS RECRUITMENT/ADMINISTRATION MANUAL

- Community information from Phoebe\Mary
- Endorsement letter: For each block group we attempt to get an endorsement letter from a city or county official, often the health officer.
- “SHOW Will Be Working in Your Area” letter: This letter, which bears our logo, indicates the time frame we will be visiting a particular block group.
- Local newspaper articles if available

Identification materials
- Laminated ID with SHOW photo and name
- Copy of advance letter, envelope, magnet
- Binder\folder of recruitment materials to show HH member

Back up paper forms (2-3 each)
- Screen
- Time 1 – In-Home Questionnaires (IHQ)
- SHOW Business Cards
- Gift pens
- Blank Thank You Cards

Survey Site slip: An appointment reminder form where we fill in the time and date for the T3 appointment. The slip also lists the address of the survey site. The Survey Site slip is placed in the T1 packet.

c. Preparation
Before traveling to a block group for the first week of recruitment, there are a number of materials to gather that will be need in the field. This includes various forms, red bags and Time 1 (In-Home Questionnaire (IHQ)) packets. Scouting forms and additional block group materials such as maps and selected households are also e-mailed to staff either in the Field Team Update or in subsequent e-mails and copies can be printed out. The Field Team Update also has lists of resources and contacts in the community, demographic information, a sex offender list, a general description of the community and a copy of the Scouting Report.

Red Bags contain information about the survey and are left at the selected household if the residents are not home on the first visit. They may also be left at a selected household prior to attempting contact. A copy of the local endorsement letter and the applicable “SHOW will be working in your area” letter should also be placed in the red bag by the field staff. Field staff should take one red bag for each household they will be visiting.

The In-Home Questionnaire (IHQ) packet contains the materials needed when completing a Time 1 visit. The packet contains:

- A copy of the Survey Consent Form brochure
- The SHOW consent form
- The Request for Payment to SHOW SP’s form
- The Euroqoul
- The Important Instructions for SHOW Exam Center Visits form
- The SAQ booklet
In addition, field staff should place the Exam Center Appointment/Survey Site slip for the block group in the IHQ packet. Field staff generally bring 5-8 IHQ packets with them to the block group.

d. Recruitment process
Recruitment includes the introduction of staff member, introduction of SHOW and invitation to participate.

- **First visit to a household**
  On a first visit to assigned households there are several strategies that can be employed. Some field staff choose to leave red bags without attempting contact at the home. The advantage here is that it alerts household members that SHOW staff will be visiting their home. It also gives them additional information about the survey so that they can make a more informed decision. This is particularly helpful for households that did not see our advance letter. Other field staff attempt contact on the first visit and leave red bags only at households where no one is home. They may also leave a red bag if someone is home but that person did not see our advance letter. The advantage of this strategy is that it moves the recruiting process along more quickly.

  When making first contact with a potential SP, field staff should introduce themselves as a member of the SHOW staff. They should be wearing apparel with the SHOW logo and their ID badge should be visible. Field staff then present the information contained in the screener script. Important points to include are:
  - SHOW is a survey being conducted by the UW School of Medicine and Public Health to help improve the health of all Wisconsinites.
  - Their household was selected at random and participation in SHOW is voluntary.
  - All information they provide will be kept confidential
  - Each household member who completes the entire survey will receive $95 plus at least $5 in mileage reimbursement

  Beyond these points it is helpful to provide information about the purpose of the survey and how our data is used by researchers. Field staff should be prepared to answer questions about the time commitment involved, who has access to our data and what our funding sources are. The SHOW website is an excellent resource for potential SP’s who want more information about the survey.

- **Non-response**
  If there is no response to an initial visit, a door hanger and flyer stating the purpose of the visit is left at the door of the household. This flyer offers two contact methods for household members to use for arranging a time for a revisit:
    - a toll-free telephone number
    - an online website with email

  Failure to respond to this door hanger will not be taken as a refusal.

  It is anticipated that six home visits, at different times of the day and days of the week, are attempted with each selected household in attempts to gain contact. Attempts beyond six visits without having made any contact with a resident, have been shown by empirical studies to have a leveling off of the response rates as a function in spite of continuing to increase the number of attempts beyond this number.
• Refusal
If the potential SP has decided that they do not want to participate in the survey, thank
them for their time and leave promptly. Field staff should not attempt to convince a
potential SP to participate if they have been given a refusal. Our job is simply to provide
information about the survey and allow each potential participant to make his/her own
decision, without coercion or pressure. If a potential SP is hesitant, would like more time
to make their decision, or wishes to discuss the survey with other household members,
field staff should return at another time. It is often helpful to ask if there is a preferred
time for another visit.

• Participation
For potential SP’s who express interest in participating, field staff should explain
that the survey has eligibility guidelines and the first step in our process is a
screening procedures used to determine who in the household is eligible to participate.
The screener takes 10-15 minutes.

Special considerations on barriers to participation

Visit times: The field team returns to households at whatever times are most feasible for
connecting with the various household members. These times may include **evening and
weekend hours** to accommodate the schedules of potential participants.

Building rapport with household members: SHOW schedules field team staff of different
genders, ethnicities, and language competencies to return to different households to minimize
barriers to participation and to assure clear communication and the building of rapport with the
household members.

Translation for non-English speakers: In the case of a language other than English, subjects
are presented with a **card that has multiple listings of languages that they can select as their
language of choice**. This method is used to determine the language spoken in the household.
In-person and telephone translation services are utilized by the field team when necessary to
accomplish screening and recruitment.

Until Spanish documents are completed, inclusion in the study depends upon ability to speak
and understand English.
C. SCREENING (1)

1. SCREENING PROCEDURES

Computer: Screener Module (SCQ)
This module is the initial information sought at the door of the residence from an adult member of the household. This information is sought in an attempt to verify that it is a household in the sample and to screen the household for potential eligible participants. Even if the individual members of the household refuse, SHOW seeks basic profile information on the household so that refusers can be compared to participators to determine the representativeness of the sample. Questions are organized by the most important, so that if refusers stop or cut off the questioning, we get highest priority data.

a. Related documents
SP file folder checklist

b. Equipment and supplies
See recruitment equipment and supplies

c. Household screening
All household and individual screening is completed by the field team. The steps in screening include the following:
- Dwelling unit identification verified by GPS coding
- Confirmation of type and number of housing units keyed for this dwelling unit
- Confirmation of respondents at this residence

These steps are completed by assuring that the respondent is, at a minimum, an 18 year-old adult, who although not eligible for study participation, is legally/ethically able to enumerate household members. It should be noted that while any household member who is 18 or older can do the screener, there are times when field staff need to use discretion before proceeding. If the household member is in high school or a young adult living at home with their parents, it is sometimes preferable to wait and do the screener with a parent, if they are willing. This is to avoid any conflict between household members about participation in the survey. Field staff members should not attempt to begin a screener with a younger household member who is hesitant or would prefer that a parent be present.

It is recognized that multiple visits to a household may be necessary to:
- Find an adult at home who can answer screener’s questions; and
- Discuss and obtain consent for participation in SHOW with each eligible household member individually.

After obtaining a response at the randomly selected address and introducing the study, the field team screens the household for eligible members by enumerating them by name, gender, and age. An attempt is made to obtain a response to these screening questions even among individuals who decline participation in the survey. This information is used to monitor differences among participants and decliners and thus assess the possibility of response and selection biases.

d. Individual screening for eligibility
An individual member of the household must meet all of the following inclusion criteria to be eligible for participation in SHOW:
The selected dwelling unit is their usual place of residence (defined as anticipated residence at this address for more than six months during a calendar year) at the time of interview or they are staying there and have no other usual place of residence.

They are ages $\geq 21$ and $\leq 74$ years of age.

They are capable of giving written informed consent and able to communicate answers to interview questions.

**Special circumstances**

During the screening process field staff may encounter individuals with special circumstances.

**Exclusion criteria**

People meeting any of the following criteria will be excluded from SHOW:

- Residents of nursing homes, hospitals, mental institutions, penal institutions, jails, halfway houses, or are under the jurisdiction of the Department of Corrections.
- Students living away from home (not currently residing in the selected dwelling unit).
- Full-time members of the armed forces or activated units of the National Guard who are currently stationed away from home and do not usually sleep in the dwelling unit.
- Anyone who is just visiting the household.
- Persons who have two residences and who spend the greater number of nights at the other residence.
- Resident where a diagnosis of mental incapacity has been voluntarily disclosed and no representative is willing and knowledgeable enough about the resident to be a proxy respondent. No one is excluded solely on the basis of any kind of diagnosis.

**Monitored by corrections system**

If a potential participant is under the supervision and monitoring of the corrections system, they may participate if they are on parole but not if they are on probation. If it is possible to schedule an appointment after their probation period has ended, they may participate.

**Cognitive impairment**

If a potential participant has a cognitive impairment, a legal guardian or has granted power of attorney to another, special care should be taken. Field staff will need to get permission from the legal guardian or POA and make sure they are willing to co-sign the consent form. They should also make sure that the participant is not under coercion or pressure and evaluate the extent of participation appropriate for the individual. These issues should be discussed with the field staff’s supervisor prior to performing the IHQ.

**Temporarily absent**

Where members of the household are temporarily absent from home during the interview period (e.g., retired members of the household living in Florida for a few months of the year; merchant seaman, those on extended business or vacation trips), a note is made in the computer database as to when these household members will be returning to the household and the home telephone number is requested. A SHOW screener or headquarters staff will call this member shortly after their return to schedule a home visit to discuss their potential participation in the study.
Up to six attempts are made to contact and recruit each eligible member who has been identified as a member of the household. There is no requirement that all eligible members of a household participate; consents and refusals are by individual, not households.

**e. Assignment of Survey Participant ID Number (SPID#)**

The subject participant (SP) ID number is generated once subject households have agreed to complete the household screening. Each eligible SP receives a randomly assigned ID number even if they refuse to participate in any other portion of the survey. The screen will associate age of individual household member with the household ID number and indicate lack of participation or willingness to continue to participate.

**f. Scheduling**

When the screener has been completed field staff will explain, if they haven’t already done so, the three parts of the survey and the time involved in each. It is helpful to reiterate that participants can complete as much of the survey as they wish and their payment is figured accordingly.

For eligible household members who wish to participate, an appointment is made for the Consent and In Home Questionnaire (IHQ). Typically the appointment will take place during the two weeks of recruitment. If this is not possible, the Consent/IHQ can be done during the survey site week.

- The appointment date and time should be called in to the SHOW office, along with the participant’s name, SPID number, address, telephone number and HHID number. This information is placed on the appointment calendar.
- If two eligible participants in a household wish to do the Consent/IHQ at the same time, information for both should be called in and two interviewers will be scheduled for the appointment. The interviews can be done simultaneously but separately.
- If the participant is unable to set an appointment time following the screener, they may call the SHOW office or have our office call them to set the appointment.
- If there are household members who are eligible to participate but decline, this should be noted in the comment section at the end of the screener. In this case, it is also helpful to immediately go to the Time One case list and code those household members as a refusal.

Participants may do the Consent/IHQ immediately following the screener. Occasionally, participants will prefer to do the Consent/IHQ/Time 3 all in the same day during the survey site week. This is allowed as long as the participant understands the time commitment involved. The office should be informed so they can schedule enough time on the appointment calendar. It should be noted that in such cases, the SAQ should not be left for the participant to complete prior to the appointment, unless the consent process has been completed first.
D. TIME 1: INFORMED CONSENT (1)

1. INFORMED CONSENT OVERVIEW
For eligible household members the field team extends an invitation to consider participating in SHOW. The consent process must be performed before the participant completes any part of the survey. It is designed to give a potential survey participant more information about the survey, resources to contact and time for discussion about the survey.

The consent process consists of a review of the Survey Consent Brochure and the signing of the Consent Form. Field staff should allow survey participants to read the Survey Consent Form themselves or review the entire document with them, including:
- the time commitment
- the scope of the interviews
- the physical exams
- the types of specimens collected

The consent is available in English. The entire set of SHOW questionnaires and consent forms are in process of being translated and will be used with Spanish speaking subjects once IRB approval is obtained. Prior to this approval, it is necessary to enroll only those people with a stated understanding and ability to speak English. The study materials will be translated into Spanish with many of the documents already having been translated by the standardized sources such as NHANES.

Subjects with limited capability or ability to read are accommodated in the following manner:
- The IRB-approved consent form will be read to the subject, with a witness present.
- The witness can be a family member but is preferable to be a friend, patient advocate, or someone else who is independent of the research team.
- The presentation of the consent form as well as the consent process will be audiotaped and a copy of the tape of this conversation will be provided to the potential subject for reference.
- The fact that the consent form was presented orally to the subject will be documented in the research record.
- The subject (as able), witness and field researcher staff all sign and date the consent.
- As would be expected for any consent process, it is the field staff responsibility to judge the subject’s comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the field staff doubts the subject’s consent comprehension, he or she should not enroll the subject in the study.

Subjects unable to provide their independent consent, such as a minor child or a subject who indicates that there is a legal guardian who signs all of their documents is not eligible for participation in the study.

The staff arranges a convenient time for a return visit for any eligible family member who is not otherwise able to complete the consent process during the visit (e.g., absent, needs to leave, needs a special consent medium, or wants extended time to consider). Household members are able to individually have their questions answered and privately sign their consent with the field team in the home after careful consideration of their options and response to their questions has been satisfactory.
D. TIME 1: INFORMED CONSENT (2)

2. CONFIDENTIALITY AND PRIVACY
This section describes the extent of privacy and confidentiality inherent in the conduct of research and in particular as it relates to SHOW.

a. Definitions
- **Privacy** - Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- **Confidentiality** - Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.
- **Certificate of Confidentiality** - A Certificate of Confidentiality is issued by the National Institutes of Health to protect identifiable research information from forced disclosure. SHOW has obtained a Certificate of Confidentiality, meaning the researchers in charge of this survey cannot be forced to disclose information that may identify survey participants or their contacts, even by court subpoena, in any federal, state, or local civil criminal, administrative, legislative or other proceedings.
- **Confidentiality and State Reporting Laws** - State reporting laws may limit the promises of confidentiality that researchers can offer subjects. Most state laws identify individuals who must report suspected child abuse and neglect. This requirement should be described when child abuse and neglect might be revealed in a research study. Specific documentation exists for reporting neglect or abuse.
- **HIPAA** - The SHOW project is not defined as a HIPAA covered project/entity for the following reasons:
  - SHOW is a part of a department that does not have direct contact with health care recipients – i.e. not a health care provider.
  - SHOW does not gather health information from health care providers.
  - However, the information gathered from subjects about their health will be regarded as covered under our requirements for privacy and confidentiality.

Note: In communities where the Marshfield team assists in interactions with subjects for recruitment and/or conduct of study visits, HIPAA (research authorization) is obtained from these subjects. Although SHOW is not a HIPAA covered entity, the Marshfield Research Foundation itself is a HIPAA covered entity and the fulfillment of this standard in the Marshfield interactive communities is therefore assured. A copy of this authorization is approved by the Institutional Review Board.

b. Responsibilities
It is a requirement of all staff involved in the conduct of any SHOW functions to maintain the privacy of all research subjects including the information that would be considered as personal identifiers or gathered information that would serve to significantly limit the number of people that have a condition or a situation, and thus could be identified.
c. Activities related to Privacy and Confidentiality

SHOW protects participants’ privacy in the following ways:

- The study is designed so that questions that are more sensitive or private are read and answered by the participants in a private room or their own home.
- The survey instruments and interview process is designed so that a subject can choose not to answer any question that makes him or her uncomfortable.

SHOW protects participants’ confidentiality in the following ways:

- Our policies and procedure for protecting your data are reviewed by the University of Wisconsin Human Subjects Research Committees and are in keeping with the requirements of Federal laws regarding privacy and confidentiality.
- All personal information, such as name and address, is stored securely and separately from the health information. Scientists who use the health information collected by SHOW will do so without knowing the identities of participants.
- Future researchers using SHOW data will not be provided with any information about your name, address, or contact information without additional consent from you.
- Each participant is assigned a Study Participant ID #, which will be linked to their health information and samples.
- Portions of the study may be audiotaped for quality assurance purposes. The tapes will be destroyed; they are not kept as part of the stored data.

Information that can be protected includes, but is not limited to:

- Substance abuse or other illegal behaviors
- Sexual attitudes, orientation, or practice
- Genetic information
- Psychological well-being
- The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.
D. TIME 1: INFORMED CONSENT (3)

3. INFORMED CONSENT PROCEDURE
The following documents the process of obtaining Informed Consent of SHOW subjects as well as to highlight the rules and ethics guiding our actions. Obtaining informed consent can only be conducted by individuals who have a current certification in Human Subject Compliance (by online certification – CITI certification).

The regulations make an important distinction between the consent process itself and the documentation of the process.

- **Process** - It is important that informed consent be viewed as a process rather than an event. Though signing of the informed consent document is the most visible feature of this process, the process of informed consent begins with the recruitment and screening of a subject and continues throughout the subject’s involvement in the research. It includes:
  - Providing specific information about the study to subjects in a way that is understandable to them.
  - Answering questions to better ensure subjects understand the research and their role in it.
  - Giving subjects adequate time to consider their decisions.
  - Obtaining the voluntary agreement of subjects to take part in the study. The agreement is only to enter the study, as subjects may withdraw at any time, or decline to answer specific questions or complete specific tasks at any time during the research.

- **Documentation** - Documentation of consent provides a record that the consent process took place. It generally consists of a consent form signed by the subject or the subject’s legal representative. In practice, this document is often used as a tool for engaging in the consent process.

**Related Documents**
Two copies of the consent form document, one copy is maintained in the subject’s binder – one copy is given to subject upon completion of signatures.

**a. Definitions**
The following are major tenets in the guidelines and ethics related to informed consent.

- **Belmont Report Principles** - In 1979, the National Commission published the Belmont Report in response to previous abuses of human subjects in research. The report laid out basic ethical principles and guidelines to be used to resolve ethical problems that surround the conduct of research with human subjects. Three main ethical principles the report identified are respect for persons, beneficence, and justice.

- **Respect for persons** - This principle requires researchers to treat individuals as autonomous human beings, capable of making their own decisions, and not to use people as a means to an end. The principle also provides extra protection to those with limited autonomy.

- **Elements of autonomy include:**
  - Mental capacity (the ability to understand and process information)
  - Voluntariness (freedom from undue control or influence of others)
Subjects have autonomy when they have the capacity to understand and process information, and the freedom to volunteer for or withdraw from research without coercion or undue influence from others.

- **Beneficence** - This principle requires researchers to minimize the risks of harm and to maximize the potential benefits of their research. This principle demands that researchers and IRBs conduct a careful assessment of the risks of harm and the potential benefits of the research and ensure that the potential benefits justify the risks of harm.

- **Justice** - The principle of justice requires us to design research so that its burdens and benefits are shared equitably. In principle, those who benefit from the research should share in the burden of being subjects in the research. Those who serve as subjects in the research should share in the potential benefits from the research.

### b. Administering the Informed Consent

After the research specialist has determined the prospective participant is eligible, he/she is responsible for ensuring that written informed consent to take part in the study is obtained from each participant. The research specialist will obtain a signed consent through one of the two following methods:

- **Method A** - The research specialist can offer the participant the option to read the Survey of the Health of Wisconsin Research Information and Consent packet. After the participant has read the Consent form, and questions have been addressed, the researcher will read each item of the Consent Signature Page to the participant. After each item is read the subject or subject’s legally authorized representative (LAR) will check “yes” or “no.”

- **Method B** - The researcher can offer the participant the option of listening to the researcher summarize the sections of the Survey of the Health of Wisconsin Research Information and Consent packet. After going through the consent form and answering any questions, the researcher will read each item of the Consent Signature Page to the participant. After each item is read the subject or subject’s LAR will check “yes” or “no.”

### c. Documentation of Informed Consent

The IRB requires documentation that informed consent, by Method A or B, was obtained. The subject or the subject’s LAR must check “yes” or “no” to each item on the Consent Signature Page. At the bottom, the subject or subject’s LAR must date, sign above “Signature of Subject” and print name. The researcher must date, sign above “Signature of SHOW staff obtaining consent” and print name. An eligible participant will receive a Study Participant Identification Number (SPID); this number will be written at the top of the consent form. The researcher will keep the top two copies of the consent and the participant will be given the pink carbon copy, as well as the SHOW Research Information and Consent form packet, as a reference and reminder of the information conveyed. The SHOW copy is placed in the Subject Binder.

### d. Informed Consent – Basic Elements

Listed below are the basic elements that must be provided to subjects as part of the legally effected informed consent.

- **A statement that the study involves research and an explanation of the purposes of the research.**
  
  *The Survey of the Health of Wisconsin is a health research project conducted by the University of Wisconsin – Madison School of Medicine and Public Health. The purpose*
of the research is to better understand the health of Wisconsin residents and to identify the factors that keep us healthy or make us sick. What we learn from this project will be used to develop public policy and health programs to improve people’s health.

- **A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue at any time.**
  Your participation is voluntary. You do not have to sign this form and you may refuse to do so. Your health care providers will continue to provide you with health care services even if you refuse to sign this form. You do not have to answer any question you don’t want to and you may refuse to do any part of the study. You may completely withdraw from the study at any time.

- **A description of the benefits to the subject or to others**
  Your involvement in this project will help us to better understand the health of your community. If you agree to participate you will be compensated $95 for your time and a minimum of $5 for travel costs. You will also be reimbursed for any child care expenses. You will receive free health test results.

- **Expected duration of the subject’s participation**
  The subject’s participation in the study starts once they sign the consent. The researcher should explain the parts of the study listed in the consent packet and the approximate time to complete each part. There are three sections to the SHOW study visit:
  - **Part 1 (Time 1): In Home Interview**
    Approx 1-1.5 hour
  - **Part 2 (Time 2): Self-Administered Questionnaires**
    Approx 45 minutes
  - **Part 3 (Time 3): Visit to Exam Center, Mobile Exam Center or Clinic Site**
    Approx 2.0-2.5 hours

  The researcher should be clear about the total time commitment expected of participants in the study. The time it takes to complete each part of the study varies from person to person, but the average time it takes for a participant to complete part 1, 2, and 3 of the study is between 4 and 5 hours.

  Subjects may choose to participate in one, two, or three portions of this study visit. Subjects must choose to participate in Time 1 in order to participate in Time 2. Additionally, subjects who wish to participate in Time 3 must have completed Time 1 and Time 2 visits. Subjects may choose to selectively not answer individual questions at any study time for their own reasons of privacy or comfort.

- **A description of the procedures to be followed once participant signs the consent**
  Below is a guideline of things to mention about the in-home questionnaire, self-administered questionnaire, exam center appointment, and follow up phone survey.
  - **In-Home Questionnaire**
    - Asks general questions about your health
    - We will record names and doses of any prescription medications, vitamins, supplements you take
    - We will record contact information of relatives or friends who would know how to reach you if your number or address changed
    - Researcher will make an appointment for you to visit one of our exam centers for a physical examination and to answer more questions about your health
  - **Self-Administered Questionnaire**
- We felt these questions were better answered by the participant on their own time
- Topics include information about stress, sleep, life experience and how you rate your quality of life
- You will be asked to complete the booklet and bring it to the SHOW survey center at the time of your health exam.

○ Exam Center Appointment
- Upon arriving at the survey center, you will be asked to change into a two-piece examination outfit
- In a private room, a researcher will measure your blood pressure, heart rate, height and weight, and circumference of waist hips and arm. You will receive a carbon copy of these results
- You will complete other tests such as the breathing capacity test and percent body fat test
- We will collect 3 tablespoons of blood and a urine sample
- Some of the blood will go to a lab to be processed right away and some will be carefully stored for future research.
- We will look at DNA bio-markers in your blood. We will not send these results to you because we do not look for any specific bio-markers (for example that cause cancer or heart disease). The DNA sample will not be sold to anyone. No one will make money from it. SHOW will not use your DNA for cloning or stem cell research.
- If you do not want to give a blood sample, we could obtain a saliva sample to store for DNA testing
- We will mail you a report that contains the result of your percent body fat test, cholesterol, blood sugar, and blood counts. If a test shows urgent health problems, we will notify you at once.
- The survey appointment is not the same as an exam by a regular doctor or nurse. It is your choice to share this information with your health care provider. If you do not have a health care provider, SHOW can give you information for your County Health department

○ Follow-up Phone Survey and Additional Tests
- Since SHOW is a long term research study we would like to learn about your health in the future.
- We will do this by contacting you on the phone to ask some questions. The survey will be less than 30 minutes and you will be paid $20 for your time.
- SHOW may look at other public health lists to update your health status (for example, state, or national vital statistic records).
- From time to time, additional tests may be added to SHOW core to help answer a specific research question. You will be told if any such tests are being offered at the time of your consent or at your visit. You may refuse to have any test.
- You may be asked in the future to be a part of other research projects related to SHOW, your participation in future studies is voluntary.

- A description of any foreseeable risks or discomforts to the subject
  Measuring your blood pressure, weight and body measurements, drawing blood, measuring lung volume, and getting urine sample are done in the same manner as if you were at your health care clinic. The measurement of body fat is safe. The questions we ask and procedure during the physical exam do not pose risks to you or your health.
The blood draw may cause you slight discomfort or leave a tender spot and maybe a bruise on the arm from which it was drawn. Some people get dizzy or feel faint after the blood draw or when blowing hard to measure lung volume. You may be embarrassed or nervous by some questions. We have organized the study to be as private as possible and you are allowed to refuse to answer any question that you choose.

- **An explanation of how the institution and researcher will maintain the confidentiality of the research records or data**
  There is a small chance that information about participants could accidentally become known, however, SHOW has designed the survey to protect participants’ privacy and confidentiality (see Definitions for additional info about privacy, confidentiality and Certificate of Confidentiality.)

- **An explanation regarding whether medical treatment is available if injury occurs**
  *In the event that you are physically injured as a result of participating in this research, emergency care will be available. Although there is no commitment to pay for your emergency care, you should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Javier Nieto at 888-433-SHOW (7469) if you are injured or for further information.*

In the event that a SHOW participant is injured, SHOW will provide medical assistance. SHOW is not responsible for payment for medical treatment. SHOW, however, recognizes that subjects have legal rights and that SHOW can be found liable for negligence.
E. OVERVIEW OF SURVEY DATA COLLECTION

Standardized interviewing techniques and data collection methods include computer-assisted questionnaire and field-team member interview completed in-home (Time 1: In-Home Questionnaire (IHQ)), a self-administered questionnaire completed by participants following the in-home visit (Time 2: Self-Administered Questionnaire (SAQ)), and questionnaires and procedures completed at the Survey Exam Center (Time 3). See Study Grid on next page.

Subjects may choose to participate in one, two, or three portions of this study visit. Subjects must choose to participate in Time 1 in order to participate in Time 2. Additionally, subjects who wish to participate in Time 3 must have completed Time 1 and Time 2 of the study visit. Subjects may choose to selectively not answer individual questions throughout the questionnaires for their own reasons of privacy or comfort.
**Study Grid** - The following displays study procedures and their time frame for completion.

<table>
<thead>
<tr>
<th>Household Screener Module with Matrix (paper – Consent)</th>
<th>Time 1 – consent and interview</th>
<th>Time 2 – self – administered</th>
<th>Time 3 – exam center</th>
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</thead>
<tbody>
<tr>
<td>In Home Interview/Computer Assisted Questionnaires</td>
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<td>Tracking</td>
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<td>Demographics</td>
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<td>Housing Characteristics</td>
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<td>Rx and OTC meds</td>
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<td>Health History Part I</td>
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<td>Sensory Dental</td>
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<td>EuroQol (Health Related Quality of Life)</td>
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<td>Health Screening and Immunizations</td>
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<td>Insurance, Access, and Utilization</td>
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<td>Occupation</td>
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<td>Physical Activities</td>
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<td><strong>Self-Administered Questionnaire (SAQ)</strong></td>
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<td>Your Health</td>
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<td>Prevention and Safety Habits</td>
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<td>Life Events</td>
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<td>Sleep Habits and Problems</td>
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<td>Discrimination</td>
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<td>Characteristics of Your Neighborhood</td>
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<td>The Foods You Eat</td>
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<td><strong>Exam Center Questionnaires</strong></td>
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<td>Smoking</td>
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<td>Alcohol</td>
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<td>Food Security</td>
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<td>Care Giving</td>
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<td>Weight Hx</td>
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<td>Reproductive Health</td>
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<td>Health History Part 2</td>
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<td>Cognitive Tests</td>
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<td>Mental Health</td>
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<td><strong>Exam Center Procedures</strong></td>
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<td>Weight, Height</td>
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<td>Waist Measurement</td>
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<td>Arm Measurement</td>
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<td>Sitting Blood Pressure, Pulse</td>
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<td>Spirometry</td>
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<td>Bioimpedance Analysis</td>
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<td>Urine Collection</td>
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<td>Phlebotomy*</td>
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<td>*Saliva Sample (with consent) by Buccal Swab</td>
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<td>if blood draw refused</td>
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(approx 1 ½ hr)  
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(approx 1-1 ½ hr)  
(approx 1 hr)
F. TIME 1: IN-HOME QUESTIONNAIRE (IHQ)

a. Related documents

Paper forms
- EuroQol questionnaire
- Request for Payment form
- Survey site instructions
- In-Home Questionnaire (IHQ) appointment cards
- Exam appointment sheet
- Self-Administered Questionnaire (SAQ) (for Time 2)
- Back-up paper copies of CAPI interview in case needed due to technical difficulties in the field

b. Overview
Upon completion of the screening process and when the consent form has been signed, the “in-home” or “Time 1” phase of the research study visit begins with each consenting eligible household member. These interviews are completed separately and are computer-assisted interviews using pre-programmed laptop computers.

If subjects are not able to complete the home interview at the time of consent or if the interviewee cannot complete the entire list of questionnaires at one time, the session will be rescheduled to a more convenient time or completed at the examination center depending on how much of the interview has been completed.

- Standardized interviewing procedures should be followed throughout.
- Field staff should make a voice recording of the interview unless the SP has declined.
- If two interviews are being conducted at the same time, effort should be made to move to separate rooms, if possible.
- At the conclusion of the interview, field staff should set up an appointment time and date for the exam part of the survey. The appointment should be called in to the office so it can be put on the calendar.
- Field staff will fill out the Survey Site appointment form and give it to the participant.
- Participants will also be given the SAQ booklet, which is to be completed and brought to the exam portion of the survey. If a participant will not be doing the exam portion they should be given a self-addressed stamped envelope to be used for returning the SAQ.
- Field staff should review the Instructions for SHOW Exam Center Visits and give a copy of the form to the participant. The appointment form, SAQ and Instructions for SHOW Exam Center Visits can be placed together in an envelope and field staff should write the SP initials, SPID number and HHID number on the envelope.
- Before concluding the appointment, field staff should make sure the participant has the SHOW office phone number so they can call if they need to cancel or reschedule their appointment.

For each IHQ field staff performs, they should retain the EuroQol, Consent form copies and the Payment slip. The address portion of the Payment slip should be filled out as well as the
Screener and IHQ information. If a participant will be in need of special considerations, specific information should be filled out in the space provided on the back of the payment slip. All three forms should be turned in at the SHOW office in the file for that block group. Field staff should make sure the SPID number is written on each form.

c. Computer and Paper-Assisted Participant Interview (CAPI/PAPI)

- VAQ: Verification of age questionnaire
- DMQ: Demographics questionnaire (including education, marital status, race and ancestry)
- HOQ: Housing characteristics questionnaire (including questions about your home and your exposure to certain hazards in the home, such as lead paint and black mold)
- RXQ: Prescription medications and select over the counter (OTC) medications
- EOQ: Euroquol (health-related quality of life questionnaire)
- HHQ: Health history questionnaire, part 1
- OCQ: Occupation questionnaire
- SDQ: Sensory and dental questionnaire
- SIQ: Screening and immunization questionnaire (including screening tests and vaccinations)
- IUQ: Insurance, access, utilization questionnaire (health insurance and health care system questions)
- PAQ: Physical activity and physical fitness
- TTQ: Tracking and tracing (Contact information for two relatives or friends not currently living in household who would know where SPID could be reached)
- Hand Cards, Time 1
G. TIME 2: SELF-ADMINISTERED QUESTIONNAIRE (SAQ)

Upon completion of each in-home interview arrangements are made for “Time 2” which are self-administered questionnaires that should be completed prior to the appointment for Time 3. The self-administered questionnaires take approximately 30-45 minutes to complete.

The self-administered questionnaires are provided to the subject in a packet. They are given a SHOW pen as a convenience to complete the packet.

A sealable envelope will be provided with each SAQ to protect the respondent’s privacy from others in the household. Participants are instructed to bring these questionnaires to the scheduled appointment at the exam center. The questionnaires are reviewed at that time. The subject will have an opportunity to ask questions or to complete the forms at the time of the appointment if they so choose.

The Time 3 study visit is dependent upon some responses derived from the SAQs, thus this step must necessarily be completed prior to moving on to Time 3.

a. SAQ Components

- Your health
- Prevention and safety habits
- Life events
- Sleep habits and problems
- Stress
- Military experience
- Discrimination
- Characteristics of your neighborhood
- The foods you eat
H. TIME 3: EXAM CENTER PHYSICAL AND QUESTIONNAIRES

After the Time 3 visit is scheduled (at the completion of the Time 1 visit, generally), the SP receives an instruction sheet for the Survey Center Visit (see Appendix). A major portion of this sheet highlights guidelines for avoiding certain activities that may affect the quality of test results.

1. QUESTIONNAIRES

Questionnaires are interspersed throughout the Time 3 interview in between the physical exam components. Generally, the Field Team begins with the CAPI interviews as listed below, followed by the anthropometry. The participant fills out the ACASI questionnaires after the anthropometry, BIA, and urine. The Field Staff then lead the participant through the PAPI tests.

**ACASI** A Computer-Assisted Self Interview,
- ALQ – Alcohol usage
- FPC - Contraception
- FSQ – Food Security
- SMQ – Smoking History
- SXQ – Sexual Behavior

**CAPI** Computer-Assisted Participant Interview,
- CGQ – Caregiving
- WHQ – Weight History
- RHQ – Reproductive Health
- HHQ – Health History Questionnaire Part 2
- PHQ-8 – Depression
- PTSD – Post Traumatic Stress Disorder
- OHQ – Oral Health
- DIQ – Diet

**PAPI** Paper-Assisted Participant Interview,
- STOFHLA – Health Literacy
- COG – Cognitive Tests
2. Location for Exam Center

The exam portion of the survey may be conducted at 1) exam center located at Madison or Milwaukee offices, 2) in the SHOW Mobile Exam Center (MEC), or 3) at a suitable facility within the community.

The MEC is a 37-foot RV-type vehicle built with three inner rooms where interviews, specimen collections, body measurements, tests, and vital signs are obtained. These vehicles run on their own generators and can also be connected to public buildings for an extended stay in a community. The MECs are clearly marked with the SHOW and the SMPH logos. SHOW's administrative team plans in advance with target communities for an appropriate location to establish the MEC for the necessary duration in a community.

Community facilities may include a space at a community center, school or university, other facility such as rental hall, American Legion, etc., or hotel conference room. These sites are visited ahead of time and selected for their ability to provide privacy, safety and comfort in the conduct of the study visits. Steps taken to insure privacy and confidentiality when conducting exams at space within the community include: 1) insuring suitability of space in terms of size and proximity to restroom and entrance, 2) providing signage and directions to exam room and 3) use of room dividers and white noise machines for when two exams are being conducted simultaneously.

Directions to the exam location are provided to each participant at the time of their in-home appointment.

Where participants have a disability or illness that prevents them from coming to an exam center, or should a participant prefer a more confidential visit, the exam team can make the home visit by car and complete most of Time 3 in the home with quick relay of the specimens to the MEC or exam site/survey center.
3. Time 3 Visit Overview

An appointment for Time 3 – or the study site visit – is made prior to the completion of the in-home interview. This appointment is made to accommodate the subject's ability to complete the exam at the Madison/Milwaukee based exam centers, the MEC exam site, or a Marshfield Clinic site or the chosen Exam Center location. This portion of the study involves the physical measurements, phlebotomy, urine sample, and completion of questionnaires, and takes approximately 1½ to 2½ hours to complete.

Appointments are made through the central office. Whenever possible, coordinating visits for all participating household members is accommodated. Assistance with transportation is offered, arranged, and financed by SHOW.

Participants are reminded of their exam appointments by mail, telephone, or email (depending on the SP's preference) both a week and two days prior to their scheduled appointments, and any travel arrangements and directions are verified. Scheduling is centrally managed at the SHOW headquarters and subjects are provided with the toll-free number if changes or cancellations need to be made.

Upon entering the exam center, each participant is checked into the computer system and his or her identity and study number is verified. The field team outlines the planned procedures, reviews and verifies consent and answers any questions. The self-administered questionnaires are collected and checked for omissions or to answer any questions.

Additional interview questions are asked, again using the pre-programmed laptop computer. These cover more sensitive questions about health and reproductive history that are more appropriately collected in an environment where the respondent has privacy from family members. Parts of the interview are done by the participant using headphones and a touch computer screen to answer questions privately (Computer-Assisted Survey Instrument, or CASI) without the technician or accompanying family members hearing the question or seeing their response. The smoking, diet, alcohol, food security, care-giving, and contraception questionnaires are administered in this manner. If the subject prefers to have these read to them, or they prefer not to use the computer, they are accommodated in this request.

4. Physical Examination Procedures

For the examination measurements, the technician takes the SP to a private room where blood pressure, heart rate, height, weight, waist circumference, and hip circumference are measured. If the clothing worn by the SP does not comfortably allow for these measurements, disposable examination clothing is provided. The technicians instruct and complete the spirometry test and apply and conduct the Bioimpedance Analysis. These measurements will be recorded via a laptop computer.
I. Anthropometry

Purpose
This section outlines the steps that field team members should follow when taking and recording six measurements (upper arm circumference, upper arm length, height, weight, waist, hip) during the physical exam of survey participants (SPs).

Process
Anthropometry is done to collect bodily measurements, as they relate to human health. Three measurements of height, waist, and hip are done. If the measurements vary by more than 10%, a fourth measurement is taken. Waist is defined as the smallest point on the human midsection, at the right ilium. Hips are measured at horizontally below the ileac crest at the widest point around the buttocks when viewed from the side. This measurement is thus done at the level of maximal protrusion of the gluteal muscles (hips). Height and weight are measured without shoes.

For detailed discussion of SHOW anthropometry, including overview and purpose, calibration of measuring instruments, preparing the SP for the exam, tips on conducting the exam, decision making regarding which arm to use for measurement, care and list of equipment, procedures for disabled SPs, and other special circumstances, please see the Anthropometry Manual of Operations and the Blood Pressure and Pulse Manual of Operations. See also manufacturers’ equipment manuals.

Equipment Needed
Blunt-edge scissors
Medical retracting measuring tape
Cosmetic pencil
Electronic scale
Stadiometer
II. Sitting Blood Pressure & Pulse

Purpose
This section outlines the steps that field team members should follow when taking and recording blood pressure and pulse during the physical exam of survey participants (SPs).

Process
Blood pressure occurs after the upper arm length and circumference have been measured. These measurements are used to correctly identify which blood pressure cuff is most suitable for the participant.

For detailed discussion of SHOW blood pressure and pulse, including overview and purpose, calibration of measuring instruments, preparing the SP for the exam, tips on conducting the exam, decision making regarding which arm to use for measurement, care and list of equipment, procedures for disabled SPs, and other special circumstances, please see the Anthropometry Manual of Operations and the Blood Pressure and Pulse Manual of Operations. See also manufacturers’ equipment manuals.

Equipment Needed
Omron IntelliSense Blood Pressure Monitor – Model HEM-907-XL
4 sizes of blood pressure cuffs that are part of the Omron device
Tubing to connect cuffs to blood pressure monitor
Luer connection to connect tubing to monitor
III. Spirometry

Purpose
This section outlines the steps that field team members should follow when performing the spirometry (lung function) test during the physical exam of survey participants (SPs).

Procedure
Spirometry is one of the best and most commonly used lung function tests. The test is done with a device called a spirometer. The spirometer is an instrument that measures lung capacity which is a reflection of lung function. This instrument displays readings which will be recorded as a part of SHOW data collection.

Contraindications for Spirometry

Because spirometry increases intra thoracic pressure, intra-abdominal pressure and intra cranial pressure, spirometry may be contraindicated. The spirometry data form collects information about contraindications to determine which SPs can have this test if they are willing. If a participant has a recent or ongoing problem in any of these particular areas (not an inclusive list) spirometry will not be done.

- A heart attack that has occurred within the last 6 months.
- Unstable angina in last 24 hours.
- Major surgery in the last 6 months. Major surgery includes any surgical procedure that involves anesthesia or respiratory assistance within the last 6 months.
- Hernia repair in the last 6 months.
- Current ear infection.
- Eye surgery of any type in the last 6 months.
- Previous spontaneous pneumothorax.
- Current hemoptysis of unknown origin.
- Recent Stroke less than 3-6 months.
- Aortic aneurysm.
- 3rd trimester of pregnancy, which is pregnancy beyond the 6th month.
- Diagnosis (current) of Tuberculosis (TB).
- Chest infection in last 6 weeks.
- Or other related conditions.

NOTES: Spirometry is one of two physical measurements that ask eligibility questions of SPs (Bioimpedance Analysis is the other). Spirometry ineligibility or nonperformance does not affect how much an SP is paid. SHOW Time 3 language and other field team documents conflict on whether results of the spirometry test will be shared with SPs; SHOW scientists are working on that issue. Screening questions for Spirometry are a part of the Spirometry CAPI.

Equipment Needed
Jaeger Asthma Monitor AM1+ Peak Flow Meter
Interviewer’s own filtered mouthpiece
Sterile filtered mouthpiece for SP (provided in sealed plastic bag)
Hand sanitizer
Antiseptic wipe

Related Documents
SHOW Training manual
Asthma Monitor AM1+ Instructional Manual
Spirometry Manual of Operations

Post Survey Processing
Asthma Monitors will be cleared of all entries as necessary; data is destroyed when downloaded as all information for the particular participants was recorded at time of appointment. This procedure removes all stored information from the monitor so that it can continue to be used.
IV. Bioimpedance Analysis (BIA)

Purpose

BIA is a method that is used to estimate body composition. BIA measures the electrical impedance of body tissues and has been used to assess fluid volumes, total body water, body cell mass and fat-free body mass. A small alternating electrical current is passed through surface electrodes placed on a hand and foot and the impedance to the current flow is measured by different electrodes placed adjacent to the injection electrodes. The voltage drop between electrodes provides a measure of impedance.

Impedance is the opposition to flow of an electric current. In human tissue, impedance is proportional to total body water. Impedance is high in fat tissue and low in lean tissue. Nonfat or lean tissue, where intracellular fluid and electrolytes are mainly found, is highly conductive and has limited resistance to alternating electrical current compared with fat tissue, which contains very little fluid and has high resistance to electrical current. The cell membrane consists of a nonconductive double layer of phospholipids between two layers of conductive protein molecules. The impedance of tissues is comprised of resistance and reactance. The resistive component is provided by the conductive characteristics of body fluids, whereas the cell membranes, acting as imperfect capacitors, provide the reactive component.

In human tissue, impedance is affected by the frequency of the flow of current. At low frequencies, there is minimal conduction through the cell membrane due to the high capacitance of the membrane. Mainly the extracellular water influences the impedance at low frequencies. At high frequencies, the capacitance of the membrane decreases and the current flows equally through both the extracellular water and the intracellular water. Impedance measures made over a range from low to high frequencies allow development of prediction equations relating impedance measures to extracellular fluid at low frequencies and to total body water at high frequencies. Lean body mass can be calculated based on an assumed hydration fraction for lean tissue and from this calculation, fat mass can also be calculated.

In SHOW, BIA is performed on all eligible and willing individuals 21 through 74 years. Women aged 21 through 59 years are asked to self-report their pregnancy status. Pregnant women will not be given BIA.

Process

BIA is done using the right arm and right leg unless this is contraindicated. Reasons for using the left limbs are documented in the data collection system. The participant lies down and electrodes are attached to the hand and foot for the reading.

Equipment Needed

Exam room
Quantum X BIA instrument
Stay-Fresh pack of adhesive electrodes
Description of Exam Room
V. Biologic Sample Collection

SHOW collects biologic samples from all consenting participants in order to create a biorepository. The biorepository is being established to support etiologic and applied epidemiologic research into the future. The biologic sample collection includes a spot-urine collection, blood draw for biochemistry, and processing for long-term storage of serum and plasma as well as DNA. If a participant refuses to provide blood but is willing to provide DNA, SHOW staff will also collect a saliva sample.

A detailed manual of operations for the biorepository and sample collection procedures has been developed. For more details on the following portions of the SHOW study, please see the Laboratory and Biorepository Manual:

Urine Collection
Phlebotomy
Saliva Sample

Laboratory Alert Values

SHOW Protocol for Out of Range Blood Pressure Readings

The field team is responsible for identifying life threatening blood pressures to participants. Although the primary purpose of the Exam Center (EC) is research data collection and not diagnosis or treatment, the blood pressure measurement may result in findings that warrant further medical attention and/or that may be previously unknown to the participant. Exam Center interviewers review the data acquired with the respondent. If an extremely high blood pressure is detected in the field, staff are instructed to call 911 on behalf of the participant and suggest that the participant seek immediate medical assistance.

Blood Alert Values

No blood test results will be immediately available when an SP is in the Exam Center. All of the immediately reportable labs will be done at a central laboratory (TBD by bid process) and reported back to SHOW headquarters within 2 weeks where they will be reviewed by Dr. Nieto. SHOW will then prepare reports to SPs to be sent back to them in the following template. Any blood test that is out of range will be flagged in the report. When an extreme value is found that Dr. Nieto believes could be dangerous, the SP will be contacted by the headquarters staff and told of the results and Dr. Nieto's recommendations for follow-up. A written report will be sent to all SPs with these values so that the SPS may take them to their health care provider if they so choose. SHOW will not be providing reports directly to health care providers. Participants receive a letter in the weeks following their appointment with the values for their blood tests, along with reference ranges and flags for abnormal results. See the following page for the Findings Report Template.
### Laboratory Tests

<table>
<thead>
<tr>
<th>Complete Blood Count</th>
<th>Result</th>
<th>Units</th>
<th>Flag</th>
<th>Reference Range for Women</th>
<th>Reference Range for Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Cell Count</td>
<td>-</td>
<td>x10^9/L</td>
<td></td>
<td>4.1-10.9</td>
<td>4.1-10.9</td>
</tr>
<tr>
<td>Red Cell Count</td>
<td>-</td>
<td>x10^12/L</td>
<td></td>
<td>3.85-5.05</td>
<td>4.15-5.55</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>-</td>
<td>g/dL</td>
<td></td>
<td>11.7-15.5</td>
<td>12.9-17.3</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>-</td>
<td>%</td>
<td></td>
<td>35-46</td>
<td>38-51</td>
</tr>
<tr>
<td>Platelet Count</td>
<td>-</td>
<td>x10^5/L</td>
<td></td>
<td>175-450</td>
<td>175-450</td>
</tr>
</tbody>
</table>

**Number of hours fasted prior to blood draw:** 10

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Result</th>
<th>Units</th>
<th>Flag</th>
<th>Reference Range for both Genders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td></td>
<td>mg/dL</td>
<td></td>
<td>70-99</td>
</tr>
<tr>
<td>Glycohemoglobin(A1C)</td>
<td></td>
<td>%</td>
<td></td>
<td>4.0-6.0</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td></td>
<td>mg/dL</td>
<td><strong>HIGH</strong></td>
<td>100-200</td>
</tr>
<tr>
<td>HDL</td>
<td></td>
<td>mg/dL</td>
<td></td>
<td>40-59</td>
</tr>
<tr>
<td>Serum Creatinine</td>
<td></td>
<td>mg/dL</td>
<td></td>
<td>0.7-1.3</td>
</tr>
</tbody>
</table>

**Note:** Tests performed during the SHOW exam were done for research purposes and do not allow a definite diagnosis to be made of any disease or problem. If abnormal results have been noted above, we recommend that you discuss these results with your health care provider, who may wish to obtain further evaluation and to determine if any treatment is needed.

--- Incomplete or Missing results
Incomplete results may have been for the following reasons:
- the test was refused
- the test failed
- the lab was not able to process the sample due to the quality or quantity of the sample
VI. Completion of Exam Visit

Final steps in the study visit include:

- Verifying contact information for sending the compensation.
- Giving the subject a t-shirt.
- Reminding the subject of SHOW’s intent to contact in the future.
- Verifying the need to compensate for any travel expenses for subjects.
- Reminding subjects that significantly abnormal laboratory values (alert values) are immediately relayed to the SHOW headquarters office and reported to the subject by phone (or mail if not able to be reached). This alert value report is accompanied by recommendations to the subject for follow-up.
- A written report to all subjects and any relevant recommendation is mailed to all subjects.
- Subject is reminded that their primary care provider will not be informed of the results and it will be the subject’s choice to follow-up with this information to their health care provider.

I. Compensation for Time and Participation

As compensation for time and participation, each survey participant will receive $95 for completion of all three segments of the survey and a t-shirt with the SHOW logo. Direct expenses incurred as a result of travel to the exam site will be reimbursed. Additionally, the results of some tests will be reported to the individual participant. The specific reports include:

- Pulmonary function test (peak expiratory flow rate)
- Bioelectrical impedance analysis results (percent body fat)
- Body mass index
- Blood pressure
- Glycosylated hemoglobin (A1c)
- Serum total and HDL cholesterol
- Serum creatinine

Pro-rated compensation for the study visit includes:

- Time 1: completion = $30.00
- Time 2: completion = $10.00
- Time 3: completion = $55.00
  - Interview = $30.00
  - Blood sample = $10.00 (attempts for a blood sample are compensated)
  - Body measurements (Completion of any tests warrant full compensation; Respiratory, BIA, Blood Pressure, Anthropometry) = $15.00
Travel and other expenses for participant
Participants are reimbursed for travel, including Mileage, bus fare, parking, taxi services. Participants are also reimbursed for childcare for the time, using the following form, filled out by the Field Team staff.

<table>
<thead>
<tr>
<th>EXPENSES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL EXPENSES are $5 or less</td>
<td>$</td>
</tr>
<tr>
<td>(mileage 10 miles or less OR other expenses $5 or less)</td>
<td></td>
</tr>
<tr>
<td>Will be reimbursed $5</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>TOTAL EXPENSES are greater than $5 (mileage over 10 miles) – check all that apply:</td>
<td></td>
</tr>
<tr>
<td>MILEAGE &gt; 10 miles to and from SC/SS/MEC</td>
<td></td>
</tr>
<tr>
<td>(drivers only! Not if subject was driven by another SP)</td>
<td></td>
</tr>
<tr>
<td>Actual round-trip mileage: _________</td>
<td></td>
</tr>
<tr>
<td>Reimbursed at UW allowed rate to max of $50</td>
<td>$</td>
</tr>
<tr>
<td>BUS FARE $___________________</td>
<td>$</td>
</tr>
<tr>
<td>PARKING $___________________</td>
<td>$</td>
</tr>
<tr>
<td>TAXI $____________________</td>
<td>$</td>
</tr>
<tr>
<td>Child Care (circle # of children):</td>
<td>$</td>
</tr>
<tr>
<td>1 child ($7/hr x 3 hrs = $21)</td>
<td></td>
</tr>
<tr>
<td>2 child ($10/hr x 3 hrs = $30)</td>
<td></td>
</tr>
<tr>
<td>3 or more children ($13/hr x 3 hrs = $39)</td>
<td></td>
</tr>
<tr>
<td>TOTAL:</td>
<td>$</td>
</tr>
</tbody>
</table>
J. Appendix

Important Instructions for SHOW Exam Center Visits

The exam center visit will include:

- Questionnaires
- Blood draw
- Urine sample
- Height, weight, body measures
- Breathing test

To get accurate test results, please do the following:

- Bring any GLASSES that you need for reading to your visit at the exam center.
- Complete and return your SHOW Health Questionnaire booklet when you come to your SHOW exam center visit.
- DO take your regular medication on schedule.
- Drink only water in the 8 hours before you come to your appointment.
- Do not exercise or do heavy physical activity in the 12 hours before your appointment.
- Do not drink alcohol in the 12 hours before your appointment.
- Do not take a sauna in the 8 hours before your appointment.
- Do not eat solid food in the 8 hours before your appointment. If you are diabetic, please follow the eating pattern recommended by your physician prior to a blood draw. If you need to eat in order to feel well, then you must do so.
- DO come prepared to give a urine sample.
- DO NOT wear jewelry and other accessories in your hair or on your body.

We realize that it may not be possible for everyone to do all of these things. If your appointment is later in the day or maybe your health will not let you do some of these things we understand and will ask you which of these things you could do.

You will be able to do the tests even if you are unable to do any of the above.

You may also refuse to have any of the tests done.

At the start of the exam center visit we will ask you to change into a lightweight, disposable clothing (top and pants go over your underwear) to make it easier to do these tests quickly and the same way for everyone. Alternatively, you may wear your own lightweight top and pants, if you prefer.

If you have any questions or need to reschedule your appointment, please call SHOW at 1-888-433-7469 (toll free). Thank you.