THE SURVEY OF THE HEALTH OF WISCONSIN

INITIAL PROTOCOL: August 2, 2007

Amendment 1: April 14, 2008
Amendment 2: July 15, 2008
Amendment 4: March 19, 2010
Amendment 5: September 9, 2011
Amendment 6: May 8, 2013
Amendment 7: May 20, 2014
Amendment 8: August 22, 2014
I. BACKGROUND AND JUSTIFICATION
   A. Background
   B. Justification

II. SPECIFIC AIDS

III. METHODS
   A. Study Design
      1. Target Population
      2. Sample Size and Sampling Procedures
         a. Stage 1
         b. Stage 2
         c. Stage 3
      3. Pitfalls to Sampling Strategy and Methods of Correction
   B. Recruitment, Screening and Consent Methods
      1. Promoting Community and Individuals’ Awareness
      2. Participant Recruitment
         a. Prior to Household Visit
         b. At the Door Recruitment
      3. Household Screening
      4. Individual Screening for Eligibility
      5. Informed Consent Procedure
   C. Study Procedures and Risk to Subjects
      1. Study Questionnaires and Procedures
      2. Procedures and risks to subjects
         a. Questionnaires
         b. Phlebotomy Procedure
         c. Urine Sample
         d. Blood Spot
         e. Saliva Sample
         f. Body Measurements
         g. Physical Activity
         h. Sample Storage and Genetic Testing
         i. Unanticipated Problems and Mandatory Reporting
         j. Confidentiality
      3. Compensation for time and participation
      4. Daily operations:
         a. Field Staffing
         b. Staff Training
         c. Sample Collection Site Selection
         d. Data Collection Procedures/Conduct of Study Visits
            i. SHOW questionnaires
            ii Assignment of Subject ID number
            iii. Conduct of study visits
               a. In-home visit
               b. Self-administered questionnaire
               c. Sample Collection
               e. Biospecimen processing and shipping
f. Retention and education

D. Data Processing, Management, Confidentiality, Analysis and Statistical Power
   1. Data Management
   2. Analysis and Statistical power
      a. Descriptive Analyses
      b. Cross-Sectional Association Studies
      c. Cohort analysis
      d. Comparative analysis
   3. Sample Size and Statistical Power

IV. DISSEMINATION OF SHOW RESULTS

V. Ancillary Studies

VI. LITERATURE CITED
I. BACKGROUND AND JUSTIFICATION

A. Background
In the National Health Survey Act of 1956, the US Congress mandated a federally-funded, ongoing survey to provide current data on the health status of the US civilian non-institutionalized population. Consequently, the National Center for Health Statistics (NCHS) was formed within the US Public Health Service in the US Department of Health and Human Services to monitor the prevalence, distribution, and effects of illness and disability in the US. The NCHS has conducted seven national surveys since the 1960s. The first three National Health Examination Surveys (NHES I–III, 1960–1970) each targeted different age groups, collecting physical and psychological health information along with demographic and socioeconomic data from its participants. A substantial nutritional component was added to the survey in the 1970s, and the subsequent three National Health and Nutrition Examination Surveys (NHANES I–III, 1971–1994) and Hispanic Health and Nutrition Examination Survey (HHANES, 1982–1984) were also broadened to include all individuals 1–74 years old. Biannual NHANES have been conducted since 1999, surveying all ages, and resulting in frequent release of datasets and estimates on topics of interest to health investigators and public health authorities.¹ The NHANES database has not only set the standard for representative health surveys in the US but has been one of the most widely used health data resources in the nation for the past five decades. NHANES data have provided the basis for health practice developments for the evaluation of policy changes including the now common growth charts for children,² addition of folic acid to food to prevent birth defects,³ elimination of lead from gasoline,⁴ documentation of the obesity epidemic among US children,⁵ and universal immunization of infants and children against hepatitis B.⁶ While NHANES data provides an important resource for such issues on a national level, the data’s application to the specific health issues and determinants in an individual state is limited. By focusing the scope of such a fundamental and objective data resource to address issues of particular concern to public health in Wisconsin, the Survey of the Health of Wisconsin (hereafter referred to as SHOW) promises to deliver great benefits to the people of this state.

In 2006, the Wisconsin Partnership Fund for a Healthy Future (heretofore called the Wisconsin Partnership Fund) provided funds to the Department of Population Health Sciences in the UW School of Medicine and Public Health to establish a permanent, ongoing, series of population-based surveys for observation and research on the health status of the people of the State of Wisconsin. The SHOW program serves as the basis for research about health needs and determinants of health in the state. In 2012, this support was renewed and SHOW continues to be a flagship program of the Wisconsin Partnership Fund. This protocol outlines how SHOW is being implemented.

B. Justification
Similar to NHANES, SHOW serves as the basis for research about health needs and determinants of health over time in the population of Wisconsin. In addition, this series of surveys offers baseline data for the evaluation of the effectiveness of statewide or community-based policies or health-related interventions. SHOW provides a powerful interface between research and application in population health to benefit the state’s residents. Survey data includes both physical and mental health measures, behavioral and biological information, health care access and health care utilization data, as well as environmental, individual, and community socio-demographic characteristics. As additional sources of funding are identified, plans are in place to re-contact survey participants to assess their overall health status and occurrence of health outcomes. (Plans for future follow-up interviews/exams are not described in this protocol.)
By measuring the health status of Wisconsin communities, SHOW will have the ability to be responsive to the core Public Health functions as identified in the state health plans (i.e., *Healthiest Wisconsin* 2010 and 2020), particularly the “assessment” function, a primordial step to scientifically guide the “policy development” and “assurance.” As a shared resource, it can provide researchers and state officials with rigorous and novel population-based data for monitoring health status throughout the state and provide important biologic and other resources for innovative etiologic research. This infrastructure adds to and enhances the value of data now being collected by the state or University because it includes the following six features:

- measurable statistical power;
- representative population-based model (through use of state-of-the-art probabilistic sampling and recruitment methods);
- objective data collection methods encompassing personal interviews, physical examinations, and evaluation of environmental data;
- mixed and modular design, including a cross-sectional component and possibility of longitudinal follow-up;
- capability for linking existing data sources to these core population health data;
- conceptually driven by a broad-based theory of health determinants.

The mandate for SHOW is to build and maintain a large database of health-related information on Wisconsin residents as an infrastructure that future researchers, public health practitioners, and clinicians can use to further understand priority health determinants in the state. Consequently, the core survey is not hypothesis driven. Rather, survey instruments are developed and incorporated into the survey based on their ability to: (1) capture key aspects of potential health determinants including social, physical, and behavioral components; (2) be anticipatory of potential future research questions; and (3) generate data comparable to other local and nationally collected data (e.g., Centers for Disease Control's NHANES and Behavioral Risk Factor Surveillance System or Wisconsin’s Family Health Survey).

The focus of survey instrument selection is thus targeted to selected major topic areas as the core of the survey instruments. The goal of creating a database helpful to as many research entities as possible is the basis of the core instruments. Annual reviews of the survey instruments by core scientific staff assure that the survey is consistent with current state-wide health care concerns. With this focus, SHOW is developing a database that can identify or verify Wisconsin’s health risks and health determinants using a longitudinal model and will serve as a resource for evaluating the impact of community health interventions and policies throughout the future of the survey.

The establishment of this survey follows a strong tradition of population-based research by investigators in the UW School of Medicine and Public Health; previous and ongoing studies, including the *Wisconsin Epidemiological Study of Diabetic Retinopathy* (WESDR), the Beaver Dam Eye Study, the Epidemiology of Hearing Loss Study, the Wisconsin Sleep Cohort Study, the Wisconsin Longitudinal Study, the Wisconsin Diabetes Registry and Risk Factors for Atherogenesis in Type 1 Diabetes Studies, the Wisconsin Cystic Fibrosis Neonatal Screening Project, and the Newborn Lung Project Regional Cohort Study. Results from SHOW can provide new and critical baseline data, including physical measures, on priority chronic and infectious diseases as well as data on access and utilization of health care from which programmatic efforts can then be guided.

Periodic repetition of the SHOW survey can be useful in examining trends on health- or health care-related data and on evaluating interventions done in the interim. The goal of SHOW has
been to establish a system for periodic follow-up contact of survey participants (SPs) to determine the incidence and nature of major health events such as new diagnoses, hospitalizations, and death. These follow-up arms will include phone, mail, or in-person contact depending on the priorities of SHOW scientists. Future follow-up studies may be developed (with funding as a consideration) to contact SPs hospitalized in a preceding year and obtaining written permission to access hospitalization records to verify diagnoses, medications, complications, and health status on discharge.

By providing objective data on the health status of Wisconsin’s residents to the state’s research community, this program allows Wisconsin citizens to become full partners with basic, clinical, public health, and social scientists in their goal to advance the health of the population of the state. Aggregate and thoroughly de-identified data from this survey will be compiled in public-use databases and made available as a shared resource for research by public and private institutions, community organizations, and citizens of the state. There may also be circumstances in which portions of the cohort may be selectively invited to participate in a subsequent study as a follow-up to significant research findings. IRB approval will be obtained for any ancillary study of this type.

Another core goal of SHOW in addition to the survey per se is to serve as a platform for broad population health research in partnership with researchers in academic, government public health agencies, and community settings. Access to SHOW resources (e.g., data and/or biological samples) and implementation of added ancillary studies (e.g., addition of exam or interview components in future cycles) is determined through review of Requests for Proposals and following ancillary study protocol procedures available on SHOW’s website (www.show.wisc.edu). These investigator-initiated proposals are considered and evaluated by the core scientific review committee based on scientific merits, IRB approval, and consideration of participants’ burden and costs.

During 2013, after five years of data collection, a strategic planning process was launched to examine past successes and explore if the SHOW program was reaching stated goals. As a result of these processes, some key protocol changes are being implemented in 2014 including expansion of SHOW to recruit all ages, modifications of the study design to support county level assessments in randomly selected regions of the state and changes to survey content to make most efficient use of available programmatic resources. These changes are driven by research priorities, core program goals to support local health assessments, and guidance that a main asset of the SHOW program is its neighborhood and household based sampling, recruitment, and in-home data collection as well as bio-specimen collection.

II. SPECIFIC AIMS

The overarching goal of this program is to maintain an infrastructure for population health research and applied public health investigation and policy development in the State of Wisconsin. This ongoing population health research laboratory enables the study of current and emerging questions regarding the health status and determinants among Wisconsin residents. The knowledge generated by this project will complement survey data collected by Wisconsin public health officials and will be shared throughout the state in an effort to inform and enable effective health care planning and policies. The specific aims of SHOW are:

**Aim 1:** Maintain a novel population health research infrastructure for tracking trends in priority health indicators and allowing transdisciplinary research examining the multiple determinants of health and health disparities in Wisconsin by:
1.1 Continuously gathering robust measures of a broad range of health determinants including: biologic, sociodemographic, behavioral, attitudinal, environmental (both built and physical), psychosocial, and health care factors in a representative statewide sample.

1.2 Maintaining a biorepository to support University-wide collaborations for mechanistic, gene-environment and/or epigenetic research on a broad range of outcomes.

1.3 Supporting local health, academic and health care organization partnerships across the state to facilitate the use of the data to support research transecting population and public health, community, clinical quality and health care system, clinic and patient level domains.

**Aim 2:** Support data dissemination and educational initiatives for applied public health practitioners, faculty, and students interested in studies examining multi-layered determinants and outcomes of priority health conditions in the state by:

2.1 Generating and maintaining complex data systems and server capacity.

2.2 Making the data collection methods and survey protocols, data collection forms, data dissemination and manuscript proposal policies available to students, faculty, and public health practitioners to facilitate data access and manuscript proposal development.

**Aim 3:** Provide a flexible platform and infrastructure that is responsive to changing health and research priorities in the state and supports a host of ancillary studies by:

3.1 Allowing researchers to access infrastructure resources or build on existing core data by adding modules and/or subsamples, specialized instruments or clinical tests in order to conduct high quality, cost-effective transformational research.

3.2 Supporting resources and partnerships for conducting rigorous community-driven health assessments and evaluations of specific interventions aimed at addressing determinants of pressing health conditions for Wisconsin residents.

**III. METHODS**

**A. Sampling Design**

A population-based probability sample of Wisconsin adults is selected over a three-year period. Participants in the baseline survey undergo a core interview and examination (including collection of biological samples). Detail of procedures for the conduct of the study visits are incorporated in a series of Manuals of Operations (MOO) and Manuals of Procedures (MOP). Each SHOW sample is independent of the previous samples; consequently, trends over time in the associations among health conditions and health determinants can be analyzed using subsequent samples. SHOW’s cyclical character allows for the introduction of additional modules to the core survey in different samples, as new priorities and sources of funding emerge. The follow-up and future repeat surveys (determined based on availability of funding) will allow the longitudinal study of the process of aging and the natural history of health conditions.

1. **Target Population**

The target population is all civilian non-institutionalized residents of the State of Wisconsin. For each independent sample, a sample size will be determined (described in section III.A.2) and the sample of households will be identified. Key considerations of this target population include the following:

- All household residents regardless of age will be invited to participate. This is new in 2014; children, young adults (<21), and older adults (>74) will be invited to participate.
While all household residents may not choose to participate, an effort will be made to enumerate all residents living in the household during the screening process.

In previous waves of the survey, only adults 21-74 years of age were eligible to participate. The rationale for the restricted age-eligibility was primarily pragmatic and budgetary. The rationale for expanding eligibility to children and older adults at this time is to support priority surveillance and emerging research priorities to better address human health across the life course. Data collection for children will start in 2014 with a limited set of instruments and be expanded based on initial recruitment experiences.

**Rationale for enumerating all household residents:** enumeration of refusing members of the household will serve to better assess possible non-response biases but, in addition, help provide as complete listing as possible for targeted recruitment into future ancillary studies (e.g., studies of children of parents with certain medical/family history, or individuals living in households with certain environmental or socioeconomic characteristics).

As detailed in the Data Collection section (III.C.4.(d), survey participants undergo a core interview and examination (including collection of biological samples). Each successive independent sample will be accrued into a progressively larger cohort that will be available for future follow-up studies, as scientific questions and additional funding sources are identified. Pooling data from several samples will allow cross-sectional analyses of relatively infrequent outcomes as well as subgroup analyses pertaining to gender, age, and ethnic/region groups. Detailed follow-up protocols and procedures to track the health status or the occurrence of health-related outcomes in the SHOW cohort will be developed.

## 2. Sample Size and Sampling Procedures

The target population is all civilian, non-institutionalized state residents. Participants are selected from a random sample of households using a stratified three-stage cluster sampling approach. The three stages involve: 1) counties; 2) census block groups; and 3) households. All age-eligible residents in selected households are invited to participate in the survey with a goal to enroll 3,000 residents over a three year period.

The stages of sampling selection are described in more detail in the following paragraphs:

**a. Stage 1** — The primary sampling units (PSUs) are counties. A total of 10 counties are randomly selected after stratification by mortality measured as years of potential life lost. Any PSU with more than 180,000 occupied housing units according to the 2010 census is automatically in the sample. Based on this criterion, Milwaukee and Dane counties are in the sample with certainty. The remaining PSUs are grouped into strata based on mortality rankings such that each stratum has approximately 212,000 occupied housing units. One PSU is randomly selected from each stratum with probabilities proportional to size, where the measure of size is the occupied housing units from the 2010 census.

The **rationale for stratifying by mortality** at this stage is primarily to ensure that the sample has representation of PSUs across the distribution of county health rankings across the state.¹

---

¹ [http://www.countyhealthrankings.org](http://www.countyhealthrankings.org)
b. **Stage 2** – The secondary sampling units (SSUs) are typically defined as census 2010 block groups. However, in smaller counties with less than 30,000 occupied housing units SSUs are defined as groups of adjacent census blocks from the same census block group totaling approximately 150 to 200 households in order to minimize variation in the size of stage 2 sampling strata and consequently the probability of selection of SSUs. On average 22 SSUs are randomly selected after stratifying according to census-based data on level of poverty. Similar to stage 1, all SSUs within a PSU are grouped into equal sized strata and one SSU is selected per stratum with probability proportional to size.

The **rationale for stratifying by poverty** in the random selection process is to maximize the likelihood of enrolling a relatively equal number of participants in different socioeconomic strata. Several factors support the use of poverty level as a stratifier.\(^{10}\) Numerous studies have found associations between different SES variables (e.g., percent poverty level) measured at the area level and health outcomes (e.g., incidence of coronary heart disease, smoking, level of inflammatory markers, etc.).\(^{11,12,13}\) Different socioeconomic variables are highly correlated at the ecological level. Gradients in poverty are associated with several characteristics such as:

- proportion of population belonging to racial minorities
- greater family size
- proportion never married
- greater proportion of female head of household
- low tenure rate
- low educational attainment
- higher rates of unemployment

Percent of population below poverty level performed as well as other more complex socioeconomic measures in detecting gradients in health outcomes and determinants at the neighborhood level.\(^{14}\) Evaluating the gradient of economic wealth was consistently associated with many health outcomes such as coronary heart disease, motor vehicle injuries, hepatitis A and B, diabetes, etc. Finally, poverty is associated with gradients in health among different subpopulations. In conclusion, percent poverty is a robust measure able to capture gradients in different health outcomes and determinants across different age-gender-race subpopulations.

**Tribal Land:** The Menominee tribe has agreed to allow recruitment on tribal property and any census block on their reservation land will be eligible for sample selection. Conversations continue with the Great Lakes Intertribal Council to get permission from each of the individual tribes for inclusion of households that fall on tribal land in the sampling frame. Respectful of these ongoing negotiations, any census block on tribal lands, with the exception of tribal lands within the Menominee tribe, will be pulled from the sampling pool for the survey.

c. **Stage 3** – All households are enumerated within each SSU (Stage 2) with the goal of selecting approximately 25 households per SSU using simple random sampling. Additional households are released into the sample in a given SSU as residential addresses are found to be vacant or ineligible at the time of screening. Within each of the SSUs selected in Stage 2, a residential housing list is generated based on commercially available United States Postal Service (USPS) Delivery Sequence File lists available from MSG-Genesys (Marketing Systems Group, Fort Washington, PA) and enhanced by Google and county GIS tax parcel
records. MSG-Genesys uses street level geocoding to link USPS addresses to census blocks.

The MSG-Genesys lists are augmented with publicly available electronic tax record data information. The Sea Grant Institute at the UW-Madison has compiled links to all of the Wisconsin local government web mapping sites on their website, http://coastal.lic.wisc.edu/wisconsin-ims/wisconsin-ims.htm (last updated November 26, 2012). Of the 72 county tax records offices in the state, 69 (96%) of the counties have their tax data publicly available in interactive web mapping sites; one of the remaining three counties have web mapping site in development. Therefore, almost universal coverage for the state with county tax record data is available to augment the MSG-Genesys household lists.

The protocol for data augmentation of MSG-Genesys list with tax records is as follows: a batch geocoding procedure is used to assign latitude and longitudes to the USPS listings. Geocoded addresses for each PSU are mapped using ArcGIS and enhanced tiger files. Final geocoded lists are compared to Google Earth and publicly available county GIS digital tax assessment data from each county to ensure, to the extent possible, that all households provided in the USPS listings actually fall within the SSUs.

Household enumeration using USPS listings is a new survey methodology and is being used by SHOW as a replacement for more time and labor intensive methods of field enumeration that are traditionally used in household surveys. These existing data sources may have some limitations for Wisconsin and not be sufficient in high growth or sparsely populated areas of the state, where new developments or PO Boxes are not on the lists. Therefore, for SSUs known to have limited population density (with the potential for a high proportion of PO Boxes), or which have experienced a large amount of growth since the 2000 census (based on a comparison of USPS household counts and 2010 census household counts), some degree of direct field enumeration will take place. Specifically, if the ratio of PO Boxes / city addresses is greater than 10 percent, or if greater than 20 percent more households are identified by current USPS listings compared to 2010 census, then direct field enumeration and address verification will be necessary prior to generating a final sampling frame for that particular SSU. These methods may be refined in subsequent years as new technologies emerge (e.g., high resolution Google Earth).

The completed sampling frame for each SSU is randomly sorted and an initial list of approximately the top 25 households is selected for recruitment. Specific target numbers of households may be adjusted annually as experience provides better direction regarding the range of response rates in the different areas of the state. The full randomized list is retained and stored for future reference.

The selected dwelling unit lists are mapped to assist field staff in locating selected dwelling units (DUs) within a SSU. SHOW field staff also conduct a missed dwelling unit procedure as outlined in the Survey Methods Manual of Operations to ensure that all eligible households have an opportunity to be selected for the survey.

3. Pitfalls to Sampling Strategy and Methods of Correction:

**Missing addresses, multiple DUs with the same address etc.** Since all sampling frames will unintentionally miss a portion of the target population, the missed dwelling unit procedure will be used to give all adult civilian non-institutionalized Wisconsin residents an opportunity to be selected to participate in the SHOW. The field staff will conduct this procedure at the time of
household screening. The procedure involves identification of all MDUs encountered within a systematic search originating from each SDU. A maximum of five missed dwelling units will be added to the sample for any given SDU based on the sampling algorithm presented in Table 1. These procedures will ensure that all eligible households will have a known probability of selection while also limiting the total number of additional eligible households within a particular PSU.

<table>
<thead>
<tr>
<th>Number of Missed DUs</th>
<th>Sampling Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No action</td>
</tr>
<tr>
<td>1 to 4</td>
<td>Automatic (all DUs added to sample)</td>
</tr>
<tr>
<td>5 to 9</td>
<td>1/2</td>
</tr>
<tr>
<td>10 to 14</td>
<td>1/3</td>
</tr>
<tr>
<td>15 to 19</td>
<td>1/4</td>
</tr>
<tr>
<td>20 to 24</td>
<td>1/5</td>
</tr>
</tbody>
</table>

*This pattern continues adding a maximum of 5 DUs per interval.

Within selected households all age-eligible habitual residents of the household will be invited to participate. Definition of household membership is outlined in section III.B.3: eligibility criteria.

B. Recruitment, Screening and Consent Methods

1. Promoting Community and Individuals’ Awareness

Prior to any contact with potential individual subjects, a public relations campaign is launched in each county (PSU). This is not a campaign to recruit volunteers, as only members of randomly selected households will be eligible to participate in SHOW. This is a campaign to increase awareness that SHOW is working in the community and is a legitimate research project that will invite randomly selected households to participate. Several weeks before the SHOW team begins on-site recruitment in a community, contact is made by phone or through an introductory letter sent to local public officials, such as the county or municipal health director. Several weeks prior to recruitment, local leaders such as the mayor, and police chief or sheriff are contacted to inform them of the timeframe for the visit of the SHOW field team. Area businesses, chambers of commerce, churches, community organizations, health care organizations, schools and libraries may also be contacted to raise awareness about SHOW. Endorsements from the local health department are sought out in each community to encourage study participation. Additional public information to build awareness and garner support of SHOW is provided by the administrative and public relations staff throughout the community including:

- Contact with formal and informal community leaders
- Contact with local public health leadership and officials (e.g. public health nurses)
- Contact with churches, etc.
- Press releases to local newspapers and radio stations in areas selected
- Television (local and regional) showings of SHOW’s Public Service Announcement
- Community wide social media outreach
- Contact with area health care providers and local health officials
- Distribution of awareness posters and fliers for posting in health care centers, public schools, churches, etc.
Subsequent community recruitment occurs as the survey team participates in outreach activities which facilitate the introduction of SHOW in the community. Examples of this community outreach include informal one-on-one or group discussions with neighbors, community groups, or targeted announcements in newsletters, bulletins, or via email, and hanging posters in locations accessible to the general public.

SHOW also has a vested interest in incorporating new and changing methods of outreach, including social media approaches. Social media provides a method of increasing communication between SHOW and health officials, researchers, members of the communities, potential and past participants, businesses, and others around Wisconsin. Social media encompasses but is not limited to the following: Facebook, Twitter, YouTube, Flickr, FourSquare, personal websites (including blogs), chat sites, etc. Through social media, SHOW can meet three aims: 1) access a forum for communication with stakeholders and the community; 2) provide resources to the community by sharing information about current public health topics in Wisconsin and the world; and 3) grow the SHOW brand to the public. SHOW will maintain the following strict guidelines for use of social media:

- All posts and information provided on social media sites will uphold one of the above aims, and AT ALL TIMES posts will protect the confidentiality of the information collected from participants.
- Known participants will not be contacted through social media. No attempts will be made to encourage participation through social media to prevent any potential coercion. Any contact through social media specifically directed at participants will go through IRB approval.
- Social media is used to alert the community as a whole to our presence. To that end, businesses, churches, employers, community centers, libraries, and other community organizations in the area being visited are contacted on Facebook with the message:

  “We are looking forward to visiting ___________(place) next month. We’ll be meeting with local residents to gather important information about the current health status and needs of the Wisconsin population— http://vimeo.com/34867566. The post contains a vimeo link to the SHOW Public Service Announcement. No posts are made on individual’s pages. All posts are documented.

SHOW is also working to build a website for dissemination of data using aggregate level statistics and displays that will help key partners better use SHOW data for decision-making. Templates will be crafted and developed and tested with formative research groups prior to implementation.

2. Participant Recruitment

A. Prior to Household Visit

One to three weeks before a SHOW team arrives in the selected block group, the randomly selected households are mailed a letter addressed to “Invited Household.” Letters are sent to each selected address informing them of their eligibility to participate in the research and to provide details about the study. This mailing:

- Describes the project
- Explains that a screener will be knocking on their door
- Explains the timeframe for approach by a screener
- Describes the random selection process
- Describes the benefits of participation
- Includes endorsements from local health department (when provided)
- Includes a refrigerator magnet to build familiarity and awareness of the study

Advance mailings are in English and coordinated through the centralized SHOW headquarters. Spanish-language outreach materials are being developed and will be provided by the field team to households with subjects who have Spanish as their dominant language. Once complete and ready for implementation, these materials will be submitted to the IRB for review.

Approximately one week prior to working in a block group a reminder post-card will be mailed to the selected household.

The consent form will be available in Spanish. All SHOW questionnaires are currently being translated and will be provided to subjects once final IRB approval is obtained. Until these questionnaires are translated and approved, only those people with a stated understanding of English will be eligible for recruitment.

Contacts have been and will continue to be made with leaders in each statewide and local community to build awareness of SHOW and encourage the participation of those in the selected households. These contacts include meeting and presenting SHOW’s purpose and objectives to community leaders, to neighborhood organizations, community advisory boards, and at community events such as health fairs and conferences.

**B. At the Door Recruitment**

SHOW hires and trains professional field staff to recruit participants in the field.

Household-based recruitment includes the introduction of self, the research study, and the invitation to participate. These steps are completed by respectfully presenting oneself at the door of a randomly selected household, asking for time in order to explain the study and posing the benefits of participation, screening participants for study eligibility and obtaining approval for moving forward with consent and study enrollment when appropriate. Successful recruitment includes this step of thoughtful, respectful presentation of the research study following study protocols outlined in the related Manual of Operations. Consent and data collection may occur at the time of recruitment or be arranged to occur at a later date.

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. SHOW attempts to recruit and schedule field 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.

If there is no response to an initial visit, a small bag with information about SHOW and stating the purpose of the visit is left at the door of the household. This information offers two contact methods for household members to use for arranging a time for a revisit:

- a toll-free telephone number
- a website with email

Failure to respond to this door hanger will not be taken as a refusal.
Up to 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.17

3. Household Screening

All household and individual screenings are completed by the field team. The steps in screening include the following:

- Dwelling unit identification
- 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 is legally/ethically able to enumerate household members.

It is recognized that multiple visits to a household may be necessary to:

1. Find an adult at home who can answer screener’s questions; and
2. Discuss and obtain informed consent for participation in SHOW with each eligible adult household member.
3. Discuss child enrollment and consent.

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.

4. 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 capable of, if age-appropriate, providing informed consent and able to communicate answers to interview questions.

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 who 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.
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 seamen, 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. Whenever possible, 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.

Pregnant women are not excluded from the study. However, if they are 6 months pregnant or more, they are screened out of spirometry testing. Exclusion of these individuals from spirometry is to avoid confounding (due to reduced lung volume during the third trimester of pregnancy) and is not a safety concern. Therefore, only adult women (age 18 or older) will be asked the pregnancy screening question.

For the core SHOW program, children will be enrolled to provide a small amount of information (10-20 minutes depending on age) to support survey goals for identifying and characterizing health status and determinants. Questionnaire information for children under 12 years of age is based on parent report. For some questionnaires, children age 12 and over are given age-appropriate questionnaires covering a short set of health indicators. When age-appropriate questionnaires are not available one parent or legal guardian will answer as a proxy. See Table 2 on page 20 for detailed information on age of administration for each questionnaire.

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.

5. Informed Consent Procedure

For eligible household members the field team extends an invitation to consider participating in SHOW. The staff provides each eligible member or proxy with a consent booklet to read and review. For subjects age 7-17, documented informed consent is first obtained from one parent or legal guardian and then written assent is obtained from the subject. For subjects under 7 years old, interviewers will attempt to verbally describe the study at an appropriate reading level. Dissent from a subject of any age will be respected.

During the initial informed consent process, field staff will discuss:

• the time commitment
• the scope of the interviews
• the physical measures
• the types of specimens collected

Those adult subjects with limited capability or ability to read (e.g., due to illiteracy or vision impairment) are accommodated in the following manner:

• The IRB-approved consent form is read to the subject in its entirety, 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 using the Short Form for Documenting Oral Consent Process document.
• As would be expected for any consent process, it is the field staff’s 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 field staff doubt the subject’s consent comprehension, he or she will not enroll the subject in the study.

Adult subjects unable to provide their independent consent, such as a subject who indicates that there is a legal guardian who signs all of their documents, will not be 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). Adult household members are able to individually have their questions answered and privately sign their consent with the field staff in the home after careful consideration of their options and response to their questions has been satisfactory. Children are able to do the same but with one parent or legal guardian present.

Special procedures must be followed when obtaining informed consent for minor subjects:

• Participation of all minor subjects will require informed consent from one parent or guardian for each child. Similar to usual SHOW informed consent procedures, the parent or guardian will have time to read the consent form, then the interviewer will review the form with parent or guardian, then each checklist item will be answered and the form signed.
• For minors age 15-17, the child is given time to read an assent form very similar to the parent/guardian consent. The interviewer then reviews the form with them and answers any questions they may have. Then the form is signed.
• For minors age 7-14, the child is given time to read an assent form with a lower reading level and less complicated details. The interviewer then reads an assent script and answers any questions the subject may have. Then the form is signed.
• Children under 7 years of age do not go through a formal assent document, but interviewers will attempt to verbally describe the study at an appropriate reading level and will answer any questions the child may have.
• Any dissent on the part of a minor subject, even if the parent or guardian agrees to participation, will be respected and refusal will be documented.

C. Study Procedures and Risk to Subjects
This is neither a treatment nor an intervention study. The main risk from participation in this survey project is the potential breach of confidentiality related to the personal health information and personal health identifiers that are being collected. As this is a study that may be done jointly with family members, there is a potential risk of revelation to family members of previously
undisclosed issues. There could be legal risks to undocumented immigrants if the contact information we collect for tracking subjects were to be disclosed.

1. **Study Questionnaires and Procedures**

**Study Questionnaires and Procedures for Adults (age 18+)**

**In-Home Visit (approximately 90 minutes)**

- Screener
  - Computer Assisted Personal Interview
  - Household Screener Module
  - Consent
- In Home Interview
  - Computer Assisted Personal Interview
    - Tracking and Tracing
    - Verification of Age
    - Demographics
    - Insurance Utilization
    - Health History
    - Rx and OTC Medications
    - Occupation
    - Physical Activity
    - Reproductive History and Contraception
    - Weight History
    - Diet
- Paper-Based Personal Interview
  - Cognitive
- Audio Computer Assisted Self Interview
  - Food Security
  - Mental Health
  - Sexual Identity

**Procedures**

- Weight
- Height
- Waist Measurement
- Hip Measurement
- Arm Measurement
- Sitting Blood Pressure
- Pulse
- Spirometry
- Accelerometry

**Self-Administered Questionnaires (approximately 45 minutes)**

- Paper and Pencil Interview
  - Quality of Life
  - Prevention and Safety Habits
  - Household Characteristics
  - Sleep Habits and Problems
  - Stress, Depression, and Anxiety
  - Discrimination
Post-traumatic stress disorder (PTSD)
Characteristics of Your Neighborhood
Smoking
Alcohol
Diet and nutritional habits

**Biological Sample Collection (approximately 20 minutes)**
- Urine Collection
- Phlebotomy (blood spots or saliva sample if blood draw refused or fails)

**Study Questionnaires and Procedures for Children (age 0-17)***

**In-Home Visit (approximately 20 minutes)**
- Computer Assisted Personal Interview
- Consent
- Health Status and Functioning
- Respiratory Health
- Diet
- Usual Physical Activity
- Sleep
- Screen Time

Procedures (completed on all minor subjects age 3-17)
- Weight
- Height

Procedures (completed on all minor subjects age 6-17)
- Blood Pressure
- Spirometry (screening questions asked of parent or guardian in RHM questionnaire)

Surveys are conducted with either minor subjects or parent proxies depending on topic area. The grid below (Table 2) describes which surveys and procedures are completed with each:

**Table 2: Age ranges for which questionnaires are completed with parent or via self-report by minor subject.**

<table>
<thead>
<tr>
<th>Survey</th>
<th>Parent proxy</th>
<th>Minor self-report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Status and Functioning</td>
<td>0-17</td>
<td></td>
</tr>
<tr>
<td>Respiratory Health</td>
<td>0-17</td>
<td></td>
</tr>
<tr>
<td>Usual Physical Activity</td>
<td>3-11</td>
<td>12-17</td>
</tr>
<tr>
<td>Screen Time</td>
<td>0-11</td>
<td>12-17</td>
</tr>
<tr>
<td>Diet</td>
<td>3-11</td>
<td>12-17</td>
</tr>
<tr>
<td>Sleep - infant</td>
<td>0-2</td>
<td></td>
</tr>
<tr>
<td>Sleep - younger children</td>
<td>3-11</td>
<td></td>
</tr>
<tr>
<td>Sleep - older children</td>
<td></td>
<td>12-17</td>
</tr>
</tbody>
</table>
2. Procedures and Risks to Subjects

General considerations: Maintaining the core interview/exam approximately constant over time will permit the examination of trends and the pooling of data from different years for cross-sectional and longitudinal analyses. However, the independent nature of each 1-3 year sample will also allow the flexibility to add and drop interview or exam components in certain years (in all or subsets of participants) as ancillary studies are incorporated and funding opportunities increase.

Pregnant women: Subjects are enrolled regardless of pregnancy status. Adult subjects six months pregnant or more are excluded from spirometry testing. Spirometry procedures include pre-procedure questions that would screen out a subject who meets this criterion. All other physical and biological measurements are standard and similar procedures would be encountered during routine prenatal care. There are no expected risks to a pregnancy or fetus from any other study procedures. As with all subjects, any procedure or question may be refused.

Children: Children of any age are eligible for SHOW. Age-appropriate questions are used in the survey component (see Table 2). Parental (or legal guardian) consent is obtained for each child. Assent is obtained for children aged 7-17. If a child dissents, they are not enrolled.

All procedures in the study are reviewed and approved by the UW Health Sciences Institutional Review Board. All SHOW personnel (from program director, program manager and field staff) are required to undergo Human Subjects training. A Certificate of Confidentiality has been obtained from NIH/DHHS to protect all information from forced disclosure under a subpoena. Separate IRB approval will be sought for all future SHOW-related ancillary studies and when additional exam components or changes to questionnaires are added to the survey.

a. Questionnaires

As this is a health survey, the primary study procedures are questionnaires about the individual subject's health, health risks, and access to health care. These questionnaires take approximately the following amount of time:

Consent: 20-30 minutes
Adult In-Home Questionnaire, and Physical Measurements: 1 ½ hours
Child In-Home Questionnaire and Physical Measurements: 10-20 minutes (depending on age of child)
Self-Administered Questionnaire Booklet: 45 minutes
Sample Collection: 20 minutes
(NOTE: children will not be asked to complete a Self-administered Questionnaire or partake in sample collection)

There are no physical risks in the completion of the questionnaires; however there is the potential that subjects will find the questionnaires to be of a sensitive or embarrassing nature. Although the survey has been designed to maximize the collection of valuable data that is sensitive, it is also structured in a manner that maximizes patient confidentiality and privacy. Questions are specifically designed for private answering either in a self-administered format in the home or at a computer while alone in a room, thus maximizing the privacy of individual and household members. For example, food security and sexual orientation questions are asked in an audio computer-assisted self-interview (ACASI) format in the home rather than through computer-assisted personal interview (CAPI) format. This design consideration both optimizes privacy while
maximizing response and truthfulness if respondents feel that their privacy is being respected and maintained. The self-administered paper questionnaires are left in the home with a sealable envelope so that the participant will be able to store the completed questionnaires and maintain confidentiality.

Subjects are repeatedly assured that they can refuse to answer any question that makes them feel uncomfortable.

The conduct of the study is not a barrier to subjects with limited ability to read. The SHOW questionnaires are all designed to be interviewer read and recorded for answers if needed. The self-administered questionnaire is a written packet that is offered to the subject with the option of having the interviewer read the question and record the answer as given.

For hearing-impaired participants, the survey can be conducted with the subject reading the printed version of the questionnaires and indicating / signaling their answer. All documents are available in written format.

b. Phlebotomy Procedure

The research staff performing the phlebotomy procedure are certified in their phlebotomy skills and receive annual updates to certification updates as needed. Alternatively, the blood draw and/or finger prick for blood spot collection will be conducted on participants ≥18 years of age by certified phlebotomists at a sample collection site established in each community, or if needed, at the subject’s home.

There is the risk of discomfort and a minor risk of bruising and/or infection at the phlebotomy site. Again, the latter risks are minimized by assuring that appropriately-trained staff conduct this procedure. Additionally, the phlebotomists are First Aid/(CPR)-certified, thus prepared for unexpected events such as syncope.

c. Urine Sample

A urine sample is collected from each participant ≥18 years old. There is no risk inherent to the completion of this procedure.

d. Blood Spot

Blood spot samples will be collected from subjects who refuse the blood draw but are willing to provide a blood spot for unspecified long-term storage. A skin prick is performed with a lancet and 8 drops of blood are collected on two sheets of filter paper.

The risks associated with the blood spot are the same as phlebotomy.

e. Saliva Sample

Saliva samples will be collected from subjects who refuse the blood draw but are willing to provide a saliva sample for DNA collection. There is no risk inherent to the completion of this procedure.
f. Body Measurements

The following physical measurement tests are conducted:

- **Pulmonary function test/Spirometry** (peak expiratory flow rate): This is a non-invasive procedure in which the subject, three times, takes a deep breath and exhales their air as quickly as possible through the tube connected to the measuring device. This procedure has the minimal risk of the subject coughing due to effort. Women six months pregnant or greater are excluded from this test to reduce confounding. SPI110 is asked prior to this test to identify ineligible subjects. Conducted on subjects age 6 and up.

- **Height and weight** are measured and are used as factors in determining **body mass index**. There is no inherent risk to this procedure. Conducted on subjects age 3 and up.

- **Waist and hip circumferences**. Conducted on adult subjects.

- **Blood pressure**: Blood pressure is taken three times and the three measurements are recorded. There is no inherent risk to this procedure. Conducted on subjects age 6 and up.

g. Physical Activity

All participants starting at age 6 will be asked to wear an accelerometer for measuring physical activity. Accelerometry has been identified as a more accurate measure of physical activity and is widely accepted as the gold standard for measuring physical activity levels in population-based research. Protocols have been developed for adults based on a pilot study conducted during the summer of 2013 and will now be implemented for all adults age 18 and older.

Adults will be asked to wear two small accelerometers: one on their waist and one on their wrist, for seven consecutive days. Minors 6-17 will be asked to wear one small accelerometer on their wrist for seven consecutive days. They will be asked to remove devices for showering and swimming or other water-related activities. Waist accelerometers will be removed during sleeping hours for comfort; the wrist device will be kept on for sleeping. Subjects will be asked to record their hours wearing the devices on a log sheet and provided an envelope to return the devices and the log sheet to their sample collection visit. If a participant decides not to participate in the sample collection visit, a self-addressed and stamped envelope will be provided for return of the equipment and log sheet by mail. All participants will receive an extra $25 for completing the accelerometry component of the study. Participants will be compensated regardless of data quality and completeness of the tracking log.

Device: The ActiGraph GT3X, available through ActiGraph Corporation (http://www.actigraphcorp.com/) will be used for this study. These devices are commercially available and are being used for measurement purposes only. This study is not investigating a medical device. The ActiGraph GT3X is a Class II medical device with FDA clearance.

The general risk associated with accelerometry may be some anxiety over results of body measurements. This risk is minimized by first assuring confidentiality of the information and then providing information about the meaning of the results. Subjects are also reminded throughout their study participation that they do not have to participate in any or all of the study.

h. Sample Storage and Genetic Testing
A portion of the blood sample is obtained and stored for future unspecified testing. This includes DNA and mRNA that will be saved for future genetic testing. Participants are asked to provide consent regarding sample storage and additional consent specifically for storage of genetic material. The samples will be available for sharing with researchers outside the original SHOW protocol upon request. Outside requests for use of existing SHOW biorepository data will have to complete a formal data request from SHOW and obtain IRB approval for use of samples. A systematic tracking system of sample sharing requests and use has been developed. Samples are provided to outside researchers only if SHOW study participants have consented to this. There are no plans to commercialize the genetic material and it will only be used for research.

The following procedures have been established for distribution and use of SHOW biologic samples collected for future unspecified testing:

1. If researchers request samples they will be required to submit a formal request and application to the SHOW Scientific Core Review Committee. The Scientific Committee is chaired by the Principal Investigator, F. Javier Nieto, and includes several Population Health Sciences Faculty affiliated with the SHOW study. The scientific merit for the request and consistency with SHOW’s mission and policies are evaluated by the science team.

2. Once the hypothesis-driven or evaluation research has been approved by the scientific review committee, researchers are asked to complete a formal data request form.

3. The form is used for identification and tracking of samples within the biorepository.

4. Before samples are provided to researchers, SHOW will obtain documentation of IRB approval or exemption for the specific proposed use of samples.

5. Any use of biologic samples from the SHOW biorepository requires review by the SHOW committee and IRB approval for sample analysis.

6. SHOW samples will remain coded and will not be linked to identifiable data such as names, addresses, and birthdates. All researchers outside of SHOW that have access to banked samples will not also have access to information that would make it possible to link names to coded materials. Any linkage of analytic results with a more detailed analytic dataset will occur in the main SHOW office, unless otherwise authorized by the IRB.

The risk related to biospecimen storage and future use of samples, including potential genetic testing, include the potential that results could accidentally become known. If this happens there is the risk that, should a serious genetic predisposition be identified, this could affect potential insurability. There might be other risks unknown at this time. The risk that the results of the samples will become known is minimized in the de-identification that will accompany sample sharing with researchers.

i. **Unanticipated Problems and Mandatory Reporting**

General unanticipated problems and complications: In the event of any unanticipated problem or adverse event, all SHOW employees are trained to follow the same procedure. Individuals report the problem to their supervisor and their supervisor reports the incident to the principal investigator. The principal investigator, in cooperation with other study team members as applicable, determines whether additional action is required. All procedures are documented and, when appropriate, reported to the IRB. Examples of unanticipated problems and complications may include but are not limited to:

- Negative reactions to sensitive questionnaires
- Breach of confidentiality
Subject complaints

In the case of extreme reactions to sensitive interview questions, SHOW field interviewers are trained to contact emergency services if necessary.

Executive order #54 and mandatory reporting: Per Executive Order 54, SHOW staff, as employees of UW-Madison, are considered mandatory reporters of child abuse or neglect. SHOW will follow all state guidelines (http://www.oed.wisc.edu/childabuse/) for reporting child abuse or neglect if it is witnessed through the course of job responsibilities. This requirement most directly affects SHOW field interviewers, who are entering the homes of potential participants and consented subjects.

While all SHOW staff will follow aforementioned state guidelines for reporting of child abuse or neglect, SHOW field staff will have special training on procedures for reporting:

- All field staff will complete the Wisconsin Mandated Reporter Online Training (http://wcwpds.wisc.edu/mandatedreporter/) provided through the Wisconsin Child Welfare Professional Development System.
- If field interviewer witnesses child abuse or neglect during the course of their professional responsibilities, they will immediately report this information (either by phone or in person) to
  - Child Protective Services (of the county where the abuse or neglect was witnessed) in the case of non-emergent situation
  - Local law enforcement in the case of an emergent situation
- Field staff will also inform their supervisor at once that this reporting has taken place. If their supervisor is unavailable, either the SHOW director or associate director should be contacted.
- Supervisor will relay the information to the SHOW director.
- The IRB will be informed of this incident and any necessary documentation will occur in conjunction with the IRB and applicable SHOW staff.

j. Confidentiality

The issue of confidentiality and data security has received attention in order to assure confidentiality of material at a personal and project level. This issue is also addressed in section III.C.4.d and III.D and details of our data security procedures are maintained for use in SHOW’s internal Data Security Manual of Operations.

The personal aspects of respect for confidentiality are dealt with by employing many methods including:

- Structuring the survey and procedures in a manner that can maximize confidentiality, e.g., food security and sexual orientation questions are asked in an ACASI format in the home rather than through CASI format.
- Continual review of survey questions to assure the relevance of all questions asked to the overall goals of the study and eliminating the questions or instruments that are not critical in order to minimize participant’s burden and potential risks.
- Respect of privacy within the community to assure that individuals are not overtly identified. For example, the temporary sample collection site may be set up at local health department.
Subjects are assured several times throughout the study that they can refuse to answer any question or complete any portion of the physical exam that makes them feel uncomfortable.

Data security for the collected data is addressed in complete detail within the Data Security Manual (see appendix A). In brief summary:

- Random subject selection yields a degree of anonymity.
- Data is encrypted on all laptops and discs and all such hardware is kept locked in secure locations.
- All paper copies of questionnaires are labeled only with an ID number. The completed questionnaires are kept in a locked/secure location until delivery to the SHOW headquarters.
- Data is either transmitted directly to the UWSC Data servers through a Virtual Private Network (VPN) or secure WiFi connection. They are encrypted and downloaded when a secure and stable connection to the VPN can be achieved.
- Personal Identifiers are stored on a separate server from survey responses addressing personal health information.
- A Certificate of Confidentiality has been obtained from the National Institutes of Health to protect all the SHOW data collected from participants from any efforts by governmental, law enforcement, or immigration agencies to have SHOW disclose their information.

3. Compensation for Time and Participation

As compensation for time and participation, each adult survey participant 18 and over will receive $100 and a t-shirt with the SHOW logo for completion of all segments of the survey. 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:

- body mass index
- blood pressure
- glycosylated hemoglobin (A1c)
- serum total and HDL cholesterol

Pro-rated compensation for the study participation for adults is as follows:

| In-home questionnaire and physical measurements: completion | $25.00 |
| Self-administered questionnaire: completion | $25.00 |
| Sample collection: completion | $25.00 (attempts for a blood sample are compensated) |
| Accelerometry: completion | $25.00 |

Compensation for children is $15.00 for completion of any portion of the child questionnaires.

4. Daily Operations

a. Field Staffing

Field staff will be hired to recruit participants and conduct survey components within the communities where SHOW is sampling households. Certified phlebotomist(s) will be hired to travel to communities throughout the state to perform blood draws.

The SHOW Program Manager, Field Team Manager, and other administrative staff work with and support the field team to coordinate initial and ongoing staff training, community awareness, community recruitment, and exam center visits, as well as support the systems for completion of
documentation, laboratory procedures, subject follow-up and logistical arrangements for the remote sites. The SHOW administrative team conduct quality assurance to assure that adherence to the Field Team Manual of Operations (MOO) is consistent and complete.

In appropriate situations, SHOW will train additional community field staff as needed. These individuals will be trained in human subjects and added to the SHOW key personnel list.

b. Staff Training

The field staff must complete all the following training protocols:
- Orientation to the University and its policies, and team building
- CITI Human Subjects Research
- Cardio-pulmonary resuscitation (CPR) certification
- First aid Certification
- Survey interviews
- Recruitment
- Cultural competency
- Questionnaires
- Standardized interviewing and consent
- Examination components and tests
- Computer and software operation, security and maintenance
- Communications and office equipment
- Confidentiality and data security policies and procedures
- Equipment maintenance and calibration

In addition, the phlebotomist must also complete the following training protocols and provide proof of certification in biosafety from the Environment, Health & Safety program at the University of Wisconsin-Madison:
- Phlebotomy
- Specimen collection
- Processing and shipping
- International Air Transport Association (IATA) certification for handling dry ice
- Personal and site safety protocols, policies, and procedures

c. Sample Collection Site Selection

The biospecimen sample collection portion of the survey (see iii.c in next section) may be conducted at 1) a suitable facility within the community, 2) in participants’ homes or 3) in the SHOW Mobile Exam Center (MEC).

Community facilities may include a space at the local health department, extension office, community center, school or university, or other facility such as rental hall, American Legion, hotel conference room, etc. 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 ensure 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.
The MEC is a 37-foot RV-type vehicle built with three inner rooms where specimens can be collected. This vehicle runs on its own generator and can also be connected to public buildings for an extended stay in a community. The MEC is 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.

Directions to the sample collection site 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 external site, or should a participant prefer a more confidential visit, the phlebotomist can complete the blood draw and urine sample in the home with quick relay of the specimens to the sample collection site or MEC.

d. Data Collection Procedures/Conduct of Study Visits

i. SHOW Questionnaires

SHOW questionnaires are reviewed annually and updated based upon the SHOW scientific review committee recommendations, review of current literature, and review of current state health issues and concerns. As appropriate and with approval from UWHS-IRB, these existing instruments may be modified or adapted or developed as new questions.

ii. Assignment of Subject 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.

iii. Conduct of Study Visits

There are several sections to the SHOW study visit: An in-home visit, a self-administered questionnaire, and biologic sample collection. Subjects that complete the in-home questionnaire may choose to participate in any or all of the remaining portions of the study. Subjects may choose to selectively not answer individual questions throughout the questionnaires for their own reasons of privacy or comfort.

iii.a. In-Home Visit

Upon completion of the screening process, the in-home questionnaire begins with each consenting eligible adult household member over the age of 18. These interviews are completed separately and are computer-assisted interviews using pre-programmed laptop computers. Parts of the interview are completed by the participant using headphones and a laptop to answer questions privately (Audio Computer-Assisted Self Interview, or ACASI) without the field staff or accompanying family members hearing the question or seeing their response. The food security, depression, and sexual identity 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.
Child questionnaires will be asked directly to children over the age of 3 where age-appropriate questionnaires are available, and will be asked by parent or guardian proxy where age-appropriate questionnaires are not available.

For the physical measurements, the field staff takes adult participants to a private room or space where blood pressure, heart rate, height, weight, waist circumference, and hip circumference are measured. The field staff also instructs and completes the spirometry test. All measurements are recorded via a laptop computer.

Physical measures for all children will be taken in the presence of parent or legal guardian. Field staff will not be alone with any children without another adult present.

If subjects are not able to complete the home visit 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.

**Alert Values on Blood Pressure.** The computer program warns field staff of any out of range values and requires retest and field staff verification of values. Confirmed alert values for blood pressure require field staff to follow a specific protocol for discussion of the alert value and completion of a data sheet on the values that are given to the participant, along with written recommendation that they visit an urgent care center, emergency room, or their physician immediately for further evaluation of their blood pressure (see “Today’s Test Values” document). Alert values are based on the Eighth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure.

### 0-59 years old:

<table>
<thead>
<tr>
<th>Systolic (mm hg)</th>
<th>Diastolic (mm hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤90</td>
</tr>
<tr>
<td>≤140</td>
<td>1</td>
</tr>
<tr>
<td>141-210</td>
<td>2</td>
</tr>
<tr>
<td>211+</td>
<td>3</td>
</tr>
</tbody>
</table>

### ≥ 60 years old:

<table>
<thead>
<tr>
<th>Systolic (mm hg)</th>
<th>Diastolic (mm hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤90</td>
</tr>
<tr>
<td>≤150</td>
<td>1</td>
</tr>
<tr>
<td>141-210</td>
<td>2</td>
</tr>
<tr>
<td>211+</td>
<td>3</td>
</tr>
</tbody>
</table>

The value assigned based on blood pressure measurement corresponds to the recommendation received on the Today’s Test Values document:
1. Continue to have your blood pressure checked regularly as indicated by your doctor.
2. Seek attention by a health care provider at your earliest convenience.
3. Seek immediate attention by a health care provider.

**iii.b. Self-Administered Questionnaire**

Upon completion of each in-home visit, instructions will be given to each adult participant on how to complete the self-administered questionnaire. The self-administered questionnaire takes approximately 30-45 minutes to complete.

The self-administered questionnaire is provided to the subject in a packet that includes a labeled and stamped envelope for use when mailing the materials back to the SHOW office. They are given a SHOW pen as a convenience to complete the packet.

A sealable stamped and addressed envelope will be provided with each questionnaire to protect the respondent’s privacy from others in the household. Participants are instructed to mail these questionnaires to the SHOW office using the provided envelope.

**iii.c. Sample Collection**

An appointment for biological sample collection is made prior to the completion of the in-home visit. This appointment is made to accommodate the subject’s availability and ability to complete the sample collection at the chosen location. This portion of the study involves the phlebotomy and urine sample. It is estimated to take approximately 20 minutes to complete.

For those subjects who prefer, due to mobility issues or simple preference, sample collection procedures may be conducted in the home.

Appointments and scheduling are done through the central office and subjects are provided with a toll-free number to call if changes or cancellations need to be made. 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 sample collection appointments by mail, telephone, or email (depending on the SP’s preference) 1-3 days prior to their scheduled appointments, and any travel arrangements and directions are verified.

Upon arriving at the sample collection site, each participant is checked into the computer system and his or her identity and study number is verified. The phlebotomist outlines the planned procedures, reviews and verifies consent and answers any questions.

No biosample collection for children is planned at this time.

The blood and urine samples are obtained at the sample collection site. Barcoded specimen labels are preprinted. Urine collection is done by clean catch and separated into 1.5 ml cryovials for long-term storage. The venipuncture is then performed. For the core SHOW, approximately 45-50 cc are collected; additional ancillary studies may be added for additional blood draws not to exceed 60 cc. This blood is drawn from the participant’s arm using standard venipuncture technique. Tubes are drawn in a prescribed order based on the type of tube and additive. Tubes are processed in the exam center laboratory following standardized processing procedures. Participants who refuse the blood draw or whose blood samples were not able to be obtained are
asked to consent to allowing a sample of saliva to be collected to obtain cells for DNA analysis. If they are willing, this sample is obtained using a sterile saliva sample collection kit. They may refuse this DNA collection method as well. All laboratory procedures are detailed in the Laboratory Manual of Operations and this document is used for training and standardization of biosample data collection. A list of tubes and amount of sample collected within each is summarized below.

For the core component of the survey, approximately 54 mL of blood will be drawn from each participant and collected into eight tubes. The order in which the tubes are collected is extremely important and must be done as follows:

1. 5 mL gold top SST with gel barrier for chemistries
2. 10mL red top for serum
3. 10mL red top for serum
4. 10 mL EDTA lavender top for plasma and DNA
5. 10 mL EDTA lavender top for plasma and DNA
6. 3mL EDTA lavender top for central lab for CBC
7. 3mL EDTA lavender top for central lab for HgA1C
8. 2.5 mL PaxGene Tube for whole blood sample collection
9. 1 additional sample for QC, when designated and SP is amenable

For participants not interested in or willing to provide a blood sample, an alternative option of providing dried blood spots will be offered. Two cards per participant with four samples each will be collected following standard data collection protocol. Cards will be dried in the lab and sealed for long-term storage. One card will be stored at -20 and another at -80. All samples will protected during transport to avoid high temperature extremes.

Staff will be instructed to wear personal protective equipment and devices during all stages of sample collection, for staff as well as participant safety.

**Alert Values on Laboratory Results.** Laboratory results are sent to SHOW from Marshfield Labs within a week after the phlebotomy is complete. These results are compiled with selected physical measurements (height, weight, body mass index, and blood pressure) and mailed to the subject in a Findings Report document. This document includes normal ranges for laboratory values and flags denoting values that are out of range. Also included is a statement that tests were performed for research purposes and SHOW recommends abnormal results be discussed with a health care provider.

Lab values will not be available to participants who provide blood spots.

Final steps in the study visit include:
- Collecting accelerometer for all adult participants.
- 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.
- Indicating that study compensation will be mailed to participant within 1-3 weeks.
- A written findings report and any relevant recommendations will be mailed to the subject.
- 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.
e. Biospecimen Processing and Shipping

Marshfield Labs, a private company, is contracted to provide lab values as described below according to the internal Laboratory Manual of Operations. Coded bio-specimens are shipped in a timely manner to this contracted testing laboratory for immediate testing and reporting. The following tests (at a minimum) are run on these samples:

- complete blood cell count
- serum glucose
- serum cholesterol
- serum high density lipoprotein (HDL) cholesterol
- serum triglycerides
- serum creatinine
- serum glycosylated hemoglobin (hemoglobin A1c)

Samples are randomly chosen for storage specifically for quality control measures by the laboratory.

With consent of the subject, a coded portion of the sample, is frozen, stored, and batch-shipped to a private company, Prevention Genetics, in Marshfield, WI (http://preventiongenetics.com), for DNA extraction and storage in their biorepository. The remaining samples of plasma (including the paxgene tube), serum, and urine are frozen in the SHOW biorepository and stored for future unspecified research.

Consent is required for the DNA and mRNA collection/storage and the long-term storage for future unspecified research of the remainder of the sample.

All shipments of samples follow IATA regulations on transport and shipping of biosamples and the use of dry ice. The phlebotomist is certified in specimen shipping. Samples are tracked via the bar-coding labeling system. Staff will wear personal protective equipment and devices during all stages of sample processing and shipping to ensure safety of staff.

Confidentiality of samples is protected by the barcode label system, which provides a link to the subject, but the link is not directly available. No personal identifiers or health information is applied to the sample tube or provided to either Marshfield Labs or Prevention Genetics. Linking of the numbers and the barcode can only be accomplished through the connection of data that is maintained in separate secured servers. Storage of these samples records only the barcode and not the link to subject information. Finally quantitative and statistical measures are applied to assure quality control of specimens: these are outlined in the MOO.

f. Retention and Education

Before leaving the home, the field team staff reminds SPs that while the initial data collection for this study is done, SHOW plans to conduct future surveys in order to conduct analysis of change in health over time. Subjects are reminded that, if they have consented to continued contact, they will receive periodic mailings and newsletters with updates about the progress of the project and that they might be contacted by phone or by mail in the future to explore their interest in participating in follow-up surveys about changes in their health. Subjects are assured that they can refuse to participate at any time and that it is their choice to tell others about their participation in SHOW since SHOW will not be disclosing their participation to anyone. The field
team also encourages SPs to keep the SHOW magnets on their refrigerators for future questions they may have or to inform SHOW when they move.

Newsletters describing the project’s accomplishments and findings are periodically produced and mailed to the subjects and participating researchers and communities. These are available on the internet for different audiences such as community members, public health, and the scientific community. The newsletters to participants are utilized to keep them aware of how their participation in the SHOW study has been important to its success.

The newsletter to participants includes:
- The progress in numbers of participants
- General findings from research on the data
- Reactions and comments from other participants
- The importance of SHOW to understanding Wisconsin’s health
- Publicity SHOW has received in the general media
- Information on follow-up contacts
- Reminders to update SHOW about change of address or phone

Community newsletters include the following topics:
- Progress in recruitment;
- Communities that have been completed and that are targeted for visits
- Participant responses and comments
- List of endorsements;
- Suggestions for how a community can spread the word about SHOW
- Forum for community suggestions on how SHOW can collaborate with the community

Newsletters to current and potential investigators include:
- The growth of the database
- The rates of recruitment and levels of participation
- Accepted ancillary and collaborative studies using SHOW data and /or resources
- Policies and systems established for applying to use the data and biosamples
- Mechanisms for requesting ancillary question study or substitutions in future survey cycles
- Results of studies and analysis using SHOW data and resources
- Mechanisms for requesting use of data

D. Data Processing, Management, Confidentiality, Analysis and Statistical Power

1. Data Management

SHOW has devised the most stringent data security plan that is feasible given the complex nature of the survey design. All data and specimens collected on human subjects in the Survey of the Health of Wisconsin are protected from technical and physical loss and damage and from disclosure of identifiable data from the initial point of collection through interim storage, transport, transmissions, downloads, processing, final storage, and distribution of datasets and specimens.

The Data Security Manual of Operations includes processes and procedures for maintaining data security and has been reviewed/approved by the UW Health Sciences IRB. The manual describes in detail all survey procedures and methods of data collection and data handling and is made available to all study personnel and future users of the database.
Data security is achieved through a collaboration of effort and responsibility between SHOW Headquarters in Middleton, WI, and the University of Wisconsin Survey Center (UWSC) on campus at UW-Madison. Data processing and management occurs at both sites with the final repository of data being at the SHOW headquarters.

SHOW headquarters staff are responsible for:
- All source documents
- Subject Identification codes
- Block group identifying systems
- Computer storage systems
- Manual data entry of any paper questionnaires used
- Back-up recording of subject visits
- Sample tracking and storage
- Database administration and some programming
- Data Quality and quality control activities
- Separation of SP identifiers from health research data.

The UWSC coordinates:
- Initial programming and revisions of questionnaires into SHOW laptops and VPN; receipt, checking, and preliminary cleaning of electronic data in real time or delayed downloads
- Secure transmission of data to SHOW

The laptops used are protected via whole-disk encryption using a certified encryption program. The computer cannot be accessed without an ID and password and the data on the disk will not be accessible if removed from the laptop.

Transmission of data is accomplished through the use of a Virtual Private Network (VPN) between the field sites, UWSC, and SHOW via air cards. This system is used for real time transmission of data. In such circumstances where a connection cannot be established, the encrypted, password-authenticated laptops are used as interim data storage until the data can be completely downloaded to the VPN.

Paper self-administered questionnaires are data-entered using a dedicated computer. Editing, routine consistency checks, and double data entry is conducted as necessary to minimize errors.

Samples are labeled with the SPID#, and no other identifiers. This allows for additional safety and tracking of these specimens in transport and storage points.

Examination and measurement equipment, with computer interface, directly records measurements (when feasible) and are linked with the participant’s identification number. Where no direct linkage to computers is possible, the field team works in pairs and/or verifies readings by repeat efforts (blood pressure measured three times).

Data is separated by type into two databases at SHOW. The SP database contains the SP identifiers and the SHOW research database contains the rest of the health data, identified only by the SP identification number. A monthly backup of all SHOW data is performed. Backup data is encrypted and stored in a second offsite location.

Individual/family addresses are geo-coded. Name, address, telephone number, social security number, and relative or friend contact information (to be used for follow-up) are entered into a
separate database that contains no health information data, only the individual’s identifiers. These data are stored using highly secured procedures with restricted password-protected access.

**Field team staff training** occurs for each staff member prior to the conduct of any subject visits. Annually, staff participates in formal re-training programs to verify accurate data entry and security compliance. Additional training is provided as content or systems are changed.

**Quality assurance and quality control procedures** are established for assurance of accurate conduct of the subject visit. All interviews are audio recorded unless the SP refuses taping. The SP is informed that the purpose of recording the interview is to monitor the interviewer’s performance for quality control purposes. Periodically, files are randomly selected and reviewed by the Field Team Manager and SHOW staff for consistency in the interview process as well as identification of problematic questions. These files are maintained and secured for quality control purposes along with other data collected from the participant. The interviewer ID and date are entered for each survey component to monitor staff performance. Audiotaping for quality control will also be conducted during study visits with minor subjects. Procedures for audiotaping minor study visits will be the same as those for adult study visits.

**Data, data systems, and process quality assurance** is monitored. All equipment used in the survey is calibrated and tested per the manufacturers’ recommendations. Range checks for individual items and multi-item consistency checks are implemented whenever possible in the data entry forms and in the health research database.

Computer security and support is managed internally by the Data Management Administrator. Additional computer support, networking and functionality is supported and managed through contracted services with the University of Wisconsin DoIT Center. Routine staff members from this organization work with the SHOW program and are also incorporated into CITI certification in order to work with SHOW systems.

### 2. Analysis and Statistical Power

Because of its comprehensive and multipurpose nature, SHOW data is analyzed in multiple ways. Public health researchers focus mainly on descriptive analyses of health status of Wisconsin populations and changes over time in health-related conditions; epidemiologists and environmental scientists analyze how health determinants relate to the occurrence of health outcomes; clinical researchers use SHOW data and samples as control data for clinical investigations; health services researchers will link SHOW data with other health care data sources to study issues related to health care quality; community health intervention researchers utilize SHOW as baseline data to evaluate the effectiveness of community-based interventions. The geocoding and linkage of participant’s addresses to census data and other administrative and environmental databases allows analyses of the correlation between survey data with broader community-level contextual determinants of health. Through the use of the social security number (an optional release from the SP) or combination of last four digits of the social security number, name, and date of birth, data can be linked to vital statistics records (e.g., national death index) and electronic health records for prospective analyses of health outcomes.

The following is a summary of some of the approaches that are used to analyze SHOW data. Due to its evolving nature, however, it is not possible at this point to anticipate all the many different ways these data will be used in the future.

#### a. Descriptive Analyses
Annual survey data (sample size approximately 800-1000) are used for descriptive assessment of prevalence of common health conditions and health determinants including health behaviors, prevalence of common conditions—such as high blood pressure or obesity—health care access and utilization patterns, etc. A focus of the study is the analysis of health disparities across socio-demographic groups and across regions of the state. Because of the complex design of the survey (multistage, cluster sampling), standard analytical software that take into consideration the sampling weights (e.g., SUDAAN\textsuperscript{20} or SAS’s PROC SURVEY[...] routines) is used.

Because of the limited sample size of any one particular survey year, consecutive annual surveys can be pooled into an increasingly large cross-sectional sample that will be used for the analysis of prevalence of less common conditions as well as for the study of more common conditions in specific population subgroups (e.g., minority populations).

Analyses of temporal trends in the prevalence of health-related outcomes can be conducted using consecutive annual surveys. Differences in trends of the conditions of interest are studied by comparing the slope over time in different categories defined by demographic, geographic, or community-based characteristics. Time-series regression techniques are used for these types of analyses.

b. Cross-Sectional Association Studies

These successive annual representative samples of the Wisconsin population are used for the study of the association of conditions of interest with other characteristics of the participants and their environment. The focus is generally the study of how individual characteristics, behaviors, environmental factors, and access to health care relate to health outcomes (including both prevalence of health conditions and quality of life indicators). Multivariate analyses can be conducted using standard statistical techniques, such as linear and logistic regression. These analyses also need to take into consideration the complex design of the survey.

As with the descriptive analyses, the successive annual samples can be pooled into an increasingly large cross-sectional sample that can be used to study the association between health determinants and the prevalence of less common outcomes as well as subgroup analyses in specific sub-populations.

c. Cohort Analysis

As follow-up data is accrued and a sufficient number of certain health events of interest (e.g., incidence of certain conditions or mortality) are identified, cohort analysis techniques will be used to assess the relation between baseline individual and contextual characteristics and the occurrence of these health outcomes over the follow-up. Incident cases will be identified by linkage with other data sources or by follow-up calls. Data analysis will be based on standard statistical techniques for longitudinal data (e.g., survival analysis and person-time based incidence rates); multivariate analyses will be conducted using Cox proportional hazards and Poisson regression techniques.

For the analyses of data involving biological samples, \textit{nested case-cohort} analytical techniques\textsuperscript{8,21} will be used. This approach is aimed at minimizing the number of samples needed for the analyses while maintaining sufficient statistical power. Thus, cases of a certain health outcome that are identified over a follow-up period will be compared to a random subset of the
baseline cohort (covering one or more annual surveys, depending on power and design considerations) using Barlow’s robust variance methods as applied to the proportional hazards regression procedure. This design takes advantage of the extensive information available to characterize subsets of participants in SHOW and ensures an efficient approach to address the multiplicity of the study’s scientific objectives. In addition to saving costs, this approach optimizes the use of the specimen banks by limiting the use of samples that will then remain available for future studies.

d. **Comparative Analysis**

Survey data can be linked to other databases (e.g., environmental databases on air and water quality, administrative databases on community-specific programs or resources) allowing comparative studies between variables within and outside the SHOW database. Linkage with health care providers’ administrative databases gives the opportunity to study unmet health needs (e.g., the proportion of individuals with undiagnosed diabetes in the community, the proportion of myocardial infarction survivors who are receiving proper secondary prevention management, the proportion of adults receiving recommended screening procedures). Linkage with administrative data such as hospital discharge codes, cancer registry, and National Death Index provides information on incident disease diagnoses and cause-specific mortality that can then be used to identify incident cases in follow-up studies.

i. **Walk Score**

SHOW researchers will pursue using address information to link to databases describing neighborhood characteristics. The first iteration of this process is obtaining a walk score for each subject’s household. By entering an address in WalkScore.com, a score is generated for the walkability of the subject’s neighborhood. The score is assigned to the individual subject for analysis but is not based on any individually identifiable information.

In order to protect subject confidentiality, any address information submitted to this database is ‘hidden’ by submitting 5 or more dummy addresses for every 1 SHOW household address.

3. **Sample Size and Statistical Power**

Annual sample sizes vary between 400-1000 and are determined by a combination of statistical power and feasibility/costs considerations. While a larger yearly sample size will increase the power of various studies, it also requires an extraordinary amount of resources for follow-up of survey participants as the study progresses.

Given the broad range of questions addressed by the study, a fixed power calculation is not possible or meaningful. The statistical power of the study will be different for cross-sectional and longitudinal analyses and will vary depending on the frequency of each specific outcome of interest. To provide a general impression of the relation between sample size and power for statistical analyses using SHOW data, we include a sample graph (Figure 2). The four lines in this graph represent a range of incidence rates of hypothetical health outcomes ranging from 1 percent (top line) to 30 percent (bottom line). All four lines refer to a risk factor (e.g., environmental exposure) for the outcome that is present in 30 percent of the population. (For example, smoking or hypertension falls in or near this range.) Sample size requirements are given for detecting relative risks for the health outcomes associated with the exposure for a range
of relative risks, up to 4. “Detection” is taken to mean in a significance test at two-sided alpha of 0.05 and 80 percent power for any given relative risk.

![Figure 2](image)

**Figure 2**
Required sample size for significance level=0.05 and power=0.80, for outcome incidence or prevalence (“risk”) ranging from 1% to 30%

The generic graph in Figure 2 can refer to either the entire study sample or to subgroups. We see that for common outcomes, even a relative risk of 1.5 to 2 is readily detectable very soon after study start-up, even in subgroups (e.g., sample size below 200 for a relative risk of 2). On the other hand, weak relative risks will require a much larger accumulated study size, as will occur after several years of accrual. Risk factors (exposures) that are rarer (affecting less than 30 percent of the population) or very common (affecting over 70 percent) will require larger sample sizes than those shown to detect a given relative risk, while risk factors affecting 31-69 percent of the population will require slightly smaller sample sizes.

Finally, it should be noted that the above power calculations refer to the so-called “effective” sample size. A somewhat larger actual sample size is needed due to survey weights and clustering; this is compensated by these estimates being based on a smaller annual sample than the recruitment target. The difference between actual and effective sample size cannot be accurately predicted at this time as it depends on factors such as how closely outcomes are correlated within a cluster (e.g., family or census block group).

**IV. DISSEMINATION OF SHOW RESULTS**

SHOW data are available to partners, including qualified researchers and public health practitioners via a standardized public use dataset and through special data requests for ancillary studies. Once an annual sample of data is processed and completely de-identified, the data are securely stored and made available upon request, and with multiple years of data a standardized, de-identified public use database has been created. This public use database can be used by a
variety of end-users to generate baseline health statistics in a timely manner which can be linked with other key health determinant data that will contribute to the promotion of health for all Wisconsin residents. These data aim to provide a unique and rich source of data for targeted policy development and health administration planning. In addition, qualified researchers and organizations interested in conducting innovative and transformation research in Wisconsin may propose ancillary studies that build on the SHOW core survey components and sample.

SHOW’s infrastructure allows for state-of-the-art population health research, and uniquely positions the University of Wisconsin system and the State of Wisconsin to be leaders in the fields of applied population and translational research. SHOW’s research and administrative teams are capable of developing, designing, and carrying out a complex survey design in an effective and efficient manner, including hiring, training, and supervising field staff capable of conducting in-person home examination surveys for short- or long-term projects. SHOW also provides unprecedented data and training opportunities for recruitment and training of the nation’s leaders in population health sciences. This infrastructure, sampling frame, and design also serve as the basis for many different types of ancillary studies.

SHOW’s extensive partnerships bridge a wide range of clinical, laboratory, social and environmental scientists, population health researchers, health practitioners and professionals from academic institutions and communities across the State of Wisconsin. Promotion and recruitment activities ensure collaboration with local health departments, community organizations, police, firefighters, and other leaders for every community in which SHOW recruits. Ongoing discussions are taking place with community organizations and with leading health research institutions across the state fostering collaborations. The sampling design is such that over time SHOW will reach the majority of communities in virtually all regions of the state; by 2013, SHOW had recruited individual subjects from 63 of the state’s 72 counties. Questionnaires address state health plan priorities and the survey content can be adapted to meet state health agency needs.

Researchers from many disciplines also collaborate with SHOW to conduct innovative population health research. These analyses, reports, and manuscripts are developed by SHOW scientific staff as well as by other UW researchers and outside investigators. Before being given access to non-public data, collaborative investigators need to submit a manuscript proposal that will be reviewed and approved by the SHOW Publications Committee (a subcommittee of the SHOW Operations and Executive Committees). This committee reviews proposals for their scientific merit, lack of redundancy with ongoing or published analyses, and ensures that proper confidentiality of the data is maintained.

### V. Ancillary Studies

SHOW has been designed to accommodate additional studies as an extension of the core SHOW protocol relative to both data and biological sample collection. Requests for additional studies are pursued and received with a subsequent scientific and logistical review to be completed by the SHOW scientific committee. Following a decision that SHOW would be compatible and able to conduct the ancillary study, IRB approval of the protocol and budgeting decisions will be completed. There are two potential methods for using the SHOW framework:

1. Studies that would involve an expansion of the core SHOW database: in this type of study, SHOW collaborates with the goals of the scientific study and these goals are consistent with the Specific Aims of SHOW.

2. Studies that do not involve an expansion of the core of the SHOW database or are not consistent with the Specific Aims of SHOW. An example of this might be: that the SHOW
staff and system could be asked to conduct a population assessment of access to recycling systems. SHOW would *not* be a collaborator with the resultant data collected, and would serve only as the mechanism for the collection process.

Each ancillary study will have unique IRB needs. Decisions on appropriate submission of IRB applications will be made on a case-by-case basis.

Full detail of IRB-approved collaborative ancillary studies is tracked over time by SHOW administrators.
V. LITERATURE

APPENDIX A

SHOW Data Security and Server Operation

SHOW has devised the most stringent data security plan that is feasible given the complex nature of the survey design. All data collected on human subjects in the Survey of the Health of Wisconsin are protected from technical and physical loss and damage and from disclosure of identifiable data from the initial point of collection through interim storage, transport, transmissions, downloads, processing, final storage and distribution of datasets and specimens.

SHOW has collaborated with the University of Wisconsin Survey Center (UWSC) to assist in data collection and they are a key partner in maintaining the security and integrity of SHOW data. SHOW field operations management and staff are in charge of interviewing, scheduling and supervision as well as sample management, case assignment, data quality controls and resolution of problematic cases. UWSC will assist with survey questionnaire formatting and development, install and maintain CASES instruments on field staff laptops, receive data in timely manner from field staff, send processed data weekly to SHOW headquarters and report any data anomalies and/or concerns to SHOW staff. It is SHOW’s database manager/administrator’s responsibility to maintain the complex multi-node longitudinal dataset, maintain complete dataset documentation, verify the integrity of the final data and process data for final distribution to PIs and other researchers.

SHOW, in conjunction with UWSC, makes use of the most up-to-date technology available to ensure data are being collected in the most efficient and secure manner possible. Technologies currently employed include: data transfers using air card connections to Virtual Private Network (VPN) connections, data encryption, secure firewalls, dedicated databases and servers and carefully constructed database management techniques. All field computers will require password-protected authentication of users. Data in computers are encrypted when files are saved and are backed up to encrypted flash drives until they can be safely downloaded to the UWSC via an air card connection to a Virtual Private Network (VPN) using authentication passwords. SHOW use appropriate firewalls to ensure only recognized computers and users are allowed access to their servers to receive and transfer data. Once data are processed at UWSC they are transmitted to two firewall protected servers maintained at SHOW headquarters in Middleton, WI with local backup servers and tape back-ups stored offsite.

The primary individual responsible for data security at SHOW headquarters is the database manager/administrator (DBM/DBA). The SHOW field team manager is responsible for working with the DBM/DBA to ensure all data quality and control checks are in place and security is being maintained. These individuals are responsible for working with UWSC staff to develop and maintain the manual of operations for data security as technology evolves and are responsible for training new hires and conducting regular trainings of field and administrative staff on data security issues.

The University of Wisconsin Survey Center (UWSC) has primary responsibility for programming of the SHOW data collection systems and is the initial receiver and processor of data from the SHOW field and headquarters staff. UWSC is very experienced in programming for the type of field conditions SHOW will operating in and knowledgeable in the security measures needed to protect the data in the process of collection, transmission/transport, and storage.

Copies of this Data Security Manual are provided to all subcontractors handling SHOW data. SHOW staff have been trained to take and follow at each of six major steps of data collections
and management: 1) household screening and recruitment, 2) household interview, 3) exam center, 4) follow-up analysis, 5) long-term storage and data backup, and, 6) data distribution. Each of these sections outlines specific data collection methods, types of confidential data being collected and interim storage and transmission processes.

SHOW contracts with UW Division of Information Technology (DoIT) for database hosting. DoIT maintains two secure, firewall-protected Oracle database for SHOW’s data collection. One database stores household and SP identifiers with census block group numbers, household addresses, and SP identification numbers. The second database holds health survey data. The two databases can only be linked through the SP identification number, which is randomly assigned by SHOW. The SHOW DBA works with DoIT staff to grant read-only access to health survey data for internal SHOW scientists. Administrative staff that need access to personal identification data for the daily conduct of the study are given separate read-only accounts for that database.

DoIT database hosting services include all software patching for Oracle, continuous log file backups, and daily backups. All backup files are stored on hardware that meets or exceeds the security policies of the database.

Data Security

Data importing
The database collects data from different parties, on different schedules. The data formatting and import procedures are as follows: The SHOW database administrator, field team manager, research data director, and program manager share responsibility in communicating with outside vendors. There are regular meetings among science staff and administrative staff to monitor data collection, transfer, storage, and security issues.

1. University of Wisconsin Survey Center provides near real-time access to a subset of data and quarterly deliveries of all data via secure channels.
2. Marshfield Labs analysis of phlebotomy samples.
3. BDSS data as provided by Nutritionquest.
4. SHOW ancillary studies (with separate IRB protocols).

Data Porting and Auditing
After receiving the delivered data from UWSC, the in-home questionnaire and screener data is divided into identifiable data and de-identifiable data. Identifiable data are imported to “Admin” server; de-identifiable data are sent to “Main” server. (See the Data Security Manual for definitions of “data” and “identifiable data.”)

Data changes in the SHOW database system are strictly managed. The field team manager identifies the need for the changes and reports the change to DBA via Data Correction Form; DBA makes the changes in the database and document the change. Changes to individual data elements and changes to database structure (tables, field names, relationships, constraints, indexes, etc.) are tracked by the DBA and the director of research data.

Table structure and access
SHOW tables are stored in two separate databases, not two separate schemas. This means that data cannot be shared between the tables with the use of SQL queries or scripts. Logins for each database are managed separately, and accounts for the Admin database are limited to the
SHOW DBA and staff in charge of the survey’s sampling procedure (research data director and biostatisticians).

De-identified data on the Main Database:

1. Marshfield Labs
2. Occupational and Industrial codes for SP
3. In-home questionnaire
4. Self-administered questionnaire

Identifiable data on the Admin Database:

1. Sampling frame addresses
2. Household address
3. Screening results
4. Interview sessions
5. SP contact information