1. General Policy

One of the core missions of the SHOW is to serve as a platform for the addition of ancillary studies that address health-related questions relevant to the population of the state of Wisconsin.

The SHOW program welcomes proposal from individual investigators and institutions to carry out ancillary studies that will amplify the impact and uses of the SHOW as a population health research tool in Wisconsin. These ancillary studies, while taking advantage of SHOW’s infrastructure, resources, and survey methods, either require additional data collection or are aimed at recruiting subjects not included in the SHOW sample.

In order to protect the integrity of SHOW and limit participants’ burden, such ancillary studies must be reviewed and approved by the SHOW Executive Committee before their inception according to criteria and procedures described below. In general, ancillary studies require outside funding.

2. Definition and Types of Ancillary Studies

An ancillary study is a study that, while based on SHOW core infrastructure or resources, is not described in the SHOW protocol and involves data which are not collected as part of the routine SHOW data set. This may include:

a) The acquisition of additional data on future or past SHOW participants. This could include:
   - Questionnaire data: single questions or additional questionnaire components
   - Additional physical exam components
   - Additional biological specimens
   - Additional environmental data (household, community)

b) Recruiting additional subjects not part of the SHOW annual sample. This could be:
   - Non-age-eligible household residents (i.e., children or older adults)
   - Additional subjects in census block groups sampled by SHOW
   - Targeted sampling of minority participants
   - Community-specific surveys (“mini-SHOWs”); e.g., community health assessments or “before-and-after” community health intervention studies

Ancillary studies may include not only studies that address a specific public health or etiological question, but also studies that focus on survey methodologies, validation studies, pilot studies, and studies supporting training of current or future public health workforce.

The policy described here does not pertain to studies that use SHOW core data or specimens and do not require additional data collection procedures. Access to SHOW data and/or biological specimens is governed by separate policies (see http://www.med.wisc.edu/show/four-researchers/36275).
3. Criteria for Consideration of Proposals

The following are the criteria that will be used for the evaluation of ancillary study proposals and their ranking compared to other competing proposals:

1) Scientific merit

2) Public health relevance of the proposal (e.g., alignment with the Healthiest Wisconsin 2020 goals—http://dhfs.wisconsin.gov/hw2020/)

3) Alignment with objectives of the Wisconsin Partnership Fund (see http://www.med.wisc.edu/wisconsin-partnership-program/main/499)

4) Complimentary nature of study objectives with overall objectives of SHOW

5) Institutional support (local, State or federal government, University, Community Organization, for profit business)

6) Funding source (NIH, state, foundation, industry)

7) Degree of burden or risk for SHOW participants

8) Compatibility with SHOW’s infrastructure (including staff training) and degree of burden on SHOW resources (staff, space, equipment, time)

Before an ancillary study can be approved, proposals will be reviewed by the SHOW Operations Committee. This committee will make sure that the proposed study will not do any of the following:

a) Interfere with the completion of the main objectives of SHOW

b) Adversely affect participant cooperation and compliance with SHOW exam and follow-up

c) Create a serious diversion of study resources (personnel, equipment or study samples)

d) Jeopardize the public image of SHOW

4. Preparation of Proposals for an Ancillary Study

A written request for approval of an ancillary study should be submitted to the SHOW Director and should contain the following information:¹

A) Body of the proposal (maximum 10 pages)

1. Description of objectives

¹ If any item in this list does not apply to a given proposal, this should be marked as “N/A.”
2. Scientific merit and public health relevance of the proposed study

3. Methods: sampling frame, data collection protocols, data processing plan, quality assurance and control

4. Statistical analyses

5. Power estimates

6. Discussion of impact on main SHOW survey, including a list of all SHOW resources that the ancillary study is proposing to utilize

7. Names of definite or possible collaborators

8. Description of funding sources or plans to obtain funding

9. Timeline/deadlines for implementation and completion

B) Evidence of IRB pending application or approval

C) Letters of support

D) Budget and budget justification—Budget for ancillary studies must include not only the net costs of the added exams/studies but also a small proportion of the SHOW core operating costs

E) Plans for data sharing and detailed administrative plan if new resources (e.g., additional personnel) are needed to carry out the proposed research

F) Appendices, relevant supplementary material, including (if applicable):

- Preliminary data

- Peer review evaluations (“pink sheets”) from study sections that reviewed related proposals for funding

- Proposed study protocol(s), including copies of consent form(s), questionnaires/data collection tools, training and piloting protocols and materials for SHOW staff, detailed specimen handling protocols, recruitment materials and personnel resources available to SHOW administrative and field teams.

For the purpose of budgeting (item D) and development of administrative plan (item E, if applicable), it is highly recommended that investigators considering an application contact the SHOW Director or Program Manager to obtain budgeting and administrative guidelines.

5. Review and Implementation of Ancillary Study Proposals

SHOW will review and approve, reject, or request modification of ancillary study proposals in a timely manner.
Once a proposal is submitted, it will be reviewed by the *SHOW Operations Committee* to make sure that the proposed study is technically feasible and does not interfere with the overall operation and SHOW resources (see Section 3). Next, the proposal will be reviewed by *SHOW Advisory Committee*. In addition, the SHOW Director might solicit ad-hoc reviews of specific proposals from recognized experts in the field pertinent to the application. Once the SHOW Operations and Advisory Committee approvals are obtained and in consultation with the SHOW Director, the proposal will be reviewed and approved or rejected by the *SHOW Executive Committee*.

While having IRB approval is a desirable feature at the proposal stage, ancillary studies might receive provisional approval that is contingent on final IRB approval.

Existing funding for the proposed study may already be available at the time of the application (e.g., from government sources). Often, however, proposals for ancillary studies will be submitted for SHOW review before funding has been obtained. The approval of proposals that are evaluated before funding has been secured will be conditional on funding being eventually obtained. (Investigators of conditionally approved proposals seeking funding may request a letter of support from SHOW to include in their funding application.)

Depending on scope of the project, availability of resources, and funding, approved proposals may have to wait until future SHOW cycles for implementation. Specifically, proposal that entail hiring additional personnel or equipment, as well as proposal that call for additional training of SHOW personnel may require months or years before implementation is possible. The proposed timeline for study implementation needs to allow for enough time for the developments of protocols, training of SHOW field teams, etc., before the field operations of the ancillary study can be launched.

Once the protocol and timeline for implementation is complete and agreed upon by both SHOW and the investigators of approved ancillary studies, a contract or memorandum of understanding will be written and signed by both parts. This contract will refer to the ancillary study protocol and budget, and will describe in detail the administrative responsibilities, lines of communication and supervision, training plan, implementation timeline, data management, and data sharing plan.

### 6. Analysis and Publication of Results of Ancillary Studies

The investigator of the ancillary study will be required to coordinate with the SHOW Director and Program Manager during data analysis to ensure that all study data used in analysis of ancillary study results are consistent with data in the main study database. If manuscripts resulting from ancillary studies rely in part on SHOW core data, these manuscripts will need to be reviewed by the SHOW Operations Committee prior to first submission for publication. The purpose of this review is to verify that the manuscript contains no errors or misrepresentations regarding SHOW’s main data.

If SHOW scientists have been significantly involved in the development of the ancillary research, they should be offered co-authorship. Explicit mention of the "Survey of the Health of Wisconsin (SHOW)" in the acknowledgement section of ancillary study publications is requested; authors of ancillary study publications are also asked to consider mentioning “SHOW” as a resource for the study in the keyword list, manuscript abstract, and/or manuscript title whenever possible.
7. Feedback of Results of Ancillary Studies to Participants

When ethically advisable or necessary, results of ancillary studies shall be reported to participants and/or their physicians. Such reporting should be approved by IRB and follow standard SHOW protocol for notification of participants.