LIST OF ATTACHMENTS

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ATTACHMENT B: Willis, G.B. (1994). Cognitive interviewing and questionnaire design: A training manual. National Center for Health Statistics: Cognitive Methods Staff, Working Paper No. 7.

ATTACHMENT C: Sample of a 2005 advance letter sent to NHIS respondents

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Sec. 242k. - National Center for Health Statistics
(a) Establishment; appointment of Director; statistical and epidemiological activities

There is established in the Department of Health and Human Services the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) Duties

In carrying out subsection (a) of this section, the Secretary, acting through the Center,

(1) shall collect statistics on -

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution;

(2) shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1);

(3) may undertake and support (by grant or contract) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided. Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended.

(c) Statistical and epidemiological compilations and surveys

The Center shall furnish such special statistical and epidemiological compilations and surveys as the Committee on Labor and Human Resources and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) Technical aid to States and localities

To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

(e) Cooperative Health Statistics System

For the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall -

(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection and other activities carried out under the System; and

(4) review the statistical activities of the Department of Health and Human Services to assure that they are consistent with the

System. States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system [1] produce uniform and timely data and assure appropriate access to such data.

(f) Federal-State cooperation

To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 5 of title 41, of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) Collection of health data; data collection forms

To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary shall prepare and distribute suitable and necessary forms for the collection and compilation of such data.

(h) Registration area records

(1) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(2) There shall be an annual collection of data from a statistically valid sample concerning the general health, illness, and disability status of the civilian noninstitutionalized population. Specific topics to be addressed under this paragraph, on an annual or periodic basis, shall include the incidence of illness and accidental injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

(i) Technical assistance in effective use of statistics

The Center may provide to public and nonprofit private entities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) Coordination of health statistical and epidemiological activities

In carrying out the requirements of section 242b(c) of this title and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by -

(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1) of this section;

(3) after consultation with the National Committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 (FOOTNOTE 2) of title 44, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards, and

(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509, [2] to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the ninetieth day after the date of the completion of the review of the collection.

(k) National Committee on Vital and Health Statistics; establishment; membership; term of office; compensation; functions; consultations of Secretary with Committee and professional advisory groups

(1) There is established in the Office of the Secretary a committee to be known as the National Committee on Vital and Health Statistics (hereinafter in this subsection referred to as the "Committee") which shall consist of 18 members.

(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of

health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Of the members of the Committee -

(A) 1 shall be appointed, not later than 60 days after August 21, 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;

(B) 1 shall be appointed, not later than 60 days after August 21, 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and

(C) 16 shall be appointed by the Secretary.

(4) Members of the Committee shall be compensated in accordance with section 210(c) of this title.

(5) The Committee -

(A) shall assist and advise the Secretary -

(i) to delineate statistical problems bearing on health and health services which are of national or international interest;

(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use

(I) within the Department of Health and Human Services,

(II) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e) of this section, and

(III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e) of this section, and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1) of this section;

(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.);

(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

(C) shall report to the Secretary not later than 4 years after August 21, 1996, recommendations and legislative proposals for such standards and electronic exchange; and

(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.).

(6) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(7) Not later than 1 year after August 21, 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.). Such report shall address the following subjects, to the extent that the Committee determines appropriate:

(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

(D) Any problems that exist with respect to implementation of such part.

(E) The extent to which timetables under such part are being met.

(l) Data specific to particular ethnic and racial populations

In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this

subsection shall be in addition to any activities carried out under subsection (m) of this section.

(m) Grants for assembly and analysis of data on ethnic and racial populations

(1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for -

(A) the conduct of special surveys or studies on the health of ethnic and racial populations or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section 242m(d) of this title do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(4) (A) Subject to subparagraph (B), the Secretary, acting through the Center, shall collect data on Hispanics and major Hispanic subpopulation groups and American Indians, and for developing special area population studies on major Asian American and Pacific Islander populations.

(B) The provisions of subparagraph (A) shall be effective with respect to a fiscal year only to the extent that funds are appropriated pursuant to paragraph (3) of subsection (n) of this section, and only if the amounts appropriated for such fiscal year pursuant to each of paragraphs (1) and (2) of subsection (n) of this section equal or exceed the amounts so appropriated for fiscal year 1997.

(n) Authorization of appropriations

(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2003.

(2) For activities authorized in paragraphs (1) through (3) of subsection (m) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2) of this section.

(3) For activities authorized in subsection (m)(4) of this section, there are authorized to be appropriated $1,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

COGNITIVE INTERVIEWING AND QUESTIONNAIRE DESIGN:

A TRAINING MANUAL

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OVERVIEW: The methods described are used to test draft survey questionnaires by performing cognitive interviews of volunteer laboratory subjects. In these interviews, we focus on the mental processes subjects use when answering the survey questions. Understanding the nature of the response process helps us to re-design the questions, so that survey respondents will be better able to answer them accurately. Also discussed are practical aspects of operating a questionnaire design research laboratory.

Contents

Preface and acknowledgements. This document describes the cognitive interviewing techniques used in questionnaire development and testing by the staff of the Questionnaire Design Research Laboratory, National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, located in Hyattsville, Maryland. Typically, NCHS questionnaires are used in large-scale household surveys, in which considerable resources are devoted to development and pretesting activities (a survey may include 50,000 households, and the pretest itself may be over 300 household in size). Therefore, the activities described apply best to surveys that are large in scope, and involve significant developmental activities. However, in order to made the document as widely useful as possible, I have attempted to indicate how the techniques used can be modified and adapted for use on a smaller scale.

I do not purport to describe "the" way of conducting cognitive interviews, as there are probably points made that others who use these techniques would disagree with. However, QDRL staff members have often been asked for a written document that describes, in detail, procedures that we have found to be effective in addressing sources of response error in survey questionnaires. This document is intended to fulfill this request.

Many current and former NCHS staff members contributed to the production of this document. I would like to thank these individuals for their specific contributions, for their patient and careful review, and especially for their efforts in developing the techniques described. In particular, I thank Monroe Sirken, Susan Schechter, Jared Jobe, Douglas Herrmann, Paul Beatty, Mary Ann Guadagno, Barbara Wilson, Patricia Royston, and Deborah Trunzo.

I. INTRODUCTION: APPROACHES TO QUESTIONNAIRE DESIGN AND DEVELOPMENT

A) THE TRADITIONAL APPROACH TO QUESTIONNAIRE DEVELOPMENT: THE USE OF DESIGN RULES

Traditionally, survey questionnaires have been developed largely through the application of questionnaire design rules (for example, see Payne, 1951). For example, we are cautioned to avoid questions that are very long, that use difficult terms, that use biased phrasing, or that are double-barrelled (contain two-questions-in-one).

These rules are certainly helpful. However, there are limits to their effectiveness:

1) Rules are often not specific enough to be helpful when actually writing particular survey questions. For example, although design rules tell us to avoid questions that are very long, they do not determine how long a question should be. They also do not tell one whether a certain term will, in practice, actually be difficult to understand.

2) Rules are often not successful in predicting respondent ability to accurately answer survey questions. These abilities can vary markedly, depending on the population subgroup surveyed.

3) The fact remains that, even if design rules are applied stringently by experts, we still observe significant levels of response error in questionnaire-based data (Jabine, Straf, Tanur, and Tourangeau, 1984). The advances obtained in survey sampling precision have not been accompanied by similar gains in reduction of response errors; in fact, I suggest that elimination of this error stands as the major impediment to the improvement of data gathered by questionnaire.

B) EMPIRICAL ("PRODUCT TESTING") APPROACHES TO QUESTIONNAIRE DESIGN

1) <u>THE FIELD PRETEST</u>:

Because we cannot always predict the problems that will be associated with particular survey questions, survey-takers have also relied on empirical, "product testing" techniques. Traditionally, we have used the *field pretest*, a small-scale survey conducted before the main survey, under conditions as similar as possible to those to be used in the full-scale implementation. Federal surveys such as the National Health Interview Survey (NHIS) may involve a field pretest exceeding 300 cases.

However, there are also limitations to the field pretest approach:

a) The field pretest tends to focus on the entire survey data collection process, rather than solely on the questionnaire itself. Thus attention to the questionnaire is diffused, as there are many other important issues that demand attention (such as formatting, issues related to interviewer training, adequacy of respondent rules, and so on).

b) The pretest focuses on overt, rather than covert, problems; problems must be clearly observable to an interviewer or other observer, given the normal question asking-and-answering process.

c) Field pretests often occur late in the development process; we often don't have time to make significant alterations afterward.

Because of limitations of the field test, survey designers and psychologists have developed another empirical approach to questionnaire testing:

2) COGNITIVE INTERVIEWING TECHNIQUES:

The cognitive interviewing approach was developed during the 1980's by survey methodologists and psychologists, and is the approach emphasized in the Questionnaire Design Research Laboratory (QDRL) at NCHS.

Some general features of this approach, as implemented in the QDRL, are as follows:

a) It focuses mainly on the questionnaire instrument, rather than on the entire survey process.

b) It pays explicit attention to the mental processes that respondents use to answer survey questions; therefore, covert as well as overt problems can be detected.

c) It tests survey questions at multiple points in the design process.

d) Generally, paid volunteer laboratory subjects are recruited, and are interviewed in a special setting devoted to the development of survey questionnaires (I use the term subject to refer to an individual who is tested in the laboratory, and respondent to mean someone who is interviewed in a fielded survey).

e) Recruitment of laboratory subjects targets persons with specific characteristics of interest.

The general cognitive approach to questionnaire design has generated much research (see Jobe and Mingay, 1991, Jobe, Tourangeau, and Smith, 1993, and Lessler and Sirken, 1985), and in the Federal statistical system, is currently carried out not only at NCHS

(Royston, Bercini, Sirken, and Mingay, 1986; Willis, Royston, and Bercini, 1991), but also at the Bureau of Labor Statistics (Dippo, 1989; Esposito, and Hess, 1992), and at the Census Bureau (Campanelli, Rothgeb, and Martin, 1989; Campanelli, Martin, and Rothgeb, 1991; DeMaio, Martin, and Sigman, 1987). A review of the work done at these agencies is contained in Jobe and Mingay (1991).

II. COGNITIVE THEORY

I will first present a short introduction to the basic theoretical background to cognitive interviewing. The specific cognitive model I apply consists of several elements:

1) COMPREHENSION OF THE QUESTION:

a) What does the respondent think the question is asking?

b) What do specific words and phrases in the question mean to the respondent?

2) RETRIEVAL FROM MEMORY OF RELEVANT INFORMATION:

a) What types of information does the respondent need to recall in order to answer the question?

b) What type of strategy does the respondent rely on when retrieving information? For example, does the respondent tend to count events by recalling each one individually, or does he/she use an estimation strategy?

3) DECISION PROCESSES:

a) Does the respondent devote enough mental effort to answer the question accurately and thoughtfully?

b) Does the respondent want to tell the truth, or does he/she say something that makes him/her look "better"?

The question-answering process is clearly complex, and may involve a number of cognitive steps. These steps are not set in an invariant sequence, but may be analogous to computer "subroutines" that are implemented as necessary. Further, some of the processes may be "conscious", but some are automatic, so that the respondent is not aware of their operation. Further, the cognitive processes used to answer survey questions may vary, depending on the type of question asked. Autobiographical questions, for example, may place a heavy burden on retrieval processes. Asking questions that are sensitive, on the other hand (for example; "Have you ever smoked marijuana?"), may place more demands on the respondent's decision processes.

The presentation above is very skeletal in nature; for more information on cognitive modelling of the survey response process, see Cannell, Miller, and Oksenberg (1981), Forsyth and Lessler (1991), Tourangeau and Rasinski (1988), and Willis, Royston, and Bercini (1991).

Those of us who apply cognitive interviewing techniques recognize that we cannot know with certainty what is going on in someone's mind as he or she answers survey questions. Rather, our goal is to simply prompt the individual to tell us things that give us valuable clues about the types of processes mentioned above. The way we go about this is described in the next section.

II. COGNITIVE INTERVIEWING METHODS

I have defined the basic approach as cognitive in nature, which simply means that it involves the study of mental information processing. The exact technique to be used can be selected by the individual or organization using it. The methods one might use, and what we feel to be the relative advantages and disadvantages of each, are discussed below. This discussion reflects our experience with each, and is meant largely as a set of issues for consideration, rather than strict rules; others who have used these techniques may have made observations that differ somewhat from ours.

A) "THINK-ALOUD" INTERVIEWING

1) DESCRIPTION:

This has been the general term often used to describe the techniques used in the cognitive laboratory. We apply the term to describe a very specific type of activity, in which subjects are instructed to "think aloud" as they answer the survey questions. The interviewer reads each question to the subject, and then records and/or otherwise notes the processes the subject uses in arriving at an answer to the question. The interviewer interjects little else, except to say "tell me what you're thinking" when the subject pauses. For example, a portion of a think-aloud interview may consist of the following:

> INTERVIEWER: How many times have you been to a dentist in the last 12 months?
>
> SUBJECT: Well, let's see- I think I went one time for a general type of cleaning and checkup- that was just a month ago or so. I really can't remember any other times I would have gone- You said in the last 12 months, so that would take us back to July of last year- I'm not sure but around that time I went in for pain in my jaw that I was worried about, but they couldn't find anything. I'm not sure what month that was, though.

From this "think-aloud protocol", the interviewer observes that the individual answers this by trying to recall each visit individually, rather than by estimating. Further, the interviewer might conclude that the individual has trouble determining whether a visit was really in the last 12 months. If, after interviewing several subjects, it becomes clear that none could really "think through" with confidence the number of times they had

been to the dentist, one might conclude that the reference period is simply too long to provide adequate answers.

2) TRAINING THE SUBJECT TO THINK-ALOUD:

The interviewer must be adept at teaching the subject how to perform the think-aloud procedure. This generally requires careful practice at the start of an interview, especially among individuals who are not especially verbally articulate.
One training approach that has been reported to work (by David Mingay, National Opinion Research Center), is the following:

> "Try to visualize the place where you live, and think about how many windows there are in that place. As you count up the windows, tell me what you are seeing and thinking about."

Depending on how well the subject responds to this task, other exercises may be needed prior to beginning the interview.

3) ADVANTAGES OF THE THINK-ALOUD TECHNIQUE:

a) *Freedom from interviewer-imposed bias*: Because the interviewer contributes little other than the reading of the survey question, he or she interjects little else that may serve to bias responses from the subject.

b) *Low burden on interviewer*: The interviewer can spend most of the time simply listening to the respondent talk, and take notes.

c) *Open-format*: Because the subject is not guided in any way, he or she may elicit information that is completely unanticipated by the interviewer. Think-aloud interviewing is especially valuable when the subject is outgoing, articulate, and has had significant experience with the topics covered by the questionnaire.

4) DISADVANTAGES OF THE THINK-ALOUD TECHNIQUE:

a) *Artificiality*: Some lab subjects find this to be a very unnatural activity, (that is, even more artificial than is answering survey questions).

b) *Training*: Because the activity is somewhat unusual, the technique can require a significant amount of training of lab subjects. The time this requires can substantially reduce the time one has to actually test survey questions.

c) *Subject limitations*: Many of our subjects are not at all adept at the think-aloud activity: We have found that, even with training, some subjects tend to simply answer the question that is asked.

d) *Subject burden*: The think-aloud activity places the main burden on the subject. We prefer to place more of the relative burden on the interviewer.

e) *Staying on task*: With think-aloud, the subject controls the nature of much of the discourse. Therefore, it is very easy for a "free associating" subject to get completely off-track, and spend a significant amount of unproductive time on one question. In general, we find that using the think-aloud technique results in fewer survey questions being tested within a particular amount of time.

f) *Depth of subject information processing*: In a truly successful think-aloud, subjects are investing a good deal of mental effort into their answers (it's much harder to justify an answer through the think-aloud process than to simply say "yes" or "no"). This additional processing may bias the subject toward more careful responding than is the case in a usual survey interview. Therefore, it is possible that the act of producing "think-aloud" speech may serve to burden or contaminate the cognitive processes that are used in answering the question. This issue is clearly still open to debate, however.

B) A SECOND COGNITIVE METHOD: USE OF PROBING TECHNIQUES

1) DESCRIPTION:

The use of **probing** is the basic technique favored at the QDRL. After the interviewer asks the survey question, and usually after the subject has answered it, the interviewer asks for other, specific information of the subject (we "probe" further into the basis for the response).

The following examples demonstrate a number of different "cognitive probes":

Examples:

Comprehension/ Interpretation probe:	What does the term "dental sealant" mean to you?
Paraphrase:	Can you repeat the question in your own words?
Confidence judgment:	How sure are you that your health insurance covers...
Recall probe:	How do you remember that you went to the dentist 3 times?
Specific probe:	Why do you think that cancer is the

most serious health problem?

General probes: How did you arrive at that answer?

Was that easy or hard to answer?

I noticed that you hesitated before you answered - what were you thinking about?

2) ADVANTAGES OF THE PROBING TECHNIQUE:

a) *Control of interview*. The use of probing to guide the interview tailors the interchange in a way that is controlled by the interviewer. This avoids a good deal of think-aloud that may be irrelevant and non-productive. Further, the interviewer can focus on particular areas that appear to be sources of potential response error.

b) *Subject training*. It is fairly easy to get subjects into the spirit of answering probe questions. In fact, subjects will often begin to expect probes and to offer their own spontaneous thoughts and critiques, an activity that becomes somewhat similar to what is desired in thinking-aloud.

3) DISADVANTAGES OF PROBING TECHNIQUES:

a) *Artificiality*. Some researchers feel that use of probing is inappropriate because the interjection of probes by interviewers produces a situation quite unlike the normal survey interview (although it is certainly no more so than the think-aloud). We find this not to be a problem, though, because the purpose is very different (to analyze questions, rather than to collect data). Further, one can counter this "unreal" element by relying less on probes during later stages of questionnaire testing, in order to produce an interview situation that is more realistic. Alternatively, one can make use of retrospective probing (see below).

b) *Bias*. A related criticism is that the use of probes may "lead" the respondent to particular types of responses. This is possible, but can be minimized by the careful use of "non-leading" probing techniques. Note that other professionals who attempt to extract information from individuals, such as police detectives, do not refrain from carrying out activities similar to probing, but are expected to do so in a relatively unbiased manner. For example, in conducting probing, rather than suggesting to the subject one possibility ("Did you think the question was asking X"), it is preferable to list all reasonable possibilities ("Did you think the question was asking X, Y, or Z"). In other words, we try to use unbiased phrasing, in the same manner that one does when writing survey questions in the first place.

4) WHEN SHOULD PROBES BE USED? - CONCURRENT VERSUS RETROSPECTIVE PROBING:

Probes can be asked at any time during the interview. Two general approaches are: a) *concurrent probing*, and b) *retrospective probing*. In concurrent probing, the probes are asked at the time the subject answers the questions. In retrospective probing, the subject is asked the probe questions during a debriefing session, after the entire interview has been administered. We generally rely on concurrent probing, mainly because the information is fresh in the subject's mind at the time of the probing. It may seem more "realistic" to wait and to debrief the subject by probing after the questions have been administered, but we find that there is a significant danger of creating a situation in which the person can no longer remember the basis for an answer, and instead fabricates an explanation. The times that retrospective probing appears to be useful are:

a) *When testing self-administered questionnaires*. Retrospective probing is useful when the purpose of testing is mainly to determine the subject's ability to complete the instrument unaided, and especially to follow sequencing instructions. We have probed "after the fact" on short, self-administered questionnaires of both teenagers and adults, with apparent success.

b) *When in later stages of questionnaire development*. When a questionnaire is in later stages of development, and one wants to simulate a more "realistic" type of presentation, it makes sense to administer the questionnaire "straight", and to perform some probing afterward.

5) HOW ARE THE SPECIFIC PROBES DEVELOPED?

There are two basic ways to develop and use probe questions:

a) *Standard probes*: For use by all interviewers; these are developed prior to the interview.

b) *Individual probes*: Used by a particular interviewer; these are developed either prior to, or during, the interview.

Standard probes are meant for use by all interviewers, and are developed prior to the interview by either a questionnaire development group or by a lead individual. For example, if it is anticipated that a particular term may not be universally understood, all interviewers can be instructed to apply the probe: "What does (TERM) mean to you?" These probes are often typed directly into the questionnaire draft.

Standard probes are practical and useful when:

a) there is sufficient time to prepare for interviews.
b) resources exist to plan and execute a fairly standardized testing approach.
c) Some interviewers are relatively inexperienced and would benefit from the guidance provided by a structured protocol.

Individual probes consist of:

i) **Prepared probes**: These are developed prior to the interview for personal use, and are based on an individual review of the questionnaire.

ii) **Spontaneous probes**: Probes that the interviewer develops during the course of the interview, based on either the subject's verbal report or non-verbal behavior. For example, a subject may answer a question, but then hesitate, which should prompt a probe from the interviewer. Or, the interviewer may think of a potentially useful probe "on the spot".

Individual probes are useful, and most practical, when there is very limited time to prepare for interviews (if, for example, a draft becomes available only a short time before a scheduled interview).

Prepared versus Spontaneous probes. Admittedly, the "spontaneous" approach to probing has the look of being "unscientific" or haphazard, especially because there is no coordination of probing across interviewers. However, there are particular advantages to this approach. We have found that the most interesting forms of probing often develop through the course of the interview, as a product of the particular relationship between the interviewer, subject, and survey instrument. These developments cannot be anticipated in advance of the interview. We have also found that, over time, interviewers become very adept at the use of this type of spontaneous probing. Further, the answer to a particular probe may well lead the interviewer to use other probes, and to follow-up on what issues emerge as the most interesting and important.

Combination of probe types. We have found that the most effective interviews actually consist of a combination of prepared and spontaneous probes described above, rather than either type alone. By way of analogy, we believe that the cognitive interview is similar to a session within a clinical psychological practice; the "therapist" has certain guiding principles, and perhaps specific questions or comments, to apply during a session with the patient. However, much of the interchange emerges spontaneously during the course of therapy. The clinical session may be approached in ways similar to other sessions, and be somewhat "scripted", but every interview is different, entails its own developmental sequence, and makes a unique contribution.

Again, because we focus on probing rather than the think-aloud at the NCHS lab, this will be the focus reflected in the remainder of the manual.

IV. EXAMPLES FROM COGNITIVE INTERVIEWING

In order to make the above discussion of probing techniques more "concrete", I have assembled the following examples of questions that have been tested in the NCHS Questionnaire Design Research Laboratory. For each question, I have listed:

1) The question in its original form.

2) A list of several probes that would be appropriate to use in testing that question.

3) A short description of the problems we found, in testing these questions, using probes of the types suggested. Each of the examples is classed generally according to whether the problems found are representative of the cognitive categories defined in Section 2 (comprehension, retrieval, decision). Some questions may have more than one type of problem, and in some cases it is arguable what class of problem is really being reflected. This type of ambiguity is not harmful, as long as it is clear how to resolve the problem in order to produce a better "next generation" survey question.

4) Finally, a suggested resolution to the problem is presented, based on our testing results.

EXAMPLE 1:

1) Original form of survey question:

Has anyone in the household ever received vocational rehabilitation services from-
... The State Vocational Rehabilitation program?

... another vocational rehabilitation program?

2) Probes:

a) **Can you repeat the question in your own words?**
(To test how well the subject comprehends the question.)

b) **What, to you, is a "vocational rehabilitation program"?**

(To test comprehension of a particular term.)

c) **How sure are you that (person) got this type of service?**
(To determine the subject's ability to recall information confidently.)

3) Results:

Comprehension problems: Subjects found it difficult to understand the question, because of its length and technical nature. Further, the meaning of "vocational rehabilitation" was not at all clear; some subjects thought this just meant any type of physical therapy. Because of the comprehension problems in the original form, we suggested the following change:

4) Suggested revision:

Has anyone in the household ever received job rehabilitation services?

If YES, ask WHO, and:

Was (person's) rehabilitation from the state, or from another job rehabilitation program?

Note: The question is "decomposed", or divided up, to make it easier to understand. The term "vocational" is also changed to the more understandable form "job".

EXAMPLE 2:

1) Original form:

How long has (name) used the (can, wheelchair, walker…)?

2) Probes:

a) **How did you get the answer of (x) years?**
(To determine the overall cognitive strategy used.)

b) **When did (x) first use the (device)?**
(To test comprehension/interpretation of the question.)

c) **How well do you remember this?**
(To test recall of the relevant information.)

3) Results:

We found that for target individuals whose use was intermittent over a long period of time, the question was interpreted in two distinctly different ways:

1) "How long has it been since (person) first used the (device)? For example, the subject may say: "since 1960, so about 30 years".
2) "For how long, overall, has (person) actually used the device since first having it? The subject counts up periods of use within a longer time- for example: "For two five-year periods since 1960, so 10 years".

Note that the problem identified can be considered a type of "comprehension" problem, but doesn't involve a failure of comprehension of a key term, as did the last example. Rather, subjects simply have alternate, but reasonable, interpretations of the question intent.

4) Suggested revision:

This required consultation with the client, in order to clarify the objective of the question. It became clear that the desired expression was:

How long ago did (person) first use a (device)?

EXAMPLE 3:

1) Original form:

In the last year have you been bothered by pain in the abdomen?

2) Probes:

a) **Why do you say (no)(yes)?** [General probe]

b) **What, to you, is your abdomen?**
[Comprehension/Interpretation probe]

d) **What does it mean to be "bothered by pain in the abdomen?"**
[Comprehension/Interpretation probe]

c) **What period of time are you thinking of here, specifically?**
[Comprehension/Interpretation probe]

3) Results:

a) To some people, "the last year" means Jan. 1 to the present. Others think that "the last year" started 365 days ago. Comprehension of this phrase is therefore somewhat varied.

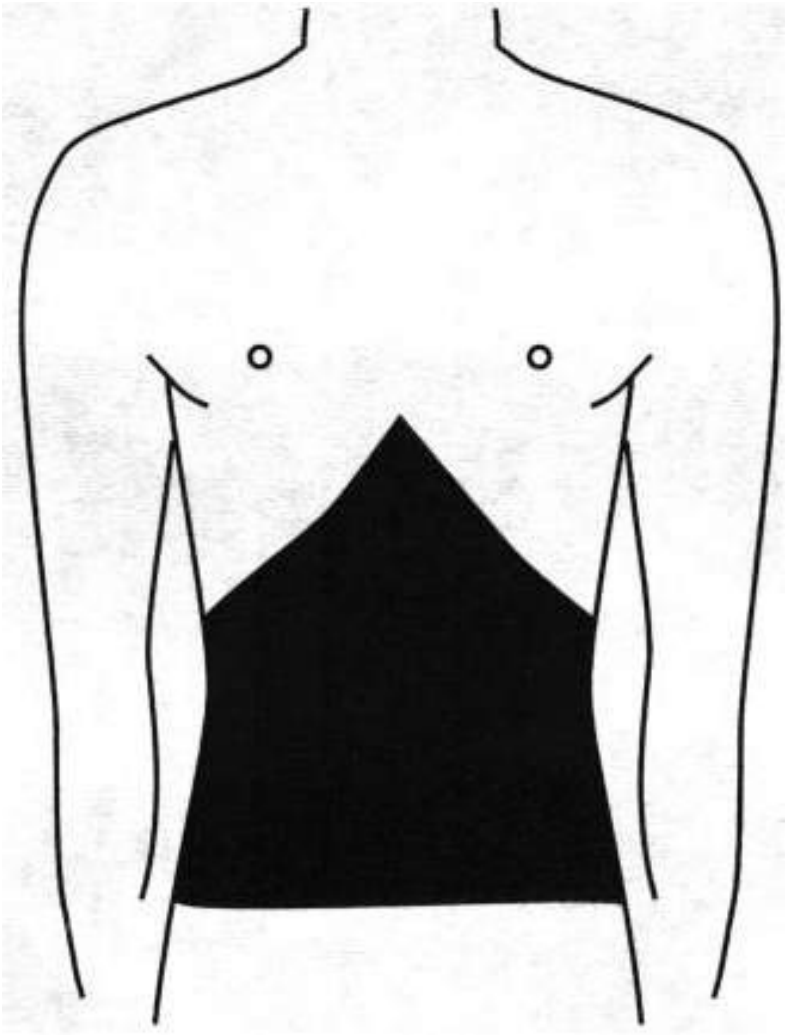
b) The phrase "bothered by pain ..." was also interpreted differently by different people. Some subjects experienced pain, but were not particularly "bothered" by it, and so responded with "No". Given that the purpose of the question was to measure the experience of pain, and not the psychological reaction to it, we saw this as a defect.

c) Finally, as one might suspect, notions of where one's abdomen is differ greatly among individuals (almost no one chose the correct anatomical region). Again, problems related to comprehension of a key term were revealed here.

4) Suggested revision:

Because the problems related mainly to comprehension, the solution we proposed focused on this process as well.

In the past 12 months, have you had pain in the abdomen?
By abdomen, we mean the region shaded on this chart (show hand card).



EXAMPLE 4:

1) Original form:

About how many miles from here is the home (child) live in before (he/she) moved to this home?

(the following is printed on the questionnaire, but not read):

___ less than 1 mile
___ 1-50 miles
___ 50+ miles

2) Probes:

a) **How sure are you of your answer?**
(to determine overall level of confidence)

b) **How hard was this to answer?**
(to determine level of difficulty, and likelihood of estimation/guessing)

3) Results:

No one had difficulty understanding the question as posed. However, we observed that some subjects needed to think for a fairly long time before giving an answer. Further, some subjects struggled needlessly with the level of specificity they thought was required (for example, deciding whether the distance was closer to 20 or to 25 miles, when this information was ultimately irrelevant, as the interviewer would mark "1-50 miles" in either case).

The problem can be described as one involving a difficult recall task, as opposed to comprehension. A rephrasing of the question that incorporated response alternatives was necessary to make clear to subjects the degree of precision that was necessary in their answer.

4) Suggested revision:

About how far from here is the home _____ lived in before (he/she) moved to this home- less than a mile, 1 to 50 miles, or more than 50 miles?

EXAMPLE 5:

1) Original form:

We are interested in your lifetime exercise patterns.
First, when you were 14 to 19 years old:

How many hours a week of brisk walking did you do?

How many hours a week of vigorous exercise such as running, cycling, swimming, or aerobics did you do?

How many hours a week of activities that required you to be on your feet (excluding running or walking) such as dancing, hiking, ... did you do?

2) Probes:

a) **Was this hard or easy to answer?**
(to determine comprehension, and overall ability to recall)

b) **How do you remember this?**
(to study recall strategy)

c) **How sure are you of your answer?**
(confidence probe)

d) **What, to you, is "vigorous exercise?"**
(comprehension/interpretation of a specific term)

3) Results:

Subjects found it very difficult to remember back to the time period specified, at the required level of detail. In fact, it seemed that some subjects really could not even answer this with respect to their current behavior, let alone their behavior many years ago. Recall of information (assuming it was ever "learned" in the first place) seemed to be the dominant problem.

As for the previous example, we needed to confer with the sponsor/client to clarify question objectives. We were able to determine that use of a broad scale of level of activity, comparing past and present behavior, would satisfy the data objectives:

4) Suggested revision:

We are interested in your lifetime exercise patterns. When you were 14 to 19 years old, were you more active than you are now, less active than now, or about as active as now?

EXAMPLE 6:

1) Original:

During a typical work day at your job as an (occupation) for (employer), how much time do you spend doing strenuous physical activities such as lifting, pushing, or pulling?

___ None
___ Less than 1 hour
___ 1-4 hours
___ 4+ hours

2) Probes:

a) **What type of work do you do? Describe a typical workday.**

b) **How did you arrive at the answer of X hours?**

3) Results:

Careful probing revealed that people who gave reports of 1-4 hours often were office workers who did little or no heavy physical work. This appeared to be due to biasing characteristics of the question; saying "none" makes one appear to be "non-physical", and is therefore somewhat socially undesirable. This problem was seen as related to respondent decision processes, rather than to comprehension or recall. A resolution was needed to make it "easier" for someone to report little work-related physical activity:

4) Suggested revision:

The next questions are about your job as a ____ for _____.

Does your job require you to do repeated strenuous physical activities such as lifting, pushing, or pulling heavy objects?

(IF YES:)

During a typical work day, how many minutes or hours altogether do you spend doing strenuous physical activities?

EXAMPLE 7:

1) Original:

Do you believe that prolonged exposure to high levels of radon gas can cause:

	YES	NO	Don't Know
Headaches?	__	__	___
Asthma?	__	__	___
Arthritis?	__	__	___
Lung Cancer?	__	__	___
Other cancers?	__	__	___

2) Probes:

a) **Why do you believe this?**

b) **How sure are you of this?**

c) **Is it difficult to answer these?**

3) Results:

Simple observation of subjects made it clear that this question is difficult to answer. Subjects took a long time to respond to each item, and tended to be unsure about several of the items. Further, probing revealed that the format encouraged a "guessing" strategy, rather than actual retrieval of information. Finally, for people who do not believe that exposure to radon is harmful, it became very tedious, and sometimes even offensive, to repeatedly ask about the specific harmful effects of radon.

We felt that in this case, the subject's decision processes were again excessively burdened

by the phrasing of the question.

4) Suggested revision:

Do you believe that prolonged exposure to radon is unhealthy, or do you believe that it has little or no effect on health?

(IF radon believed unhealthy:)

[SHOW HAND CARD] Which, if any, of these conditions do you believe can be caused by radon exposure?

___Headaches	**___ Lung cancer**
___Asthma	**___ Other cancers**
___Arthritis	**___ Don't Know**

The revised phrasing gives the respondent a way to say, one time, that he or she does not believe that radon is harmful. Then, if he/she does believe it to be harmful, the next question simply allows him/her to "pick and choose" the items that seem appropriate. The burden on decision processes appeared to be reduced, using this alternative.

EXAMPLE 8:

1) Original:

What is the primary reason you have not tested your home for radon?

2) Probes:

a) Is it hard to think of the main reason?

b) Can you think of any other reasons?

c) How much have you thought about having your home tested?

3) Results:

Although the question is easily enough understood, it was very difficult for subjects to produce a reasonable answer, especially for subjects who had never given the issue much thought. Instead of simply saying "I never thought about it", or "I haven't gotten around to it", subjects tried to think of more "appropriate" answers, that appear to be more defensible. Here both recall and decision processes appeared to be operating.

4) Suggested solution: **--- DELETE QUESTION ---**

The sponsor/client agreed that it was not especially useful to ask the reason that someone had not carried out this activity.

This example demonstrates an important point worth emphasizing; sometimes, there is no obvious "correction" to a survey question. Especially when subjects simply don't have information that we want, it is better to acknowledge that we may not want to ask that question. Thus, one effect of lab testing is to test the boundaries of "what can be asked and what can't."

V. DETECTION OF "NON-COGNITIVE" PROBLEMS IN SURVEY QUESTIONS

The discussion above has focused almost completely on cognitive problems in questionnaires; that is, problems involving the comprehension, recall, or decision processes necessary to adequately answer the question. However, we have found that lab interviewing has several overall positive effects, in addition to the understanding of particular cognitive processes:

a) We explore the nature of the underlying concepts to be measured in the survey, and the specific subject matter (by relying on lab subjects as "experts").

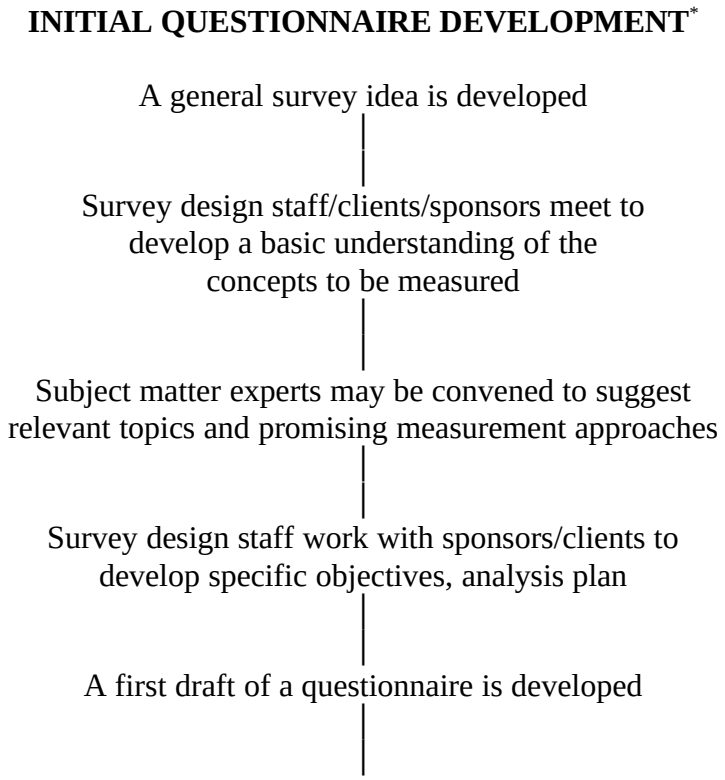
b) We learn about non-cognitive defects in the questionnaire.

Non-cognitive problems. Item b) is especially worthy of clarification. We have found that an important, beneficial effect of lab testing is to detect structural, or logical problems, not normally viewed as a part of the cognitive approach. By structural problems, we mean those features of the questionnaire such as erroneous skip patterns, unclear layout, and other elements that do not clearly involve the cognitive processes of the respondent. We also include in this category logical problems inherent in the statement of the question that do not clearly involve a cognitive element. For example, if I ask the question: "How long have you owned your house?" the subject may simply respond that he is a renter. Here, it should not be strictly necessary to study cognitive processes to make the discovery that the question is flawed, because simple knowledge of the appropriate logical relationships ("some people own, some people rent") should have been sufficient to avoid such a problem. However, survey designers often fail to take into account all of these logical truths when constructing a questionnaire, and the laboratory-based interview allows the subject spontaneously point out flaws.

It is of course true that most of the structural, non-cognitive problems I have referred to could be detected by either a careful expert review, or in the field pretest. However, from a practical point of view, the expert review may never get done, and it can be imperfect. The field pretest generally occurs late in the process; it is much better to detect the problems earlier rather than later, and the lab serves this purpose well. Note that it takes no special "techniques" to detect the types of problems mentioned above, beyond simply attending to the possibility that they can occur.

VI. SEQUENCE OF LABORATORY ACTIVITIES

The discussion above has provided the background necessary to understand the main techniques used in the NCHS Questionnaire Laboratory. The following sections will place these techniques into the broader context of actually conducting this testing within a "real-life" survey development process. To appreciate the overall picture regarding this process, it is useful to first consider an overview of the general sequence of events that occurs when a questionnaire is designed. I provide below a schematic diagram of some basic steps that can be taken to develop a questionnaire, incorporating laboratory cognitive interviewing techniques into the developmental sequence:



(continued on next page)

*See Aday (1989) for a more complete description of these preliminary steps

LAB TESTING PHASE

Laboratory staff determine staff allocation to:
- a) recruitment,
- b) conducting of interviews
- c) communication with clients/sponsors

PREPARATION FOR INTERVIEWING

Lab staff perform an initial review of the questionnaire, and may make suggestions for modifications prior to testing

Staff develop basic probes to use in first round of interviewing

RECRUITMENT

Lab staff determine the types of subjects to be interviewed

A recruitment strategy is developed and implemented (advertisements, flyers, ...)

Subjects are recruited, scheduled

LABORATORY INTERVIEWING ROUNDS

> Individual interviews are conducted with 5-10 subjects
(In early rounds, emphasis is on general concepts)
(In later rounds, emphasis is on question wording, format)

Interviewers write up comments on each interview done

Interviewers meet (as a group, or with sponsors/clients) to discuss results, propose potential modifications

The questionnaire is revised by designers

< A decision is made concerning whether another round of interviewing can/should be conducted

YES

NO

FIELD PRETESTING PHASE

OPTIONAL: Return questionnaire to lab for additional round(s) of laboratory testing

SURVEY IS ADMINISTERED

VII. PRACTICAL ASPECTS OF LABORATORY INTERVIEWING

Because this manual focuses mainly on the *Lab Testing Phase* of development, the remainder of the discussion will concern activities relevant to that phase. I will therefore address, in turn, several basic issues that we are frequently asked about with respect to conducting laboratory cognitive interviews.

A) HOW LONG SHOULD A LABORATORY INTERVIEW BE?

We have found that one-hour interviews are optimal; longer interviews make excessive demands on laboratory subjects. In general, we recommend that the interview process be as flexible as possible, and not require interviewers to cover a certain number of pages of a questionnaire. Questionnaires often have skip patterns that result in widely varying actual questionnaire lengths for different individuals, and subjects vary in their overall speed and the degree to which they respond in detailed ways to either the survey questions, or to probe questions.

Note that even though the interview itself may take only an hour, the interviewing process requires considerably more time. In all, preparation, interviewing, and writing up results of the interview usually take a total of about three hours. Because of this, and because cognitive interviewing can be a taxing activity, we recommend that any individual do no more than three interviews in a single day (and preferably fewer).

B) WHAT TYPES OF INDIVIDUALS MAKE GOOD INTERVIEWERS?

It is unnecessary to have an advanced degree in psychology to be a good cognitive interviewer (although a behavioral sciences background appears to be helpful). We have found that good interviewers are those people who:

a) Have experience in questionnaire design, and are knowledgeable about both survey design and about the purpose of the questionnaire to be tested. These skills are essential when the time comes to apply the results of the interviews in revising the questionnaire.

b) Have learned the basic premises of cognitive interviewing, and are familiar with the ways in which fundamental cognitive processes may influence the survey response.

c) Have been exposed to social science research concepts such as bias, context effects, scale effects, and so on.

d) Perhaps most importantly, have good inter-personal skills, are capable of putting a subject at ease, and remaining non-judgmental in approach. There is still an open question, however, concerning how "professional" versus "friendly" the interviewer should be during the interview itself, in order to get the best quality data (we tend to take the "friendly" approach).

An oft-asked question is whether field interviewers can be taught to perform laboratory cognitive interviews. We believe that this is possible if interviewers can be induced to "unlearn" some habits that are very valuable for field interviewing, but that may be counterproductive for cognitive interviewing. In particular:

a) Field interviewers have learned over time simply "to make a question work", for example, by repeating it slowly, so that a confused respondent will ultimately provide a codeable response. It must be emphasized that our task in the lab is the reverse; to find flaws in the questions.

b) Interviewers tend to work as fast as possible in the field, usually in order to complete a very long interview before the respondent becomes uncooperative. Interviewers must be reminded to work at an unhurried pace in the lab.

c) Field interviewers often focus their attention on very detailed formatting and other structural features such as skip pattern errors and redundant questions. They must be instructed that the format of the questionnaire may be very rough, and that it is the content that is of primary concern in lab testing.

d) Field Interviewers are taught to ask questions exactly as worded, and not to deviate from the instructions contained in the instrument. In the laboratory, cognitive interviewers must be comfortable departing from the questionnaire flow when this appears to be called for. They also must be able to adjust to a situation in which sequencing instructions are incorrect or missing, which often occurs in the testing of a draft questionnaire.

C) HOW IS COGNITIVE INTERVIEWER TRAINING DONE?

Cognitive interviewing is an acquired skill, consisting of a number of separate skills. Optimally, good interviewers can serve as "detectives" who can find problems in survey questions, and as "engineers" who can work toward developing workable solutions to the problems defined. We have found that the former skill is obtained more quickly than the latter, and that the attainment of mastery is very gradual. Interviewers can be taught in an incremental, step-wise fashion, consisting of the following steps:

a) Trainee interviewers should conduct technical reviews of questionnaires to make determinations of structural and potential cognitive problems. They also attend early questionnaire design meetings, as well as meetings where cognitive interviewers discuss the results of lab testing.

b) Trainees familiarize themselves with material on the philosophy and purposes of the cognitive aspects of survey methodology and intensive laboratory interviewing.

c) They are taught the specific probing methods for use in the laboratory.

d) They are shown examples of the way that probing is used to detect problems in survey questions. This can be in both written form, and through the use of audio- and video-taped recordings of previous interviews.

e) Trainees observe experienced interviewers performing actual interviews. Unless a topic is very sensitive, subjects generally have no objection to being observed by an individual who is described as "in training".

f) Trainees perform one or more interviews while being observed by a practiced interviewer, or compile tape recording of the interviews for review by other staff. The trainee can then be given feedback.

g) Trainees attends questionnaire review meetings, subsequent to the interviews, and attempt to make specific recommendations for solution of the observed problems.

For organizations that do not have existing cognitive interviewers available to teach new staff, this manual is itself intended to serve as "training". There is no substitute for experience, however, and interviewers should begin interviewing as soon as they have a fairly good idea of what is involved.

D) OTHER CONSIDERATIONS FOR INTERVIEWING:

There are several features of laboratory interviewing that are important for cognitive interviewers to understand, and that are useful to express to the subject, before beginning a laboratory interview:

a) Stress to subjects that we are not primarily collecting survey data on them, but rather testing a questionnaire that has questions that may be difficult to understand, hard to answer, or that make little sense.

b) Make clear that although we are asking the subject to answer the survey questions as carefully as possible, *we are primarily interested in the ways that they arrived at those answers, and the problems they encountered*. Therefore, any detailed help they can give us is of interest, even if it seems irrelevant or trivial.

c) If think-aloud responding is desired, tell subjects, at the least, to "think out loud to the extent possible, so we can tell what you are thinking about when you answer the questions". Be warned that this introduction generally does not produce a great amount of thinking-aloud, however! To get more of a true "think-aloud", you need to have subjects practice the technique.

d) It also is somewhat helpful to add: "I didn't write these questions, so don't worry about hurting my feelings if you criticize them- my job is to find out what's wrong with them". This helps to "bring out" subjects who may otherwise be sensitive about being overly critical.

E) FEATURES OF LAB OPERATION

(See Appendix 1, entitled: "Details of day-to-day lab operations" for more complete information.)

1) RECRUITMENT:

We identify and recruit volunteers from appropriate sub-populations for testing the survey questionnaire:

a) Subjects either have characteristics of interest for the survey (a particular status with respect to health, work, age, sex characteristics), or they may be "general" subjects, for questionnaires that are asked of the general population. However, even for a questionnaire that is intended for special populations, it is worth testing the initial screening sections on people who don't have the characteristic of interest. This allows the interviewers to make sure that the questions don't create problems in the majority of cases in which the questionnaire will be administered (where the respondent does not have the characteristic of interest). Because this is an important point, I provide a specific example. A questionnaire that is intended to identify individuals with Podiatric conditions might be tested only on individuals who answer an advertisement for "people with foot problems". However, failure to test the screening questions on individuals who do not have foot problems could be catastrophic. If for example, virtually everyone answers initial, screening questions (in effect asking: "do you have any foot problems") in the affirmative, a large number of inappropriate respondents might wind up "passing" the screener and be subjected to a series of completely irrelevant follow-up questions. As a general rule, questionnaires that seek to "identify" a particular population should be tested to determine that they adequately 1) screen in people having the characteristic of interest, and 2) screen out those who do not.

b) Subjects are recruited through newspapers, fliers, service agencies, and support groups. An example of a newspaper ad and a flyer are provided in Appendix 2.

c) Statistical sampling methods are NOT normally used in obtaining laboratory subjects. At most, we use a "quota" sample, in which we try to obtain a range of ages, genders, and socio-economic levels, if possible.

2) PAYMENT:

As of 1994, we pay subjects $30 for a one-hour interview. This amount is sufficient to pay for the subjects' travel time and for basic inconvenience involved in travelling to the laboratory. Further, this payment is enough that it is not simply a "token" remuneration; this way, we are less likely to only recruit individuals who are "practiced volunteers" and have a particular interest in volunteering mainly out of interest in health topics, and who are therefore very different from the usual household survey respondent. However, the amount of payment should be determined by considering a number of issues, such as the

general demographic status of the types of subjects required, difficulty of getting to the interview location, difficulty of the task, and so on.

3) ADMINISTRATION MODE: FACE-TO-FACE VERSUS PHONE:

We have performed most cognitive interviews "live" in the laboratory, on a one-on-one basis. However, it is also possible to conduct these interviews over the phone, once an interview has been scheduled. We have never called "out of the blue" to someone selected randomly, as in a Random-Digit-Dial telephone survey). We have found telephone interviews to be useful for several specific purposes:

a) To test questionnaires intended for telephone administration.
b) To interview subjects (elderly, disabled) who are unable to travel to the lab.

Generally, we prefer in-person interviews when possible, because this allows observation of non-verbal cues, and provides a more natural type of interchange between the subject and the interviewer. However, we advocate the imaginative use of many different testing modes (for example, we have even conducted telephone interviews in the laboratory, where the interviewer and subject are placed in different rooms).

4) PHYSICAL LAYOUT OF LAB:

Any quiet room, such as a conference room or empty office, can serve as a "laboratory" in which to conduct interviews. Optimally, a special interviewing room can be set up, with one-way mirrors, though this is not vital. Interviews can even be conducted "off site", such as at a location where health services are given, or where the target group will be found (for example, elderly centers, schools, and so on).

5) STAFFING:

It is helpful to have permanent staff members who have a "history" of cognitive interviewing experience. As mentioned above, interviewing skill is an acquired capacity, and it helps to avoid the need to constantly train new staff members. It also helps to have a particular staff member who can be responsible for lab management; making phone calls, scheduling, and generally monitoring laboratory operations. The details of lab management are discussed in more detail in Appendix 1, Details of day-to-day lab operations. Further, staff should have experience in relating to clients or sponsors of questionnaires, in order to communicate the findings from laboratory interviews, and the questionnaire design experience necessary to translate laboratory findings into realistic and practical solutions.

6) EQUIPMENT:

All one really needs is a tape-recorder, as it is helpful to have recorded interviews (most subjects don't mind being recorded, as long as a consent form is used). Video-taping is

another possibility that we have used to a limited extent. We recommend that if respondents are to be videotaped, a means be found for hiding the camera or making it minimally obtrusive (though of course informed consent from the subject for taping is obtained). A camera that is in full view may strongly affect the nature of the interaction. Some organizations also make use of one-way mirrors for observation; these might also affect the interchange, however, especially when the questions that are asked are sensitive or potentially embarrassing.

VIII. WHAT HAPPENS AFTER THE INTERVIEW?

1) RECORD KEEPING:

We find that the most efficient way to process "data" is to abstract from written comments that interviewers make during the interview. Each interviewer can simply enter comments below the appropriate question on a computerized version of the questionnaire (see the sample comment sheet in Appendix 4). These comments can then be aggregated, over interviewer, and over interview, for a complete review of a particular draft of the questionnaire.

2) ANALYSIS OF TAPED INTERVIEWS:

Some researchers prefer to rely on standardized analysis of tape recordings of interviews. We have found, however, that this is a very time-consuming activity, and the appropriateness of this activity depends on the nature of the testing. For "production" work, in which revisions are made at a fairly quick rate, it is often not possible to devote the resources necessary to transcribe or analyze taped interviews. In this case, reliance on written notes is sufficient. Tape-recording is still valuable, however, where a sponsor or client may want to listen to the tape to get a "first-hand" impression of how the questionnaire is working. Transcription or analysis of these tapes can also be valuable for purposes of research, in addition to pure questionnaire development.

Generally, we do not make use of much quantitative data; mainly, we look for:

a) Dominant trends across interviews (problems that seem to emerge repeatedly).

b) "Discoveries": Even if they occur in only a single interview, there are some problems that prove to be very important, because they can severely threaten data quality in a few cases, or because these problems are expected to be fairly frequent in the actual survey.

We rely strongly on interviewer judgment, in determining the implications of the laboratory results, as these have ramifications for the fielded survey. For example, one might conclude that a particular interview was very idiosyncratic, and should be ignored. Or, it may be felt that the set of subjects tested was much more sophisticated than the population to be surveyed, so even a hint of comprehension problems might serve to motivate the designers to attempt a simplification of the questionnaire. The general point

is that it is usually dangerous to conclude, for example, that if problems are found in 30% of lab interviews, then they are to be expected in 30% of field interviews. We must always be careful to apply a type of subjective "correction factor" to the lab findings, based on our knowledge of the likely differences that exist between the lab and field environments.

3) MEETINGS AND SUBSEQUENT MODIFICATION:

Because the focus of cognitive interviewing is the detection of questionnaire problems, there is often a tendency to "get into the lab quickly", and then deal with the problems that emerge. It is imperative, however, that initial meetings be conducted prior to interviewing, to make clear the objectives of the questionnaire, and that interviewers conduct a technical review of the first draft. In fact, experienced cognitive interviewers can often anticipate the types of difficulties that may be expected, prior to interviewing. Once an initial review, and perhaps a modification, has been conducted, interviewing can start in earnest. After a sufficient number of interviews are completed, and interviewer notes are compiled, one can convene a group meeting to discuss findings. The determination of what a "sufficient" number of interviews is depends on several factors:

a) If it becomes obvious after several interviews that there are major problems to be rectified, then there is little use in conducting more interviews before modifications are made to the questionnaire. Especially in the very early stages of development, as few as four interviews may be sufficient to constitute a "round" of interviewing.

b) Even if it appears that more interviews should be done, we have seldom found it necessary, or helpful, to conduct more than 12 - 15 interviews before meeting or delivering comments concerning that round of interview results.

At the meeting, interviewers should discuss their findings in detail with any questionnaire designer who has not participated in the interviewing process. *As a general rule, it is very beneficial that all everyone who is actively involved in the questionnaire design process, including clients, participate in laboratory testing, even if simply as observers*. Clients or sponsors should also be encouraged to observe interviews, or to listen to tape recordings; the impact of a question that is confusing or long-winded is very difficult to ignore when such evidence is used. Very often, where abstract discussions concerning the flaws contained in a questionnaire are unconvincing to a sponsor or client, the evidence from only a few laboratory interviews can have a positive impact. This is a point that we stress; beyond its strength in *identifying* problems, a major positive feature of the cognitive laboratory approach is in the *persuasiveness* of the information it collects.

Meetings should be used both to point out identified problems and to suggest resolutions to these problems. An advantage of the cognitive approach is that, if one understands the basis for the failure of a particular question, a resolution to the problem may be readily

suggested. For example, if a term is clearly not understood, the group may search for an easier-to-understand substitute. Likewise, if it is found that a reference period for a question is far too long for subjects to recall information with any confidence, it is indicated that the use of a shorter interval is in order.

4) THE NEXT LAB TESTING ROUND:

After the questionnaire has been revised, based on the comments from the group meeting, and based on any discussions with clients or sponsors, a new round of interviewing can be conducted to test the changes made, and to provide additional testing of questionnaire segments that were not yet changed. Several issues are pertinent at this stage:

a) *Number of interviewing rounds to conduct*. In one sense, a questionnaire could be tested forever, and still have problems (there is no such thing as a perfect question). Optimally, one wants to test until all the major problems have been detected and satisfactorily addressed. Usually, however, surveys are subject to strict developmental time-frames, and there is limited time for testing. Thus, the usual scenario involves conducting as many rounds as possible (three to four), prior to the pretest, or to actual administration. Though limited lab testing may not produce a perfect questionnaire, the final product should be markedly better than if not subjected to any testing of this type (although this is always subject to the client or sponsors' willingness to make recommended changes).

b) *Changes in the nature of interviewing*. As noted earlier, the nature of the interviewing rounds tends to change over the course of development of a questionnaire. Early in the process, findings relate not only to particular question wordings, but to more global issues, such as the appropriateness of the survey measurement of major concepts that the questionnaire is attempting to cover. For example, it may be determined that a class of information is simply not available through reliance on respondent knowledge and memory (for example, we have found that fathers especially tend to have appallingly bad knowledge of their toddlers' immunization histories). Or, it may be determined that a concept is much too complicated to be measured in a few short questions, and that a long series would actually be required to adequately cover this level of complexity.

Once major conceptual problems have been ironed out, later rounds of interviewing tend to be focused more exclusively on the appropriateness of individual questions (as in the examples in Section IV). Still, the unit of analysis is not the particular survey question, apart from its context; relevant findings may cover a series of questions, and relate to clarity, appropriateness of the series, biases due to ordering, and so on. One of the challenges of engaging in a useful cycle of testing and development activities is that we must be cognizant of all of these levels, both small- and large-scale, simultaneously.

IX. LIMITATIONS/CRITICISMS OF THE LABORATORY APPROACH TO QUESTIONNAIRE DEVELOPMENT

Here, I address specific potential criticisms and limitations of the cognitive laboratory approach:

1) LABORATORY SUBJECTS DIFFER FROM SURVEY RESPONDENTS:

Laboratory volunteers are self-selected into participation, and are therefore clearly not representative of the survey population as a whole. Most importantly, we find that laboratory volunteers tend to be higher in eduction than the average survey respondent. This could have important ramifications, in that we might miss problems that occur in "real life", and the laboratory findings therefore underestimate of the severity of problems. However, note also that if a question does not work in the lab, with our more "able" subjects, it will almost certainly be expected to cause problems in the field (and we generally find no shortage of problems in the lab). We suggest that relying on the field pretest, on additional forms of pretesting (such as behavior coding of the interaction between interviewer and respondents), on a subjective assessment of the abilities of our lab subjects, and on a concerted effort to use multiple recruitment sources, be used to counter this problem as much as possible.

2) THE LABORATORY CONTEXT IS DIFFERENT FROM THE FIELD:

This is another reason why the lab is not a substitute for the field test. To see how the questionnaire works in "real-life" circumstances, it has to be tested under field conditions, and this is worth doing, even for a small survey, with a few test respondents. We believe that the extent to which the differences in question-answering contexts between lab and field matters depends greatly on the type of question. For example, comprehension processes appear not to differ greatly between the lab and the household; if someone does not know the location of his or her abdomen in the lab, it is doubtful that he or she will know this when at home. Retrieval processes, similarly, will be different between lab and field to the extent that the home environment provides cues that affect the nature of the retrieval process. This again does not appear to be a great problem, in our experience. The case is much different, however, for survey questions that ask about sensitive topics. Here the environment appears to be critical, and in fact often overshadows the other, more basic cognitive processes. Therefore, we never use the laboratory to attempt to directly assess how likely people will be to answer survey questions about such activities as drug use or sexual behavior. Rather, we use the lab only as a context for more indirect, experimental studies, in which we interview individuals about their understanding of questions, or about conditions they believe would be more or less likely to prompt them to answer truthfully in a fielded survey.

3) SAMPLE SIZES FROM COGNITIVE INTERVIEWING ARE SMALL:

It is sometimes argued that the laboratory is deficient, compared to the field pretest, because the samples used are too small to make reasonable conclusions. There are at

least three faults in this argument:

a) *The purpose of laboratory interviews is not statistical estimation*. We do not desire sample sizes large enough to supply precision in statistical estimates. Rather, we strive to interview a variety of individuals.

b) *The nature of laboratory interviews is qualitative, not quantitative*. We do not evaluate problems in survey questions simply by counting the number of interviews in which a problem occurs. Of course, if every interviewer reports a problem with a particular question in every interview, that is significant. However, a finding can be based on one interview; that is, an interviewer may say that "I had a person with a particular disease for which this question does not work...". This points out a potential problem which does not need to be verified by finding a large number of other individuals with the same situation; the problem is there, and needs to be addressed.

c) *The apparent increased sample size of the field pretest is often illusory*. As discussed previously, questionnaires often contain initial screening questions, and then long follow-up sections that apply only if one "passes" the screener. However, in cases where it is relatively infrequent that respondents receive the follow-up questions, the general-population-based field pretest tends to provide only a few cases in which these follow-up questions are actually tested. For example, we found that one pretest of 300 households passed less then 10 individuals on to an important section on "use of assistive devices" (canes, wheelchairs, etc.). On the other hand, prior laboratory testing of the same questionnaire had specifically incorporated recruitment of subjects who would naturally screen-in to the follow-up questions, and so the "effective" size of the lab sample turned out to be significantly larger.

4) DEMONSTRATION OF THE EFFECTIVENESS OF COGNITIVE INTERVIEWING:

It has been pointed out that there are few comparative experimental studies that demonstrate the superiority of cognitive interviewing to other pretesting methods (however, see Presser and Blair (1993) for a study containing some features of such a study). We have addressed the question of utility of cognitive interviewing elsewhere (Willis, Royston, and Bercini, 1991). We have used a range of pretesting activities, and our belief is that cognitive interviewing should not be directly "stacked up" against any other particular type of evaluation activity, such as the field pretest, the expert review, behavior coding, and so on. Each type of activity appears to be useful in its own right, and provides information that is unique to that activity. Different processes seem to be most applicable at different points in the developmental sequence-- one does not conduct a field pretest on an embryonic questionnaire, and on the other hand, the final "dress rehearsal" of a forms-designed questionnaire is not usually tested with a round of cognitive interviews. The challenge to pretesting is to utilize a cohesive developmental plan that takes advantage of the strengths of each method.

References

Aday, L.A. Designing and conducting health surveys (1989). San Francisco: Jossey-Bass Publishers.

Campanelli, P., Martin, E., & Rothgeb, J.M. (1991). The use of respondent and interviewer debriefing studies as a way to study response error in survey data. The Statistician, 40, 253-264.

Campanelli, P., Rothgeb, J.M, & Martin, E. (1989). The role of respondent comprehension and interviewer knowledge in CPS labor force classification. Proceedings of the Section on Survey Methods Research, American Statistical Association, pp. 425-429.

Cannell, C.F., Miller, P.V., & Oksenberg, L. (1981). Research on interviewing techniques. In S. Leinhardt (ed.), Sociological methodology (pp. 389-437). San Francisco: Jossey-Bass.

Dippo, C. (1989). The use of cognitive laboratory techniques for investigating memory retrieval errors in retrospective surveys. Proceedings of the International Association of Survey Statisticians, International Statistical Institute, pp. 323-342.

DeMaio, T.J., Martin, E.A., & Sigman, E.P. (1987). Improving the design of the decennial census questionnaire. Proceedings of the Section on Survey Methods Research, American Statistical Association, pp. 256-261.

Esposito, J., & Hess, J. (May, 1992). The use of interviewer debriefings to identify problematic questions on alternative questionnaires. Paper presented at the annual meeting of the American Association for Public Opinion Research, St. Petersberg, FL.

Forsyth, B., and Lessler, J.T. (1991). Cognitive laboratory methods: A taxonomy. In P. Biemer, R. Groves, L. Lyberg, N. Mathiowetz, and S. Sudman (eds.), Measurement errors in surveys. New York: Wiley.

Jabine, T.B., Straf, M.L., Tanur, J.M., & Tourangeau, R. (eds.). (1984). Cognitive aspects of survey methodology: Building a bridge between disciplines. Washington, DC: National Academy Press.

Jobe, J.B., & Mingay, D.J. (1991). Cognition and survey measurement: History and overview. (1991). Applied Cognitive Psychology, 5, 175-192.

Jobe, J. B., Tourangeau, R., & Smith A. F. (1993). Contributions of survey research to the understanding of memory. Applied Cognitive Psychology, 7, 567-584.

Lessler, J.T., & Sirken, M.G. (1985). Laboratory-based research on the cognitive aspects of survey methodology: The goals and methods of the National Center for Health Statistics study. Milbank Memorial Fund Quarterly/Health and Society, 63, 565-581.

Payne, S.L. (1951). The art of asking questions. Princeton, NJ: Princeton University Press.

Presser, S., & Blair, J. (1993). An evaluation of alternative pretest methods. Contract Final Report, submitted to the Division of Health Interview Statistics, National Center for Health Statistics.

Royston, P., Bercini, D., Sirken, M., & Mingay, D. (1986). Questionnaire Design Research Laboratory. Proceedings of the Section on Survey Methods Research, American Statistical Association, pp. 703-707.

Tourangeau, R., & Rasinski, K.A. (1988). Cognitive processes underlying context effects in attitude measurement. Psychological Bulletin, 103, 299-314.

Willis, G.B., Royston, P., & Bercini, D. (1991). The use of verbal report methods in the development and testing of survey questionnaires. Applied Cognitive Psychology, 5, 251-267.

APPENDIX 1: DETAILS OF DAY-TO-DAY LAB OPERATIONS

This section is mainly of benefit to those who are interested in more detail on recruitment and scheduling. We have found it highly beneficial to establish a dedicated laboratory-manager position, and an integrated computerized control system to monitor the operations of our laboratory. This section will be of interest to those who envision the adaptation of cognitive interviewing techniques on a fairly large scale, as we have done.

I. RECRUITMENT METHODS:

Clearly, efficient recruitment methods are essential to running a questionnaire laboratory. Flexible and timely methods are needed to handle the wide range of subject characteristics that are often needed in a short period of time. The methods we use to recruit subjects include newspaper ads, flyers, interviews scheduled through outside organizations, and re-contacts with previous subjects. We also reach a fair number of subjects through word-of-mouth. A lot of thought goes into deciding the best approach to get volunteers to test any given questionnaire. Sometimes recruitment involves only one method, while other times several methods are used. The recruitment method used for a particular questionnaire depends on several factors, such as the testing schedule, the subject characteristics we require, and how many subjects we need.

1) Newspaper ads:

Appendix 2 contains an example of an ad we placed in the Washington Post to recruit subjects for a questionnaire on smoking. In newspaper ads, we list any requirements such as age, health conditions, or gender; we also specify that we pay $30 for a one hour interview. For "general purpose" subjects, we often advertise in local county newspapers. When we need people with very specific health conditions (use of an implanted medical device, such as a pacemaker), we advertise in the weekly health magazine of the Washington Post. Because we receive many responses to most newspaper ads, we use an answering machine to receive the calls, and transcribe the calls later. When using the answering machine, we have found that we can ask people for about three pieces of information without their forgetting one. For example, we will ask for their name, daytime phone number, and one other criterion such as age.

2) Advertising through flyers:

Appendix 2 contains an example of a flyer we used to recruit subjects for the survey on disability. Flyers cost far less than newspaper ads, and can be better for reaching specific groups. Further, we use flyers when we need only a few subjects, because flyers are much less effective in locating large numbers of subjects. We are able to place flyers directly in places or areas where people with the desired characteristics are likely to see them. In the past we have placed flyers in churches, libraries, and Y.M.C.A.s, as well as special interest organizations such as Easter Seals or the Polio Society. To reach people who are unlikely to see our ad in the newspaper, flyers are especially useful. For example, we have had more success recruiting low-income and lower-educated people through flyers than with newspaper ads.

When we want to place flyers in a particular organization, we need to obtain the organization's

consent, which can sometimes take several weeks. Phone calls in response to flyers tend to trickle in rather than come all at once as with newspaper ads, so flyers require a longer lead-time than newspaper ads. Answering calls in person, rather than using the answering machine, is advisable when flyers are used, or when the number of calls expected is fairly low.

3) Interviewing at outside organizations:

Another way we reach subjects is through the staff of outside organizations that let us conduct interviews in their facility. These off-site interviews are necessary for people that are not able or willing to come to our laboratory. These have included elderly persons, high school students, and the severely disabled who cannot travel easily, as well as drug clinic patients who are reluctant to go to a government office to talk about drug use. Setting up interviews in outside organizations requires a considerable amount of time and effort. When we interview off-site we need organizations to provide us with a private place to interview, and we need help with scheduling. For example, to conduct interviews in high schools, we had to get the approval of the school board. This required a considerable amount of correspondence with various levels of the organization. So far, the organizations we have contacted have been very receptive to our projects.

4) Use of "old" subjects:

Finally, a useful way of obtaining subjects is to use the same subject for more than one project; this saves considerable time and effort. We keep a computerized database of all subjects who are interviewed, and their specific characteristics. When we re-use subjects, we can select the "best" ones for our purposes - both in terms of ability to take part in a cognitive interview and desired characteristics. Because of the danger of "over-educating" the subjects, we limit them to three interviews. We do not want subjects to become so familiar with our process that they try too hard to give us suggestions and fail to react spontaneously.

II. EFFECTIVENESS OF RECRUITMENT METHODS.

Newspaper ads generate the most subjects. Washington Post ads that list specific criteria such as people with disabilities will yield over 100 responses in a few days, and those for general purpose subjects may return as many as 400 responses. County or college papers tend to yield far fewer responses. An important point to note is that when we increased our payment from $20 to $30 for a one-hour interview, this greatly increased the number of responses.

III. SUBJECT CONTROL INFORMATION.

1) Subject data sheets.

Appendix 3 contains an example of a subject sheet that we use to collect information about each volunteer. We use this form to obtain the information at the time of the interview; the information is entered into the computerized database later. We keep track of the day, time, questionnaire version, and the interviewer. We also note the specific criteria pertinent to the

subject, if any, such as the type of disability. At the bottom of the sheet we list the specific instruments that were tested and the usefulness of the subject.

2) Database programs.

All of the information contained on the subject sheet is entered into the computer in a set of user-friendly programs created in a database management package (DBASE IV). These programs help keep track of and organize most of the day-to-day operations of the lab. Computerized databases are maintained both for every subject who is interviewed, and for every questionnaire that is tested. The subject database keeps track of the demographic variables, and also keeps records of people who are scheduled for interviews but fail to arrive, the number of times a subject is interviewed, and the overall usefulness of each subject. Information contained on the questionnaire database includes the questionnaire, the version number, and the number of interviews per version. Additional tasks that the database system performs include keeping track of interviewers' schedules and of amount of subject payment money available, generating various reports, selecting subjects with various criteria, as well as other routines.

3) Timing of subject scheduling.

Timetables for recruiting and scheduling subjects are important. We do not start new recruitments unless a new project will begin within the next month. Although it may seem effective to have a large pool of people "in reserve", we have found that this is not realistic, because subjects have a limited "shelf-life". If a subject is contacted more than a month after he or she responds to an ad, the probability increases that the person is no longer available; he/she may have changed jobs or had some other schedule change, or has simply lost enthusiasm for the project. Additionally, as more time passes, it is more likely that a person has a different residence or phone number.

We schedule subjects no more than a few days before the interview. If the subject is scheduled any earlier, he or she is more likely to be a no-show. If we must schedule more than a week in advance, a reminder call is necessary. Interviews last about one hour, which is about how long subjects can maintain their attention in the lab before becoming fatigued or losing interest. We usually schedule no more than 12 interviews per round, depending on how many people are going to be doing the interviews. This is usually enough to find flaws and suggest changes before conducting another round of interviews. It is inefficient to conduct too many interviews per round. Once a flaw is found, there is little point in conducting many more interviews until attempts are made to solve the problem.

In summary, in order for a recruitment and management system to work, it needs to be flexible, and rely on a variety of techniques as they appear warranted.

APPENDIX 2: EXAMPLES OF NEWSPAPER ADVERTISEMENT AND FLYER

Newspaper advertisement used to recruit subjects for a survey on health promotion practices:

EARN $30 IN ONE HOUR

The U.S. Public Health
Service in Hyattsville, MD
needs paid volunteers,
AGES 16 - 64
to spend one hour
answering survey questions
on a variety of health topics.
Anyone may participate, but we
especially need people
AGE 40 OR ABOVE
OR
WHO SMOKE CIGARETTES.

For more information, please call
301-436-7460

Centers for Disease Control and Prevention/
National Center for Health Statistics

Flyer used to recruit subjects for a disability survey:

(ORGANIZATION LETTERHEAD APPEARS AT TOP OF FLYER)

WE NEED YOUR HELP!

THE U.S. PUBLIC HEALTH SERVICE is planning an important national survey on DISABILITY. We need volunteers to participate in interviews so that we can test the survey questions.

VOLUNTEERS WILL BE PAID $30.

You may help with this study if you, your child, or another family member living in your household has a disability. We need volunteers with many different kinds of disabilities. Interviews will be held one block from Prince George's Plaza, at the National Center for Health Statistics in Hyattsville, Maryland. Interviews take about one hour and are conducted during regular business hours.

For more information, or to volunteers, please call
301-436-7460, weekdays between 9 AM and 4 PM.

APPENDIX 3: SUBJECT DATA SHEET

SUBNO: S-_____	☐ Entered	☐ Closed	☐ No Show	☐ Cancelled
STUDY		CRITERIA:		
DAY				
TIME				
INTERVIEWER				

INTERVIEWERS PLEASE FILL IN BELOW:

Name:_____ Date:_____

Home phone:_____ Employed Y/N Work#_____

Where did you see our ad/flyer? ☐PG Sentinel ☐PG Journal
☐Shoppers Food ☐Giant ☐Unemployment Office
☐ P.G. Social Services ☐Friend

Sex: ☐Male ☐Female Birthdate:___/___/___Age:____ Education_____

Marital Status: ☐Married ☐Divorced ☐Widowed ☐Separated
☐Never been married

Household Income: ☐ 20K or less ☐ over 20K
☐ 30K or less ☐ over 30K

Racial/Ethnic Group:

☐White ☐Black ☐Asian/Pacific Islander ☐Hispanic ☐Eskimo, Aleut, or American Indian

Address_____

INSTRUMENTS TESTED: _____				
Interviewer rating of overall subject usefulness:				
1 (poor)	2	3	4	5 (excellent)

Comments: _____

APPENDIX 4: EXAMPLE OF INTERVIEWING NOTES TAKEN BY A COGNITIVE INTERVIEWER

NOTES:

1) The example represents notes taken by one interviewer from three cognitive interviews, on one version of a questionnaire draft.

2) The use of PROBE refers to prepared probe questions embedded in the draft of the questionnaire, for use in all interviewers.

3) Comments preceded by "S#" were findings specific to that subject (for example, S#1).

4) General comments (not pertaining to any particular subject) are not preceded by a subject number, and are simply observations about the questionnaire made by the interviewer either during or subsequent to interviewing.

5) The interviewing notes contains only those questions that were found to contain problems or issues to be resolved. That is, the original draft is "abstracted" to create the report, but the original question numbers and section headings are retained for reference.

PRELIMINARY 1994 Health Promotion and Disease Prevention Questionnaire:

Draft 1: 5/17/93

Subject #1 = female, 51
Subject #2 = male, 77
Subject #3 = female, 21

SECTION A: ENVIRONMENTAL HEALTH

These next questions are about this home.

2. How many floors or levels does this home have? Do not include unfinished basements or attics.

QUESTION DOESN'T WORK FOR APARTMENT BUILDING- SUBJECT #3 REPORTS ALL LEVELS IN BUILDING

---

4. Do you have at least one smoke detector on each floor of your home not including unfinished attic or unfinished basement?

THIS CAN BE COMPLEX IF WE WANT TO MEASURE THIS EXACTLY: S#2 HAS A 4-LEVEL SPLIT-LEVEL. THERE ARE 3 SMOKE DETECTORS, EACH ONE IN THE STAIRWAY BETWEEN LEVELS. SO, YES, THEY ARE <u>COVERED</u> BUT DON'T LITERALLY HAVE "ONE DETECTOR PER FLOOR".

9b. How many PEOPLE smoke cigarettes, cigars, or pipes anywhere inside this home?

PROBE: WHO SMOKES IN THIS HOME?

_____
Number

S#1: WANTS TO KNOW WHETHER TO INCLUDE VISITORS. DO WE MEAN "EVER" OR "USUALLY" HERE?

9d. On the average, on the days that there is smoking, about how CIGARETTES are smoked per day ANYWHERE INSIDE this home?

PROBE: IS THIS EASY OR DIFFICULT TO SAY?

00 [ ] Less than cigarette per day/Rarely
_____Cigarettes per day

09 [ ] DK

S#1: SHOULD WE ADD A RESPONSE CATEGORY FOR PACKS? (THIS SEEMS TO BE A NATURAL TYPE OF RESPONSE GIVEN)

SECTION B: SMOKING

5. During the past 12 months, have you quit smoking for one day or longer?

1 [ ] Yes
2 [ ] No

PROBE: FOR HOW LONG HAVE YOU QUIT SMOKING? HOW MANY TIMES?

SUBJECT #1 THINKS THAT "STOPPED SMOKING" IS A BETTER PHRASE.

6b. On average, when you smoked DURING THE PAST 30 DAYS, about how many cigarettes did you smoke EACH day?

NOTE: I CHANGED THE WORDING ON THIS ONE (ADDED IN CAPS) - THIS SEEMS TO WORK OK.

---

7. Would you like to completely stop smoking cigarettes?

1 [ ] Yes
2 [ ] No
9 [ ] DK

MAKE IT "QUIT SMOKING"

---

8. Have you ever used snuff such as Skoal, Skoal Bandits, or Copenhagen?

1 [ ] Yes
2 [ ] No
9 [ ] DK

PROBE: HAVE YOU EVER TRIED IT?

IF NO, SKIP TO 11.

---

11. Have you ever used chewing tobacco, such as Redman, Levi Garrett, or Beechnut?

1 [ ] Yes
2 [ ] No (next page)
9 [ ] DK (next page)

SECTION C: EXERCISE

1. Do you exercise or play sports regularly?

1 [ ] Yes
2 [ ] No
9 [ ] DK

PROBE: WHAT DOES "EXERCISE REGULARLY" MEAN TO YOU?

S#1 THINKS THIS MEANS 7 DAYS A WEEK. NOT WHAT WE MEAN- TOO VAGUE.

S#2: HE SAYS NO. AFTER PROBING, I FIND OUT THAT HE WALKS 2-3 MILES

EVERY DAY AFTER DINNER. THE CONCEPT OF "REGULARLY" IS TOO VAGUE AND RESPONDENT-DEFINED.

S#3 IT'S NOT CLEAR TO HIM WHAT "REGULARLY" IS.

SECTION D: OCCUPATIONAL SAFETY AND HEALTH

ITEM T1:
During the past 2 weeks, did you work at any time at a job or business not counting work around the house? (Include unpaid work in the family [farm/business].)

THIS IS A REALLY TECHNICAL AND COMPLEX WAY TO ASK WHETHER THEY HAVE WORKED IN THE PAST TWO WEEKS

---

a. Altogether, does your employer have 50 or more employees?

S#3: HOW IS >1 JOB HANDLED?

2a. Does your employer have an official policy that restricts smoking in any way?

S#3: THE EMPLOYER DOESN'T, BUT THE BUILDING OWNER DOES.

---

3. Does your employer offer a quit smoking program or any other help to employees who want to quit smoking?

1 [ ] Yes
2 [ ] No
9 [ ] DK

S#1: DO WE MEAN A PROGRAM PAID FOR BY THE EMPLOYER HERE? THIS WAS UNCLEAR.

—

5. Which of these exercise programs are made available to you by your employer?

S#1: THE TERM "MADE AVAILABLE" IS VAGUE.

1 [ ] Walking group
2 [ ] Jogging/Running group
3 [ ] Biking/Cycling group
4 [ ] Aerobics classes
5 [ ] Swimming classes
6 [ ] Non-aerobic exercise classes
7 [ ] Weight lifting classes
8 [ ] Fully paid membership in a health/fitness club
9 [ ] Partially paid membership in health/fitness club
10 [ ] Physical activity or exercise competitions
98 [ ] Other - Specify
_____
00 [ ] No programs
99 [ ] DK

S#3 IS INVOLVED IN A "WELLNESS PROGRAM". WHERE DOES THIS FIT IN?

IF NO PROGRAMS OR DK, GO TO 6A.

—

5c. About how often do you participate in (exercise program) that was made available by your employer?

PROBE: TELL ME ABOUT THE PROGRAMS YOU'VE PARTICIPATED IN.

S#3 SAYS "ONCE"- MEANING ONE PERIOD IN WHICH SHE ACTUALLY EXERCISED SEVERAL TIMES A WEEK.

—

6. In the past 12 months, did you participate in a quit smoking program made available by this employer?

IF THEY DON'T SMOKE, DON'T ASK THIS.

—

6a. Does your employer make available screening tests for:

	Yes	No	DK
(1) blood pressure?	1 [ ]	2 [ ]	9 [ ]
(2) cholesterol?	1 [ ]	2 [ ]	9 [ ]
(3) cancer?	1 [ ]	2 [ ]	9 [ ]

S#3: FOR FREE? SHE WANTS TO KNOW.

NOTE: SHOULDN'T THIS BE "IN THE PAST 12 MONTHS"?

7a. Does your employer make available brochures, programs, talks, or counseling concerning ANY OF THESE (CARD T5):

1 [ ] Weight control
2 [ ] Nutrition information
3 [ ] Prenatal education **SIMPLIFY THIS TERM**
4 [ ] Medical self-care
5 [ ] Stress reduction and management
6 [ ] Alcohol and other drugs
7 [ ] Sexually transmitted diseases (including HIV or AIDS)
8 [ ] Job hazards and injury prevention
9 [ ] Back care and prevention of back injury
10 [ ] Preventing off-the-job accidents

SUBJECT #3 WANTS TO KNOW WHAT "MEDICAL SELF-CARE" (#4) IS. GOOD QUESTION.

7b. In the past 12 months, have you participated in any of these activities or used any the information made available by this employer?

1 [ ] Yes
2 [ ] No
9 [ ] DK

S#1 SAYS NO, EVEN THOUGH SHE HAS READ THE FLYERS. WE NEED TO MAKE MORE CLEAR WHAT WE MEAN BY "USED ANY OF THE INFORMATION". MAYBE WE EVEN NEED ONE QUESTION ON "PARTICIPATING IN ACTIVITIES"

AND ANOTHER ON "READING ANY INFORMATION".

SUBJECT #2 SAYS NO, BUT ACTUALLY DOES READ THE BROCHURES. THE CONCEPT TO "USING THE INFORMATION" IS NOT COMING ACROSS.

8b. Which of these best describes your employer's smoking policy for indoor public or common areas, such as lobbies, rest rooms, and lunch rooms? (CARD T2)

THIS IS COMPLEX AND DIFFICULT TO UNDERSTAND. S#2 DOESN'T REALLY LISTEN- JUST LOOKS AT THE CARD AND FIGURES OUT WHICH RESPONSE APPLIES.

1 [ ] Not allowed in ANY indoor or common public areas
2 [ ] Allowed in SOME public areas, including designated smoking areas
3 [ ] Allowed in ALL indoor or common public areas
9 [ ] DK

SECTION E: CLINICAL PREVENTIVE SERVICES

1. About how long has it been since your last routine check-up by a medical doctor or other health professional?

S#3 REPORTS ON A LIMITED FOLLOW-UP VISIT, RATHER THAN AN ACTUAL "CHECK-UP", SO THE FOLLOWING QUESTIONS ARE NOT MEANINGFUL. MAYBE WE NEED TO ASK EXPLICITLY IF THE LAST VISIT WAS A GENERAL CHECKUP, A FOLLOW-UP VISIT, OR A VISIT FOR A PARTICULAR HEALTH PROBLEM. ONLY IF IT'S THE FIRST DO WE REALLY WANT TO ASK Q2, 3, ETC.

---

2. During this last check-up, were you asked about:

	Yes	No	DK
a. Your diet and eating habits?	1 [ ]	2 [ ]	9 [ ]
b. The amount of physical activity or exercise you get?	1 [ ]	2 [ ]	9 [ ]
c. Whether you smoke cigarettes or use			

other forms of tobacco?	1 [ ]	2 [ ]	9 [ ]
d. How much and how often you drink alcohol?	1 [ ]	2 [ ]	9 [ ]
e. Whether you use marijuana, cocaine, or other drugs?	1 [ ]	2 [ ]	9 [ ]
f. Sexually transmitted diseases?	1 [ ]	2 [ ]	9 [ ]

S#2: SHOULD WE SKIP E AND F IF OVER A CERTAIN AGE? SEEMS KIND OF RIDICULOUS FOR HIM.

Refer to age

1 [ ] SP (Sample Person) is 65 + (4)
8 [ ] Other (6)

4a. During this last check-up, were you asked about the symptoms of a transient ischemic attack (TIA)? 1 [ ] Yes 2 [ ] No 9 [ ] DK

S#2: THIS IS VERY TECHNICAL. THE SUBJECT SAYS "YES" BECAUSE HE WAS ASKED ABOUT SHORTNESS OF BREATH. IS THIS A SYMPTOM OF TIA? MAYBE WE SHOULD ASK ABOUT WHETHER THEY WERE ASKED ABOUT THE SPECIFIC SYMPTOMS EXPLICITLY, RATHER THAN ABOUT THE CONDITION.

b. During this last check-up, were you asked about whether you have difficulty taking care of yourself, including dressing, using the toilet, bathing, eating, or getting around inside your home without help? 1 [ ] Yes 2 [ ] No 9 [ ] DK

c. During this last check-up, were you asked about whether you have difficulty doing every day activities and chores, including preparing your meals, managing your money, using the telephones, doing light housework, and shopping? 1 [ ] Yes 2 [ ] No 9 [ ] DK

S#2: B AND C ARE REALLY LONG TO READ. I REALLY DOUBT THAT RESPONDENTS CAN KEEP IN MIND ALL THAT WE'RE ASKING HERE.

---

5. During this last check-up, did you have:

S#2: THE SUBJECT MISSES THE REQUIREMENT THAT THIS BE "THE LAST CHECK-UP". WE NEED TO SPECIFY THIS BETTER. THIS NEEDS TO BE EMPHASIZED MORE. MAYBE "DURING THE ROUTINE CHECK UP THAT YOU JUST TOLD ME ABOUT".

	Yes	No	DK
a. A vision test to see how well you see?	1 [ ]	2 [ ]	9 [ ]

"SEE HOW WELL YOU SEE" IS KIND OF AWKWARD.

b. A hearing test?	1 [ ]	2 [ ]	9 [ ]
c. A urine test?	1 [ ]	2 [ ]	9 [ ]
d. A blood test to check your thyroid function?	1 [ ]	2 [ ]	9 [ ]

S#2: HE HAD A BLOOD TEST: HOWEVER, HE DOESN'T KNOW THAT IT WAS SPECIFICALLY TO TEST THYROID FUNCTION.

e. A stool test to check for blood in the stool?	1 [ ]	2 [ ]	9 [ ]

---

12. A breast physical exam is when the breast is felt for lumps by a physician or other health care professional. About how long has it been since you had a breast physical exam done by a doctor or other health care professional? Was it within the past year, 1-2 years ago, or over 2 years ago?

LOTS OF WORDS TO READ HERE.

SECTION F: ESTROGEN REPLACEMENT

13. Have you ever been counseled by a physician or other health care

professional about the benefits of taking estrogen pills after menopause in order to prevent bone loss?

"COUNSELING" IS PROBABLY TOO MUCH HERE (SUBJECT #1 THINKS IT IMPLIES "IN-DEPTH" DISCUSSION. MAYBE WE JUST WANT TO ASK IF THE PHYSICIAN TALKED ABOUT THIS WITH THEM.

ALSO, IF PREVENTING BONE LOSS THE ONLY REASON TO TAKE ESTROGEN PILLS? IF NOT, THE PERSON MIGHT HAVE BEEN TOLD ABOUT ESTROGEN REPLACEMENT, BUT NOT NECESSARILY WITH RESPECT TO BONE LOSS.

SECTION G: FAMILY

1. In the past month, have you had any discussions with family members in your household about health issues related to:

PROBE: WHAT DO YOU THINK OF WHEN WE ASK ABOUT "DISCUSSIONS WITH FAMILY MEMBERS"?

[ ] Drinking beer, wine, liquor, and other alcoholic beverages?

MAKE IT "WINE, LIQUOR, <u>OR</u> OTHER ALCOHOLIC..."

[ ] Nutrition and healthy eating habits?

[ ] Exercise, sports or other physical activities?

PROBE: WHAT DO YOU THINK OF WHEN WE SAY "PHYSICAL ACTIVITIES"

[ ] Sexual behavior, such as risk of infection with HIV or other sexually transmitted diseases or unwanted pregnancy?

[ ] Smoking cigarettes or use of other forms of tobacco, including chewing tobacco and snuff?

[ ] Using illicit drugs, including steroids?

"ILLICIT" DRUGS IS TOO TECHNICAL.

[ ] Safety and things that you can do to prevent injuries, including using seat belts?

S#1 THINKS THAT "HAD DISCUSSIONS" IS TOO MUCH HERE- JUST "TALKED ABOUT" IS BETTER FOR HER.

S#2 THINKS THAT "TALKED ABOUT" IS BETTER THAN "DISCUSSIONS"

S#3: THE CONCEPT OF "DISCUSSIONS" IS VERY VAGUE AND IT'S DIFFICULT FOR HER TO SAY FOR SEVERAL OF THESE. IF SHE TELLS HER MOTHER TO WEAR HER SEAT BELT, IS THIS A "DISCUSSION"? "TALKING ABOUT" THESE THINGS MAY BE SOMEWHAT BETTER (BUT MAY STILL HAVE PROBLEMS).

Attachment C
Sample of a 2005 advance letter send to NHIS respondents

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

HIS-600(L)
(11-2005)

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

WE NEED YOUR HELP

...to improve the health of all Americans. You may be invited to take part in the National Health Interview Survey. The survey is sponsored by the National Center for Health Statistics, a part of the Centers for Disease Control and Prevention (CDC).

A Census Bureau interviewer will show you an official identification card. You will be asked about your and your family's health and health care. Your answers will help us make better decisions about health programs. A small number of households will be asked in a few weeks to confirm that correct procedures were followed.

Everything you tell us will be kept strictly private. Your data will be used only for health research. Unless you agree, federal law does not allow us to release information that could identify you or your family. The only parties that can receive such data are those we've told you about on the back of this letter.

We may obtain data about your family's health and health care from records of other government agencies. Examples of information that would allow linkage with other records are you Social Security and Medicare numbers. Any data obtained will also be kept strictly private.

You may take part in the survey or not. That is your choice. No penalties or loss of benefits will come from refusing. You may choose not to answer any question and can stop at any time. The survey will take about an hour to do all parts, depending on the size and health of your family. You may be asked to take part in other government surveys sometime in the future. Taking part in any other survey is voluntary.

Please contact the Census Bureau, toll-free, at 1-800-992-3530 for questions about the survey or to schedule an interview.

You may want to ask about your rights as a participant in this research study. If so, please call the office set up to oversee research, toll-free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say you are calling about Protocol # 2004-13. Your call will be returned promptly.

Learn more about the survey at our website: www.cdc.gov/nchs/nhis.htm

Thank you for your cooperation. We are grateful for your help.

Sincerely

REGIONAL OFFICE
U.S. CENSUS BUREAU
15350 SHERMAN WAY STE 300
VAN NUYS, CA 91406
1-800-992-3530

Edward J. Sondik, Ph.D.
Director, National Center for Health Statistics

FREQUENTLY ASKED QUESTIONS ABOUT THE NATIONAL HEALTH INTERVIEW SURVEY (NHIS)

1. HOW WAS I CHOSEN FOR THE SURVEY?

Every week about 1,400 addresses are chosen by scientific sampling methods to serve as a cross section of the entire United States. The people at those addresses are interviewed to obtain information used to describe the health of all Americans.

2. WHY NOT INTERVIEW AT THE HOUSE ACROSS THE STREET? WHY IS MY PARTICIPATION IMPORTANT?

Because scientific sampling methods do not permit the substitution of another address for those originally selected, we cannot change another address for yours. It is important that the people living in the address selected be a part of the survey in order to provide the most accurate picture of the Nation's health.

3. I'M NOT SICK –WHY SHOULD I BE INCLUDED IN A HEALTH SURVEY?

This is a survey of the Nation's health. We want to know how many people are sick and why they are sick, but it is also important to know how many people are healthy and why they are healthy. These answers will help keep the Nation healthy.

4. WILL THE DATA BE HELD CONFIDENTIAL?

The NHIS is authorized by Congress in Section 306 of the Public Health Service Act (42 USC 242K). All information collected in this survey will be held in strict confidence according to law [Section 308(d) of the Public Health Service Act (42 United States Code 242m (d) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347)]. Aside from NCHS employees, the only parties that can receive your personal information are the U.S. Census Bureau and our collaborators (persons who have worked as our full partners from the earliest stages of this survey). These parties, who will use your information for statistical research only and to carry out this survey, are bound by strong restrictions designed to guarantee your privacy. By law we cannot release information that could identify you or your family to anyone else without your consent. If any federal employee or contractor gives out confidential information not authorized by law, he or she can be fired and fined and/or imprisoned.

5. WHAT KIND OF INFORMATION IS COLLECTED IN THE NHIS?

The NHIS covers a wide range of health topics such as doctor visits, health insurance, exercise, vaccinations, and injuries. Most respondents have no difficulty answering the questions in the NHIS. However, some people may consider questions on a few topics, such as income, sensitive. You do not have to answer any questions you don't want to.

6. WHY SHOULD I PROVIDE MY SOCIAL SECURITY NUMBER OR MY MEDICARE NUMBER?

We would like to know your Social Security and Medicare numbers so that we may obtain data about your family's health and health care from vital records and records from such agencies as the Centers for Medicare and Medicaid Services and the Veteran's Administration. This way we do not have to ask you questions for which information is already available. We will hold in strict confidence any information we obtain about you from these agencies. There will be no effect on your benefits if you do not provide the numbers.

7. HOW ARE THE NATIONAL HEALTH INTERVIEW SURVEY DATA USED?

NCHS was authorized by Congress to conduct this survey and to produce health information for the Nation. Government agencies, universities, private health planners and researchers use the data to conduct research on health problems. The data are also used to determine how best to use available dollars and personnel to solve these health problems. While you will not receive any immediate benefit from participating in this survey, you will benefit along with all Americans from decisions about health problems that are based on the best available information.

HIS-600(L) (11-2005)

EXPORT-IMPORT BANK OF THE UNITED STATES

Sunshine Act Meeting

AGENCY: Export-Import Bank of the United States.

ACTION: Cancellation of a Government in the Sunshine Meeting.

ORIGINAL TIME AND PLACE: Thursday, April 27, 2006 at 9:30 a.m.

PLACE: Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

The Export-Import Bank of the United States has cancelled the Government in the Sunshine meeting which was scheduled for April 27, 2006. The Bank will reschedule this meeting at a future date. Earlier announcement of this cancellation was not possible.

FOR FURTHER INFORMATION CONTACT: For further information, contact: Office of the Secretary, 811 Vermont Avenue, NW., Washington, DC 20571 (Tele. No. 202–565–3957).

Howard A. Schweitzer,

General Counsel (Acting).

[FR Doc. 06–4101 Filed 4–26–06; 4:08 am]

BILLING CODE 6690–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 16, 2006.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Biegert Family Trust, Laramie, Wyoming, its trustees, Larry R. Cox; Henderson, Nebraska, Judith Ackland, Geneva, Nebraska, and Larry R. Cox, individually; Charles Flaming, individually, and as owner of Sadle Cattle Company, Inc., both of Paxton, Nebraska; Alan Janzen, Christopher Vanderneck, Matthew D. Siebert, Fredrick Regier, Arvid Janzen, and Brian Janzen, all of Henderson, Nebraska; Ronald Preheim, Aurora, Nebraska; Jeff Pribbeno, Imperial, Nebraska; and Wesley Kroeker, Enid, Oklahoma; and thereby indirectly acquire shares of Henderson State Company, Henderson, Nebraska, of Henderson State Bank, Henderson, Nebraska.

Board of Governors of the Federal Reserve System, April 26, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–6530 Filed 4–28–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of March 27 and 28, 2006

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on March 27 and 28, 2006.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with increasing the federal funds rate to an average of around 4 3/4 percent.

The vote encompassed approval of the paragraph below for inclusion in the statement to be released shortly after the meeting:

"The Committee judges that some further policy firming may be needed to keep the risks to the attainment of both sustainable economic growth and price stability roughly in balance. In any event, the Committee will respond to changes in economic prospects as needed to foster these objectives."

[1] Copies of the Minutes of the Federal Open Market Committee Meeting on March 27 and 28, 2006, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

By order of the Federal Open Market Committee, April 20, 2006.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. E6–6492 Filed 4–28–06; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–0222]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Questionnaire Design Research Laboratory (QDRL) 2007–2009, (OMB No. 0920–0222)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Questionnaire Design Research Laboratory (QDRL) conducts questionnaire pre-testing and evaluation activities for CDC surveys (such as the NCHS National Health Interview

Survey, OMB No. 0920–0214) and other federally sponsored surveys. The QDRL conducts cognitive interviews, focus groups, mini field-pretests, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common questionnaire evaluation method is the cognitive interview. In a cognitive interview, a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews; ideally, the questionnaire is re-worked between rounds and revisions are tested iteratively until interviews yield relatively few new insights. When possible, cognitive interviews are conducted in the survey's intended mode of administration. For example, when testing telephone survey questionnaires, participants often respond to the questions via a telephone in a laboratory room. Under this condition, the participant answers without face-to-face interaction. QDRL staff watch for response difficulties from an observation room, and then conduct a face-to-face debriefing with in-depth probes. Cognitive interviewing provides useful data on questionnaire performance at minimal cost and respondent burden. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. NCHS is requesting 3 years of OMB Clearance for the project. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents per year	Number of responses/ respondent	Avg. burden response (in hours)	Total burden hours
2007 test volunteers	500	1	1.2	600

Dated: April 25, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–6501 Filed 4–28–06; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0273] (formerly 03N–0273)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Research Study Complaint Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Research Study Complaint Form" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 16, 2005 (70 FR 74817), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0579. The approval expires on March 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: April 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6457 Filed 4–28–06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0166]

Agency Emergency Processing Under the Office of Management and Budget Review; MedWatch—The Food and Drug Administration Safety Information and Adverse Event Reporting Program; Proposal to Survey MedWatch Partners Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on a proposal for the MedWatch program to deploy and conduct a web-based customer satisfaction survey of certain health care professional trade and specialty organizations that voluntarily have chosen to participate in the FDA MedWatch's Partners program. The survey will solicit information about the utility of the FDA MedWatch safety alerts and monthly safety labeling changes that are posted on the MedWatch Web site and disseminated to partner organizations for sharing with members of the organizations.

DATES: Fax written comments on the collection of information by May 31, 2006. FDA is requesting approval of this emergency processing by May 31, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, Fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
QDRL Interviews

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like you. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you agree to take part in this test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

The questions that we are working on today are about [FILL].

Your interview will show us how to improve these questions. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last no more than [duration], and we will give you $XX. In order to receive the $XX, you will need to fill out the attached SF-1164 form. You will also be asked to fill out a personal information sheet.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop the interview at any time. While the interview is going on, researchers from [FILL AGENCY] who are working with us on this project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings
We would like to video/audio[1] record your interview. The recording allows us to more carefully study the questions. At

the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to retain the portion already taped.
If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

At the end of the interview, we may ask you for special permission to play the recording in a more public setting. For example, the interview could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than staff working directly on this project to [watch/listen to] the recording.

Privacy
We are required by law[2] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks
Other than the $XX you receive, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full $XX.

If you have any questions about this study, please call the office of the Ethnics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this research study.

When video recording is selected:

- I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

When tape recording is selected:

- I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

_____ _____

Participant Signature **Print name** **Date**

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K) and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

OMB #0920-0222; Expiration Date: 01/31/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
Parental/Guardian Permission

Your child is being asked to take part in a research study. This consent form tells you about the study and what your child will be asked to do. You can choose to have your child take part in the study or not. If you permit your child to take part, you will need to sign this form. Your child will also have a consent form to read and sign.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like your child. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you permit your child to take part in this test, we will ask your child to answer the survey questions. Then, we will ask your child to explain what he/she was thinking and how he/she came up with their answers.

The questions that we are working on today are about [FILL].

Your child's interview will show us how to improve the questions for this survey. In the future, we may also study your child's interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
An interviewer will ask your child some survey questions. Then, the interviewer will ask your child to explain what he/she was thinking as he/she answered the questions. The interviewer will ask your child if there were any words that were confusing and if he/she understood what was being asked.

The interview will last [duration], and we will give your child $XX. In order to receive the $XX, you will need to fill out the attached SF-1164 form. The form is attached for your review. We also ask that you fill out for your child a personal information sheet.

Your child may find that some of the questions we are testing are sensitive. He/she may choose not to answer any question for any reason. If he/she does not want to answer a question, he/she can say so, and we will move on to the next one. Your child may also stop the interview at any time. While the interview is going on, researchers from [FILL AGENCY] who are working with us on this project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings
We would like to video/audio[1] record your child's interview. The recording allows us to more carefully study the questions. At the bottom of this form, you will be asked if you are willing to have your child's interview recorded. If you agree, your child may ask to stop the recording at any time, and we will turn off the machine. If your child decides to stop taping, we

will ask his/her consent to retain the portion already taped. When the interview is finished, your child may also [watch/listen to] the recording. So that your child feels comfortable answering the questions, you will not be allowed to watch/listen to the interviewing while it is being recorded or watch/listen to the recording at a later time.

If you agree to record your child's interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may watch the interview. However, they must agree to keep your child's personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

Privacy
We are required by law[2] to tell you what we will do with your child's recording. We must also tell you how we will protect your child's privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only QDRL staff have access to this material.

Your child's name or other personal facts that would identify your child will not be used when we discuss or write about this study. People working on this project, however, may recognize your child or your child's voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks
Other than the $XX your child receives, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your child's privacy. Your child does not have to give us any information that he/she does not want to, and he/she can choose not to answer any question in the interview. He/she may also stop at any time and still receive the full $XX.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I allow my child to take part in this research study.

When video recording is selected:

- I allow NCHS to video record his/her interview. I also allow NCHS to play his/her video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record his/her interview.

When tape recording is selected:

- I allow NCHS to audio record his/her interview. I also allow NCHS to play his/her audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record his/her interview.

_____ _____

Parent or Guardian **Print name** **Date**

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K) and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

OMB #0920-0222; Expiration Date: 01/31/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
Minor's Form

Your parent or guardian says you can take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like you. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you agree to take part in this test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

The questions that we are working on today are about [FILL].

Your interview will show us how to improve the questions for this survey. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last [duration], and we will give you $XX.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop the interview at any time. While the interview is going on, researchers from [FILL AGENCY] who are working with us on this project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings
We would like to video/audio[1] record your interview. The recording allows us to more carefully study the questions. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to retain the portion already taped. When the interview is finished, you may also [watch/listen to] the recording. So that you feel comfortable answering the questions, your parent or guardian will not be allowed to watch/listen to the interviewing while it is being recorded or watch/listen to the recording at a later time.

If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

Privacy
We are required by law[2] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks
Other than the $XX you receive, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full $XX.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I agree to take part in this research study.

When video recording is selected:

- I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

When tape recording is selected:

- I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

_____ _____

Participant Signature **Print name** **Date**

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K) and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

Public reporting burden for this collection of information is estimated to average XX minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0222).

OMB #0920-0222; Expiration Date: 01/31/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
Focus Groups

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like you. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs.

If you agree to take part in this test, you will be part of a discussion group about new questions for [FILL survey name here].

The discussion group will show us how to improve the questions for this survey. In the future, we may also study the group interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
A group leader will ask you to share your thoughts and ideas about the questions with other people in the group. You will not be asked your personal answers to the questions. We will ask you to pick a name and put it on a name tag. You do not have to use your real name.

The discussion will last XX minutes, and we will give you $XX. In order to receive the $XX, you will need to fill out the attached SF-1164 form. You will also be asked to fill out a personal information sheet.

You may leave the discussion group at any time. You may also choose not to discuss any question for any reason. While the discussion is going on, researchers from [FILL AGENCY] who are working with us on this project may watch the discussion.

If you have any questions about how the project works, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Road, Hyattsville, MD 20782.

Recordings
We plan to video/audio[1] record the discussion. The recording allows us to more carefully study the questions. At the bottom of this form, you will be asked if you are willing to have the discussion recorded. When the discussion is finished, you or anyone in the group may watch/listen to the recording. Since recording is essential for this project and you do not wish to be recorded, you should not join the discussion. If you decide that you do not want to be recorded, you will still receive the full XX.

Recordings are kept in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research

Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

At the end of the discussion, we may ask you for special permission to play the recording in a more public setting. For example, the discussion could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than the staff working directly on this project to [watch/listen to] the recording.

Privacy
We are required by law[2] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks
Other than the $XX you receive, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the discussion. You may also stop at any time and still receive the full $XX.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03- XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this discussion group.

When video recording is selected:

- I allow NCHS to video record me. I also allow NCHS to play the video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record me.

When tape recording is selected:

- I allow NCHS to audio record me. I also allow NCHS to play the audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record me.

_____ _____

Participant Signature **Print name** **Date**

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K) and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

OMB #0920-0222; Expiration Date: 01/31/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
Interviews Conducted Off-site

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like you. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you agree to take part in this test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

The questions that we are working on today are about [FILL].

Your interview will show us how to improve the questions for this survey. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last [duration], and we will give you $XX. In order to receive the $XX, you will need to fill out the attached SF-1164 form. You will also be asked to fill out a personal information sheet.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop the interview at any time. While the interview is going on, researchers from [FILL AGENCY] who are working with us on this project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings
We would like to video/audio[1] record your interview. The recording allows us to more carefully study the questions. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to retain the portion already taped.

If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

At the end of the interview, we may ask you for special permission to play the recording in a more public setting. For example, the interview could be played at a conference or for students who want to learn how to write survey questions. If you do not agree to this special permission, we will not allow anyone other than staff working directly on this project to [watch/listen to] the recording.

Privacy
We are required by law[2] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored in a locked room. Only QDRL staff have access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks[3]
Other than the $XX you receive, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full $XX.

<u>Conducting an interview at a business location</u>
The interview will be conducted in a closed office. We will protect any materials that contain your personal information and transport them to NCHS.

<u>Conducting a home interview</u>
In order for you to take part in the study today, we agreed to come to your home. Meeting in your home is your choice. However, you are urged to choose a place that is private so that you will feel comfortable answering the questions. We will protect any materials that contain your personal information and transport them to NCHS.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03- XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this research study.

When video recording is selected:

- I allow NCHS to video record my interview. I also allow NCHS to play my video recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

When tape recording is selected:

- I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

_____ _____

Participant Signature **Print name** **Date**

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K) and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

[3]Depending on the study, select either *conducting an interview at a business location* or *conducting a home interview*.

Public reporting burden for this collection of information is estimated to average XX minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0222).

OMB #0920-0222; Expiration Date: 01/31/07

Attachment E - Template 5
Form for assurance of confidentiality and informed consent/Off-site:
Waiver of SF-1164 & signed informed consent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Assurance of Privacy and Informed Consent Form
Interviews Conducted Off-site

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to read this form.

Purpose of the Research
Surveys are used to collect information on the health and well being of Americans. The surveys help to develop programs to improve the health and health care of people living in the United States.

Before health surveys are conducted, the questions are tested with people like you. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way. The National Center for Health Statistics conducts these tests for the surveys it sponsors and for other survey programs. If you agree to take part in this test, we will ask you to answer the survey questions. Then, we will ask you to explain what you were thinking and how you came up with your answers.

The questions that we are working on today are about [FILL].

Your interview will show us how to improve the questions for this survey. In the future, we may also study your interview along with interviews from other projects. This type of study will teach us about the different kinds of problems people have answering survey questions. The study will help us write better questions in the future.

Procedures
An interviewer will ask you some survey questions. Then, the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will ask you if there were any words that were confusing and if you understood what was being asked.

The interview will last [duration], and we will give you $XX.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop the interview at any time. While the interview is going on, researchers from [FILL AGENCY] who are working with us on this project may [watch/listen to] the interview.

If you have questions about how the project works, contact Ms. Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings
We would like to video/audio[1] record your interview. The recording allows us to more carefully study the questions. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may ask to stop the recording at any time, and we will turn off the machine. If you decide to stop taping, we will ask your consent to

retain the portion already taped.

If you agree to record the interview, we will keep it in a locked room or in the safe keeping of a staff person from the Questionnaire Design Research Laboratory (QDRL). At a later time, staff from the [FILL AGENCY] who are responsible for developing questions on these topics may [watch/listen to] the interview. However, they must agree to keep your personal data private. Also, they must [watch/listen to] the interview in the QDRL or with QDRL staff present.

Privacy
We are required by law[2] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Audio and video recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project, however, may recognize you or your voice.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

Benefits and Risks[3]
Other than the $XX you receive, there are no other direct benefits from taking part in this study.

There are no known physical or psychological risks from taking part in this study. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full $XX.

<u>Conducting an interview at a business location</u>
The interview will be conducted in a closed office. We will protect any materials that contain your personal information and transport them to NCHS.

<u>Conducting a home interview</u>
In order for you to take part in the study today, we agreed to come to your home. Meeting in your home is your choice. However, you are urged to choose a place that is private so that you will feel comfortable answering the questions. We will protect any materials that contain your personal information and transport them to NCHS.

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03- XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible.

Please Read and Check Below if You Agree

- I freely choose to take part in this research study.

- I allow NCHS to audio record my interview. I also allow NCHS to play my audio recording to other people working on this project either in the QDRL or in another location under the direct supervision of QDRL staff.

- I do not allow NCHS to record my interview.

[1]Either video or audio will be selected.

[2]The Public Health Service Act provides us with the authority to do this research (42 United States Code 242K)

I hereby certify that the participant has read and filled out the above form.

Signature of interviewer: _____ Date: _____ Time: _____

Signature of 2nd interviewer: _____ Date: _____ Time: _____

and requires us to hold everything you tell us in strict confidence (42 United States Code 242m(d)). In addition, the provisions of the Privacy Act of 1974 (5 United States Code 552a) and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) apply, with the latter providing for a felony conviction and/or a fine of up to $250,000 if we violate this promise.

[3]Depending on the study, select either conducting an interview at a business location or conducting a home interview.

OMB #0920-0222; Expiration Date: 01/31/07

FOR OFFICE USE ONLY

Attachment F
Participant Data Collection Sheet

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

OMB# 0920-0222; Approval expires 01/31/07

Participant Data Collection Sheet

For our records we would appreciate it if you would take a minute to fill out this form.

1. How did you hear about us?

Newspaper Ad:	Flyer:	Word of Mouth:
Gazette	Giant	Friend
Sentinel	Safeway	Co-worker
Washington Post/Express	Other	We called you to come back

2. Are you male or female?

Male Female

3. What is your date of birth?

Date of Birth: ____/___/___

4. What is your marital status?

Married Divorced Widowed Separated Never been married

5. Are you Hispanic or Latino?

Yes No

6. What is your race? Mark one or more races to indicate what you consider yourself to be.

American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White

7. What is the highest grade of school you have completed?

9th
10th
11th
12th no diploma
High School Graduate - High School Diploma or the equivalent (for example: GED)
Some college but no degree
Associate Degree in college - Occupational/vocational program
Associate Degree in college - Academic program
Bachelor's degree (For example: BA, AB, BS)

Master's degree (For example: MA, MS, MEng, MEd, MSW, MBA)
Professional or Doctorate (for example: MD, PhD, DVM, JD)

8. Are you currently employed?
Yes No

9. What is your total household income?
20K or less 30K or less over 30K

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

OMB #0920-0222; Expiration Date: 01/31/07

Special Consent for Expanded Use of Video and Audio Recordings

Purpose
QDRL staff often presents what we learn from our projects at conferences or professional meetings. We would like your permission to show this recording to those who are interested in survey questions but who are not working directly on this project. If you agree, we may show the recording at conferences, for students, or for other people who write survey questions. In these cases, the recording is always under the control of QDRL staff.

Why do we want to show the recordings?
The recordings show how people react to survey questions. They show how questions can be hard to understand or hard to answer. They help people write better survey questions. It may also teach other researchers how to test survey questions.

Where might the recordings be shown?
We may show parts of the recording in a small meeting room, a classroom, or a large group at a professional meeting.

What information will be on the recording?
The whole recording could be shown. But it is more likely that a short piece will be shown about a problem with a question. No information about you will be added to the recording. However, your face and/or voice will appear on the recording.

What if I say yes now, but change my mind later?
If you change your mind, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782. You may change your mind at any time. When she receives your request, we will not allow special uses of your recording.

Questions
If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible. Your call will be returned as soon as possible.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

If You Agree, Please Read and Sign Below

- I allow NCHS to show my recording to people at conferences and meetings, to students, and to other people who write survey questions. I understand that my face and/or voice will appear on the recording. The recording will not be altered. The recording will be in the control of QDRL staff. If I change my mind at any time, I will contact Karen Whitaker, the

NCHS Lab Manager.

- I do not allow NCHS to use my recording in this way.

_____ _____

Participant Signature **Print name** **Date**

Attachment H
Form for special consent for expanded use of video and audio recordings for individual participants of discussion groups

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

OMB #0920-0222; Expiration Date: 01/31/07

Special Consent for Expanded Use of Video and Audio Recordings for Individual Participants of Discussion Groups

Purpose
QDRL staff often presents what we learn from our projects at conferences or professional meetings. We would like your permission to show the group discussion recording to those who are interested in survey questions but who are not working directly on this project. If you agree, we may show the recording at conferences, for students, or for other people who write survey questions. In these cases, the recording is always under the control of QDRL staff.

Why do we want to show the recordings?
The recordings show how people react to survey questions. They show how questions can be hard to understand or hard to answer. They help people write better survey questions. It may also teach other researchers how to test survey questions.

Where might the recordings be shown?
We may show parts of the recording in a small meeting room, a classroom, or a large group at a professional meeting.

What information will be on the recording?
The whole recording could be shown. But it is more likely that a short piece will be shown about a problem with a question. No information about you will be added to the recording. However, your face and/or voice will appear on the recording.

What if I say yes now, but change my mind later?
If you change your mind, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782. You may change your mind at any time. When she receives your request, she will edit the recording to erase any section in which you are heard or seen.

Questions
If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #2002-03-XX [Note: The amendment number will be inserted into the form once NCHS ERB approval has been received]. Your call will be returned as soon as possible. Your call will be returned as soon as possible.

If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

If You Agree, Please Read and Sign Below

- I allow NCHS to show the recording to people at conferences and meetings, to students, and to other people who write survey questions. I understand that my face and/or voice will appear on the recording. The recording will not be altered.

The recording will be in the control of QDRL staff. If I change my mind at any time, I will contact Karen Whitaker, the NCHS Lab Manager.

- I do not allow NCHS to use the recording in this way.

_____ _____

Participant Signature **Print name** **Date**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

OMB #0920-0222; Expiration Date: 01/31/07

Special Consent to Send Video and Audio Recordings to Off-site Researchers

Purpose
We are asking for your permission to send the recording to [FILL AGENCY] so that the staff working on this project can view it at their location.

Only staff working on this project from [FILL AGENCY] will be allowed to borrow the recording. They must sign a contract with NCHS saying how they will protect your privacy and the recording until it is returned to NCHS.

What information will be on the recording?
The whole recording could be sent but, more likely, a short piece of the recording will be sent that shows a problem with a question. No information about you will be added to the recording. However, your face and/or voice will appear on the recording.

How will the recording be shipped?
The recording will be sent using Federal Express. It will be returned to NCHS by the same method.

What if I say yes now, but change my mind later?
If you change your mind, contact Karen Whitaker by phone at (301) 458-4569, or by mail at NCHS, Room 3101, 3311 Toledo Rd., Hyattsville, MD 20782. You may change your mind at any time. When she receives your request we will not allow the recording to be sent out.

Questions
If you have questions about NCHS privacy laws and practices, contact Alvan Zarate, Ph.D., Confidentiality Officer at (301) 458-4601.

If You Agree, Please Read and Sign Below

Permission to allow shipment of the recording to other locations:

- I allow NCHS to ship my interview to [FILL AGENCY] by Federal Express. I understand the recording will be returned to NCHS by Federal Express. If I change my mind at any time, I will contact Karen Whitaker, the NCHS Lab Manager.

- I do not allow NCHS to use my interview in this way.

Participant Signature	**Print name**	**Date**

Attachment J

NCHS Ethics Review Board Approval documentation for research involving human subjects

From: LaRochelle, Dewey H.
Sent: Wednesday, October 19, 2005 11:01 AM
To: Woo, Marsha; Beatty, Paul C.; Miller, Kristen S.; Whitaker, Karen R.; Willson, Stephanie
Cc: Zarate, Alvan O.; Akinbami, Lara; Blumberg, Stephen J.; Madans, Jennifer H.
Subject: Continuation of Protocol #2002-03 NCHS Laboratory-Based Questionnaire Design
October 19, 2005

From: Lara Akinbami, MD
Chair, NCHS Research ERB
Stephen Blumberg, Ph.D.
Co-Chair, NCHS Research ERB

Continuation of Protocol #2002-03 NCHS Laboratory-Based Questionnaire Design

To: Karen Whitaker,
Paul Beatty,
Kristen Miller,
Stephanie Willson,

The NCHS Research ERB reviewed the request for approval of Continuation of Protocol #2002-03 NCHS Laboratory-Based Questionnaire Design on 10/19/2005. Continuation of Protocol #2002-03 NCHS Laboratory-Based Questionnaire Design is approved for the maximum allowable period of one year.

IRB approval of protocol #2002-03 NCHS Laboratory-Based Questionnaire Design will expire on **11/19/2006**.

OF NOTE:
1. The Board noted that the word "with" is missing from the first sentence of page 11. The Board trusts this will be corrected.

If it is necessary to continue the study beyond the expiration date, **a request for continuation approval should be submitted about 6 weeks prior to 11/19/2006.**

There is no grace period beyond one year from the last approval date. In order to avoid lapses in approval of your research and the possible suspension of subject enrollment, please submit your continuation request at least six (6) weeks before the protocol's expiration date of 11/19/2006. It is your responsibility to submit your research protocol for continuing review.

Any problems of a serious nature should be brought to the immediate attention of the Research ERB, and any proposed changes should be submitted for Research ERB approval before they are implemented.

Please submit "clean" copies of the revised protocol or consents and any other revised forms to this office for the official protocol file.

Please call or e-mail me or Dewey LaRochelle if you have any questions.

Lara Akinbami, MD
Chair, NCHS Research ERB

Stephen Blumberg, Ph.D.
Co-Chair, NCHS Research ERB

Attachment K
Template 1: participant recruited from newspaper advertisement

Sample screening script for participant contact by QDRL Laboratory Manager
For cognitive testing and evaluation of [FILL]
recruited from newspaper advertisement/flyer

REVIEWERS: NOTE THAT THE FOLLOWING IS A PROTOTYPE SCRIPT THAT IS GENERALLY FOLLOWED BY THE QDRL LABORATORY MANAGER FOR PLACING RETURN CALLS TO POTENTIAL PARTICIPANTS WHO HAVE RESPONDED TO OUR RECRUITMENT ADVERTISEMENT BY LEAVING THEIR NAME AND A DAY TIME PHONE NUMBER ON OUR ANSWERING MACHINE. THE QDRL LABORATORY MANAGER DEPARTS FROM THIS AS APPROPRIATE, GIVEN THE NATURE OF THE PARTICULAR STUDY BEING CONDUCTED.

Dial participant's telephone number [hereafter referred to as *P*] as indicated on audiotape recording.

- **Note: Speak only to *P*. If the number is answered by an answering machine, call back at another time.**

- **Laboratory Manager:** Good morning/afternoon, may I speak to (name)?

- **If *P* is not available or not at home, say, "Thank you" and try again at another time.**

- **If *P* has been successfully contacted, continue...**

...Hello, my name is [Laboratory Manager's name]. I am calling from the National Center for Health Statistics. You may remember that you responded to the advertisement we placed in the [name of newspaper] on [date] or flyer looking for people to answer some questions about [FILL].

- **Wait for acknowledgment, such as, "Oh, yes, I remember."**

...In order to determine if you are eligible for our study, I'll need a few minutes of your time to ask some background questions. Answering these questions is completely voluntary. Your answers will be kept strictly confidential. Is this a good time to ask the questions or should I call back later?

- **If not a good time to talk, schedule a time to call back.**
- **If good time to talk, continue...**

Note: Additional questions may be asked which are specific to the project for which the participant is being recruited.

1. Where did you see our advertisement?

   _____

2. How old are you? **[If under age 18, go to exit script 1].**

_____

3. How many years of education do you have?
   □9 or less □10 □11 □12 □13 □14 □15 □16 □17 □18 □19

4. Are you Spanish, Hispanic or Latino?
   □ Yes
   □ No

5. What race or races do you consider yourself to be? You may indicate more than one race.
   □ White
   □ Black or African American
   □ Asian
   □ American Indian or Alaska Native
   □ Native Hawaiian or Other Pacific Islander

6. Please tell me which of the following categories represents your total household income last year:
   □ $20,000 or less
   □ $20,001 - $40,000
   □ $40,001 - $60,000
   □ more than $60,000

If quota has been met go to exit script 2.

Entry Script:
...Based on your answers to the questions, we would like you to take part in our study. For this study an interviewer will ask you a variety of questions about [FILL]. Then the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will also ask you about your opinions of the questions. Your answers will help us find out if the survey questions will be easy for other people to answer. Everything you say will be kept private. With your permission, we would like to audio/videotape your interview. The tape is a record of what we asked and what you said. Do you give permission to have your interview audio/video taped? *Yes/No*. **[If no, go to exit script 3. Videotaping is essential for this project].**

Do you have any questions at this point? *Pause to answer questions.* If (not/you have no other questions), then let's get you on the schedule, ok? We will be interviewing (Day, Month/Date) through (Day, Month/Date) from 8 a.m. to 6 p.m. Looking at your schedule, when would you be available to participate? *Schedule.* **[If date/times not available go to exit script 4.]**

A reminder call will be made to you a few days in advance. Should you have any questions or need to change your appointment, please feel free to contact me [name] at [phone number]. Thank you for responding to our ad, and I look forward to seeing you here at (DATE/TIME) *Get respondent to cite date*

& time if possible.

Exit script 1: I'm sorry, you have to be over the age of 18 to take part in this study and therefore we won't be able to use you at this time. However, I would like to put your name and telephone number you gave me into our database so that I can contact you about other studies coming up in the future. Is that OK? *If yes, record name & telephone number. If no: OK, thank you for your time. Your name and telephone number will not be added to our database.*

Exit script 2: Based upon your answers, it seems that we may already have a number of volunteers with very similar answers to yours. At this point we need to talk with people with some different characteristics. However, if we have cancellations or other slots open up, I may wish to call you back. Would it be okay if I kept your name, telephone number, and the information you provided in response to the eligibility questions until the end of this study? *If yes*, make notation. *If no,* Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Exit script 3: I'm sorry, willingness to be videotaped is required in order to take part in this study and therefore we won't be able to use you at this time. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Exit script 4: I see...ok, we were hoping to complete this particular study between (Month/Date) and (Month/Date), so it looks like we won't be able to schedule you at this time. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Sample screening script for participant contact by QDRL Laboratory Manager
For cognitive testing and evaluation of [FILL]
recruited from QDRL Database

REVIEWERS: NOTE THAT THE FOLLOWING IS A PROTOTYPE SCRIPT THAT IS GENERALLY FOLLOWED BY THE QDRL LABORATORY MANAGER FOR PLACING RETURN CALLS TO POTENTIAL PARTICIPANTS WHO HAVE RESPONDED TO OUR RECRUITMENT ADVERTISEMENT BY LEAVING THEIR NAME AND A DAY TIME PHONE NUMBER ON OUR ANSWERING MACHINE. THE QDRL LABORATORY MANAGER DEPARTS FROM THIS AS APPROPRIATE, GIVEN THE NATURE OF THE PARTICULAR STUDY BEING CONDUCTED.

Dial participant's telephone number [hereafter referred to as *P*] as indicated in the QDRL database.

- **Note: Speak only to *P*. If the number is answered by an answering machine, call back at another time.**

- **Laboratory Manager:** Good morning/afternoon, may I speak to (name)?

- **If *P* is not available or not at home, say, "Thank you" and try again at another time.**

- **If *P* has been successfully contacted, continue...**

...Hello, my name is [Laboratory Manager's name]. I am calling from the National Center for Health Statistics. You may remember that you participated in a research study back in [date] testing questions on [topic].

- **Wait for acknowledgment, such as, "Oh, yes, I remember."**

…We are in the process of testing a variety of questions about [FILL] and wondered if you might be interested in participating.

- **If P indicates they are interested in participating continue…**

- **If P indicates they are NOT interested in participating, go to exit script 4.**

...In order to determine if you are eligible for our study, I'll need a few minutes of your time to ask some background questions. Answering these questions is completely voluntary. Your answers will be kept strictly confidential. Is this a good time to ask the questions or should I call back later?

- **If not a good time to talk, schedule a time to call back.**
- **If good time to talk, continue...**

Note: Additional questions may be asked which are specific to the project for which the participant is being recruited.

1. Where did you see our advertisement?

   _____

2. How old are you now?

   _____

3. How many years of education do you have?
   □9 or less □10 □11 □12 □13 □14 □15 □16 □17 □18 □19

4. Are you Spanish, Hispanic or Latino?
   □ Yes
   □ No

5. What race or races do you consider yourself to be? You may indicate more than one race.
   □ White
   □ Black or African American
   □ Asian
   □ American Indian or Alaska Native
   □ Native Hawaiian or Other Pacific Islander

6. Please tell me which of the following categories represents your total household income last year:
   □ $20,000 or less
   □ $20,001 - $40,000
   □ $40,001 - $60,000
   □ more than $60,000

If quota has been met go to exit script 1.

Entry Script:
...Based on your answers to the questions, we would like you to take part in our study. For this study an interviewer will ask you a variety of questions about [FILL]. Then the interviewer will ask you to explain what you were thinking as you answered the questions. The interviewer will also ask you about your opinions of the questions. Your answers will help us find out if the survey questions will be easy for other people to answer. Everything you say will be kept private. With your permission, we would like to audio/videotape your interview. The tape is a record of what we asked and what you said. Do you give permission to have your interview audio/video taped? *Yes/No*. **[If no, go to exit script 2. Videotaping is essential for this project].**

Do you have any questions at this point? *Pause to answer questions.* If (not/you have no other questions), then let's get you on the schedule, ok? We will be interviewing (Day, Month/Date) through

(Day, Month/Date) from 8 a.m. to 6 p.m. Looking at your schedule, when would you be available to participate? *Schedule.* **[If date/times not available go to exit script 3.]**

A reminder call will be made to you a few days in advance. Should you have any questions or need to change your appointment, please feel free to contact me [name] at [phone number]. Thank you for responding to our ad, and I look forward to seeing you here at (DATE/TIME) *Get respondent to cite date & time if possible.*

Exit script 1: Based upon your answers, it seems that we may already have a number of volunteers with very similar answers to yours. At this point we need to talk with people with some different characteristics. However, if we have cancellations or other slots open up, I may wish to call you back. Would it be okay if I kept your name, telephone number, and the information you provided in response to the eligibility questions until the end of this study? *If yes*, make notation. *If no,* Would it be okay if I kept your name, telephone number, age, educational level, and race in our database so that I can contact you about other studies coming up in the future? If yes, make notation. If no: OK, thank you for your time. Your name and any information you gave me will be deleted from our database.

Exit script 2: I'm sorry, willingness to be videotaped is required in order to take part in this study and therefore we won't be able to use you at this time. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Exit script 3: I see...ok, we were hoping to complete this particular study between (Month/Date) and (Month/Date), so it looks like we won't be able to schedule you at this time. Would it be okay if I added your name, telephone number, age, educational level, and race to our database so that I can contact you about other studies coming up in the future? If yes, add to database. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Exit script 4: I see...ok. Would it be okay if I kept your name, telephone number, age, educational level, and race in our database so that I can contact you about other studies coming up in the future? If yes, make notation. If no: OK, thank you for your time. Your name and any information you gave me will not be added to our database.

Attachment L
Sample recruitment flyer

Participants Wanted for Research Study

The National Center for Health Statistics
is looking for parents of children 19 to 35 months of age, for a [XX] minute interview testing questions that will be used on a national health survey. All parents are welcome, but we are especially interested in those whose children are not up-to-date with their immunization shots.
Participants will receive [$XX].

FOR MORE INFORMATION,

Please call Karen at: **301-458-4676**
by month, Day, Year

Centers for Disease Control and Prevention
National Center for Health Statistics

Attachment M
Sample Newspaper advertisement

Parents Wanted for Research Study

The National Center for Health Statistics is looking for parents of children 19 to 35 months of age, for a [XX] minute interview testing questions that will be used in a national health survey. All parents are welcome, but we are especially interested in those whose children are not up-to-date with their immunization shots. Participants will receive [$XX].

FOR MORE INFORMATION,
Please call: **301-458-4676**

Centers for Disease Control and Prevention
National Center for Health Statistics

Attachment N- Sample script of answering machine

Thank you for calling the Questionnaire Laboratory at the National Center for Health Statistics in Hyattsville, Maryland. As stated in our advertisement placed in the [Name of newspaper] on [Month, date] we are looking for parents aged 18 and older who have children between the ages of 19 - 35 months to help us test survey questions on immunization. Volunteers spend one [time, i.e., 1 hour/ 1 ½ hours] answering survey questions and will receive $XX. If you would like to volunteer for this study, please leave the following information: 1) your name, 2) a daytime phone number and 3) the number and age of children you have between 19-35 months of age. Someone will call you back shortly to see if you are eligible for our survey. Thank you for calling and have a nice day.

Detailed explanation of cognitive interviewing procedure read by interviewer to participant

Reviewers: Note that the following is a prototype script that is generally followed by the interviewer. The interviewer departs from this as appropriate, given the mode of the study being conducted, i.e., face-to-face, telephone, self-administered, CAPI, CASI, etc. The script is read after the subject has read and signed the Assurance of Confidentiality and Informed Consent (Appendix E), filled in their demographic characteristics on the Participant Data Collection Sheet (Appendix F), filled out their payment form, and confirmed that they understand that the interview will be audio/videotaped.

Thank you for agreeing to participate in this interview today. You have read the Assurance of Privacy and Informed Consent and you have chosen to take part in this research study. Is that correct? *[Interviewer waits for verbal acknowledgment]*. You have given your permission for me to audiotape/videotape your interview today. Is that correct? *[Interviewer waits for verbal acknowledgment]*. The lab manager/[Karen] has told you that we are testing questions on [health topic advertised in newspaper or flyer] for [name of survey if applicable]. Before they are used on a survey which may involve thousands of people, we want to see whether they make sense, whether they are difficult to answer, and learn how easy it is to remember the things we ask about.

I will ask you these questions, and I'd like you to answer each of them. If you can, I'd like you to think out loud while you're doing that, to let me know how you're figuring out your answer to each question. I'd also like you to tell me if any question seems confusing or if you're having a hard time answering. After you answer, I might ask you to explain what you meant in more detail, tell me more about how you came up with your answer, and so on.

Do you understand what I'm asking you to do? (Explain again if needed). Do you have any (more) questions? Okay, let's begin. We will do this for [time stated in newspaper advertisement/flyer], unless we get done with the questionnaire first.