SEARCH 4 MOP
Section 2 - General Research Guidelines & Interviewing
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2. General Research Guidelines

2.1. HUMAN SUBJECTS INFORMATION

SEARCH investigators will comply with federal regulations governing human subject research as outlined in the Code of Federal Regulations (CFR) Title 45 Part 46. Since SEARCH investigators will register and recruit cases of diabetes in young people diagnosed <20 years of age, regulations of Subpart D, Additional DHHS Protections for Children Involved as Subjects in Research, will be followed.

2.1.1. *HIPAA Privacy Act*

The Office of Civil Rights has established a Privacy Rule for research, OCR Health Insurance Portability and Accountability Act (HIPAA) Privacy TA.5121.001. The Privacy Rule establishes conditions under which protected health information may be used or disclosed for research purposes. The Privacy Rule protects an individual's identifiable health information while allowing for the conduct of vital research, with researchers accessing necessary medical information. The means of informing individuals of use or disclosure of medical information are also defined in the Privacy Rule. SEARCH centers will comply with HIPAA guidelines contingent on the interpretations and processes defined by the local Institutional Review Boards (IRBs) and Privacy Boards. As an added protection for the privacy of study participants, SEARCH investigators will have a renewed Certificate of Confidentiality from the Department of Health and Human Services that was received previously obtained in SEARCH 1, 2, and 3.

2.1.2. *Informed Consent*

2.1.2.1. Overview

The success of every research study depends on full disclosure of study processes to its participants in order to ensure informed participation. To meet SEARCH study objectives, *informed consent* and in many instances – *assent* -must be obtained. Obtaining informed consent is the responsibility of the study team and should be an ongoing process throughout the course of the study.

45 CFR 46.116 "General Requirements for Informed Consent" states:

- *No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient*

opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

- *The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.*
- *No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release.*

2.1.2.2. Basic Elements of Informed Consent

While each IRB maintains specific policies relating to informed consent, there are some basic elements that should be included in both the written informed consent documents and the verbal communications between study staff and study participants. These include:

- A statement that the procedures are for research, an explanation of the purposes of the research, the expected duration of the participant's involvement, and a description of the procedures to be followed. A description of any reasonable foreseeable risks or discomforts to the participant;
- A description of any benefits to the participants or to others that may be reasonably expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; the data that is collected from this study and will be maintained by a Coordinating Center; the sharing of data and samples with a central Laboratory that will process and store all specimens; and the sharing of data with central reading centers, including for studies of neuropathy, retinopathy, and cardiology.
- An explanation as to whether compensation and medical treatments are available if any injury occurs, and, if so, what these treatments may consist of and where further information on these treatments can be found;
- An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of research-related injury to the participant; and

- A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled. Additionally, the participant may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

When appropriate, the following additional elements will be included in the consent document:

- A statement that the particular treatment or procedure may involve currently unforeseen risks to the participant;
- Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the participant's consent;
- Any additional costs to the participant that may result from participation in the research;
- The consequences of a participant's decision to withdraw from the research, and procedures for orderly termination of participation;
- A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided;
- The approximate number of participants involved in the study;
- Incentives and any travel or other reimbursements that will be provided to the participants; and
- Required language regarding the Certificate of Confidentiality.

As required by NIDDK, the consent forms include language requesting permission to share blood, urine and DNA samples (and associated de-identified data) with the NIDDK central repository. Standard language is provided.

SEARCH study participants should have a clear understanding of what this study makes available to them, e.g., laboratory testing that might not be part of their usual diabetes care.

Informed consent shall be documented as specified by the local IRB. The requirements for obtaining informed consent may vary depending on the participant's level of participation in SEARCH (e.g., a participant whose participation is limited to the IPS or online/mailed forms may be approved for verbal consent, or a waiver of documentation of consent may be approved by the local IRB). For participants taking part in an in-person visit, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form.

2.1.2.3. Non-English Speaking Participants

- Informed consent documents should be available in a language spoken by non-English speaking participants/parents/legal guardians, and will include all of the basic essential elements described above (2.1.1.2.);
- Alternative consenting processes for non-English speaking participants will be site-specific per local IRB requirement.

2.2. RESEARCH WITH CHILDREN

While IRBs are concerned with protecting the rights of all research participants, the vulnerability of children makes consideration of them as research participants particularly important. In consideration of this, Title 45 CFR Part 46, Subpart D provides for "Additional Protections for Children Involved as Subjects of Research."

Given that children have not reached their full intellectual and emotional capacities and are legally unable to give valid consent, parental or guardian permission is required. While children may be legally incapable of giving informed consent, they may possess the ability to *assent*[1] to or *dissent* from participation. In general, out of respect for children as developing persons, they should be asked whether or not they wish to participate in the research, and their wishes should be honored. The specific process for and age of assent shall be determined by individual IRB requirements.

2.2.1. *Re-consenting Participants Who Reach the Legal Age of Consent*

The Office for Human Research Protections (OHRP) notes that informed consent should be viewed as an ongoing process throughout the duration of a research project. When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research is no longer regulated by the requirements of 45 CFR part 46.408 regarding parental or guardian permission and subject assent.

Unless the Institutional Review Board (IRB) determines that the requirements for obtaining informed consent can be waived, the investigators should seek and obtain the legally effective informed consent, as described in 45 CFR 46.116, for the now-adult subject for any ongoing interactions or interventions with the subjects. This is because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult subject. However, the IRB could approve a waiver of informed consent under 45 CFR 46.116(d), if the IRB finds and documents that the required conditions are met.

[1] Assent can be defined at the child's affirmative agreement to participate in research.

Similarly, if the research does not involve any ongoing interactions or interventions with the subjects, but continues to meet the regulatory definition of "human subjects research" (for example, it involves the continued analysis of specimens or data for which the subject's identity is readily identifiable to the investigator(s)), then it would be necessary for the investigator(s) to seek and obtain the legally effective informed consent of the now-adult subjects. The IRB may consider, if appropriate, a waiver under 45 CFR 46.116(d) of the requirements for obtaining informed consent in order for the subjects to continue their participation in the research.

2.3. GUIDELINES TO INTERACTING WITH STUDY PARTICIPANTS

The following section provides an overview of interacting with study participants. For more information on interviewing and building rapport, see the appendix at the end of this chapter.

2.3.1. *The Role of the Study Staff*

Study investigators and staff play an integral role in setting the tone of the participant's involvement in SEARCH. Study personnel should establish and maintain a positive rapport with the participant in order to ensure the willingness of the participant to remain in the study.

Once rapport is established and the participant indicates a willingness to participate in the study, the interviewer should attempt to maintain a positive rapport while asking study questions in a way that does not overly influence the participant's perception or response to a question. Here are some methods that can enhance the neutrality of the interview:

- Utilization of structured or scripted interviews or instructions that provide specific information and assure limited interviewer bias;
- Monitoring one's own non-verbal and verbal responses that may influence a participant's response;
- Conveying a sense of impartiality that does not impose judgment on the participant's response;
- Maintenance of a professional appearance, dress and speech;
- Maintaining a pleasant and friendly attitude, to place the respondent at ease.

2.3.2. *The Study Visit Environment*

In order to maintain the privacy and confidentiality of the data collection, the visit should be conducted in a quiet, private area free from interruption.

2.3.3. *Questionnaire Data Collection*

Most SEARCH questionnaires are designed to be collected via self-administration (with assistance from staff as needed). If the forms are completed via interview, the study staff person should attempt to determine a comfortable pace for the participant. Instructions

and questions should be read as written. If the participant does not respond, the question should be repeated.

While scripted interviews reduce the potential of interviewer bias, it is occasionally necessary to prompt respondents or probe for additional information. Additionally, the developmental age of the child and cultural variation may require elements of prompting to elicit a response. Methods of prompting should be driven by the age and needs of the respondent.

Remember that the balance between probing and directing responses is a difficult one to maintain. The interviewer should be certain that they are merely eliciting *clarification* and not pushing or coercing a participant to respond in a particular manner. It is important that the interviewer be able to assess when probing should stop. The participant should not perceive themselves as ignorant or feel their responses are inadequate.

Additional information about interviewing techniques and questionnaire data collection can be found in the appendix below.

2.3.4. *Confidentiality*

Participants must be assured that confidentiality will be maintained throughout the study. Westat (1987) noted:

> *"An interview must often ask questions that one would not think of asking even a close friend. Most people, however, are willing to answer such questions when they are asked in an interview. They are willing to give information because they trust that it will be used only for serious purposes. Your protection of all information about subjects gained during the conduct of research is therefore essential. This means to protect not only the information you get in direct answer to the questions you ask in an interview, but also the information you gather through incidental observation of the participant.*
>
> *It is important that care be taken in maintaining confidentiality of completed questionnaires while in your possession. Always make sure that questionnaires are not left where non-research staff can view them. You must safeguard the completed questionnaires by not leaving them unattended, such as in your car where they might be stolen, or in a schoolroom, clinic room or office where anyone could walk in and read them.*
>
> *It is your duty to keep the promise of confidentiality. Never divulge names or tell facts about or reveal the opinions of anyone you interview.*
>
> *Information collected or seen during an interview can be shared only with the research team, whose members are under the same ethical or moral obligation as you are to the people interviewed. As you may know, persons*

who participate in research studies have rights to privacy that are protected by federal law. Maintaining confidentiality of data is not just a philosophical issue for an interviewer. It means that an interviewer must be aware of the importance of protecting the confidences of the study subjects on a day-to-day basis. For example, a comment to a friend outside of the research team about a particular subject or subject's response is a breach of confidentiality, violates the HIPAA Privacy Act, and is unprofessional conduct as an interviewer."

2.4. TECHNIQUES FOR COMPLETING STUDY FORMS

The goal of data management activities is to provide high quality data. In order to maintain data quality, accurate completion of study forms and data entry is essential. Most issues of form completion are common sense, but the importance warrants attention.

For data collected on paper, an important issue is to complete the forms neatly so data entry personnel can accurately enter the information. Be aware that numerals 1, 2, and 7 are the most often confused.

- Develop habits of making clear strokes at the bottom of a "2" (that would distinguish it from a "7").
- Refrain from making downward strokes at the top of a "1" that could confuse it with a "7."
- If mistakes are made, mark through the incorrect response with a single line, record and circle the correct response. Place your initials next to the correct response.
- Forms should be completed using a pen, preferably with black ink.
- Review completed forms for accuracy.

Participants may also elect to complete data collection forms before, during, or after the in-person visit. If the participant chooses to complete the forms at a time other than at the visit, the questionnaires will be mailed or an online link will be sent to the participant with clear instructions about completion.

For more specific guidance on issues related to self-administered questionnaires see the appendix below.

APPENDIX: INTERVIEWING & BUILDING RAPPORT

Overview

Interviewing is a science with definite rules that produce valid results. Interviewing is also an art. While general guidelines provide a blueprint to follow, much depends on the sensitivity of the interviewer. The procedures and techniques that follow will help you to conduct interviews that will yield valid data.

Developing a Good Relationship

Interviewing is a factor of the SEARCH study and therefore it is important that the interviewer present questions appropriately, record the participant's replies precisely and accurately, and probe meaningfully. In order to maintain an objective, information- gathering atmosphere, the interviewer must convey an understanding persona and be capable of accepting information in a non-judgmental manner. The interviewer must also portray an interest in what the participant is saying. The participant must find satisfaction in talking to a receptive person without the fear of appearing inadequate.

It is be the interviewer's responsibility to obtain complete and accurate information. Interviewers are skilled professionals. Their skills make it possible for participants to give frank, complete, relevant answers to questions.

Most of the questionnaires in SEARCH 4 can be self-administered, or they may be completed in interviewer format.

<u>Increasing the Participant's Cooperativeness</u>

Previous studies have identified several factors that will increase the respondent's receptiveness.

- Be prepared and know your material. Participants need to feel that you are interested in the study and interested in their opinions. Be an active listener and establish comfortable eye contact with the participant.
- Offer convincing statements about the purpose of the study.
- Describe the beneficial uses of the research findings to both the respondent and to the community.

Interviewer Administered Questionnaires

There are several standard procedures for reading questions:

- Read in a natural conversation rhythm and in a normal tone of voice.
- Read as if you are speaking.
- Be cautious about reading questions too rapidly; the participant may not feel comfortable asking you to repeat questions and consequently the answer will not reflect his/her true thoughts on the issue.
- Be aware of the participant's facial expressions, e.g., puzzled, confused.

- Repeat the question if it is answered inappropriately, but repeat it exactly as written.
- Show no impatience when being asked to repeat a question.

Instructions are provided throughout SEARCH forms as needed. Instructions should be read to the participant.

Ask the questions exactly as worded and in the same order as they appear in the questionnaires. Minor changes in wording can completely change the meaning of a question. Similarly, you must follow the sequence of questions. Do not ask questions out of order unless you are given special instructions to do so.

Ask every question. It is the interviewer's responsibility to ask every question. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. Do not omit questions and do not assume that you know the answer to the question. Skip questions only as dictated by the participant's response and interviewing instructions.

How to Get Satisfactory Answers

Learn the purpose of each question. In order to do a good job of interviewing, you need to understand the kind of information we are trying to gather through each particular question. Unless you understand its purpose, you will not be able to judge when a response is adequate and when you must probe for clarification or for additional information.

Do not attempt to interpret/explain the question - maintain neutrality. If a participant does not seem to understand a question, repeat the question slowly and clearly. Give the participant time to think about the question (while simultaneously being aware of time allowed for administering the questionnaire). Unless you have other instructions about handling specific questions, the acceptable reply for a participant who wants to know what a question means is "whatever it means to you". Do not attempt to explain the purpose of a question unless the interviewer instructions specifically authorize you to do so.

Don't define terms used in questions. Some participants may ask what is meant by a word used in a question. Leave the matter of definition to the participant, suggesting "whatever you think ____ means" or "however you use the term _____". The exception to this is when a term has a specific diabetes definition. Information related to these types of questions can be found in the Manual of Procedures section related to that form.

Don't leave a question until you have an adequate answer or have determined that a participant can't give a clearer answer.

Be sure the time reference is appropriate. In any follow-up study, it is critical that the participant understands the time frame that is appropriate to the question. Many of the questions are prefaced by "In the past 6 months" or "Have you ever..." Always read these phrases within the questions as they appear on the form.

Probing Techniques

The two most effective neutral probes are silence and repeating the original question.

Silence. The value of silence cannot be overestimated. Many people, including interviewers, react to silence as a vacuum that must be filled with constant chatter. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence is more than most participants can take, and the participant will often expand or clarify a previously inadequate answer.

Repeating the Question or Answer Categories. Be sure to repeat the question as stated in the questionnaire. This is particularly useful when the participant answers a question irrelevantly. In some cases it will be necessary to remind the participant of your frame of reference, i.e., to acknowledge what the participant has said and then bring the participant back to the topic by repeating the question.

Do Not Accept a "Don't Know" Answer without Probing at Least Once. If a participant replies to a question with a response of "I don't know", gently probe by asking: "Well, what do you think?" or "I'd like to know your opinion" (if the question asks for an opinion rather than facts). If the question deals with facts, we prefer an approximation to no answer at all, and you might probe "what's your best guess?" or "approximately?" to convey the idea that 100% accuracy is not required.

Use Neutral Probes That Do Not Suggest Answers. Probes are needed to obtain more complete, accurate answers. All probes must be non-directive, i.e., the probe must not suggest any particular answer to the participant. Probes should be used whenever the participant is hesitant in answering questions; when he/she seems to have trouble expressing him/herself; when he/she seems too shy to speak at length; whenever there is any reason for the interviewer to believe that the participant has not given a complete report of his/her thoughts; and finally, whenever reassuring probes are needed for a participant who seems to lack confidence.

Examples of Other Neutral Probes:

1. In what way?
2. What is that? Why do you feel that way?
3. How do you mean?
4. I would like your impression.
5. I would like your opinion.
6. What do you think?
7. Can you give me an example? or For example?
8. Can you explain that in a little more detail?
9. How are you using the term. . .?

10. How is that? or How does that work?
11. Anything at all - even little things?
12. If you had to choose, which would you say?
13. What else can you tell me about that?

Generally Speaking, Some Probes Should Be Avoided in Favor of Others.

- Instead of "anything else?" you'll find that "what else can you tell me about that?" is more likely to elicit answers.
- Instead of "why?" you'll find "why do you feel that way?" or "I'd be interested in your reasons" accomplishes the same purpose and is less likely to be threatening.

Questions Used in Ordinary Conversation Should Be Avoided Because They Suggest Answers.

- Refrain from suggesting the answer to the participant. Do not ask "do you mean A or B". This suggests two possible answers and there may be others which may occur to the participant.
- Don't ask, "Do you mean…". People tend to say "yes" to any suggestion because they think it is the right answer.

Do Not Leave a Probe Dangling. Always record the response to a probe even if it's only "No" or "That's all I can think of".

Always Cross Reference. When you probe to clarify a response, always indicate which response you are clarifying. There will be times when a participant will say something ambiguous and continue talking.

If there's not enough space to record the respondent's answer, use the margin. Be sure to label the continuation of the response clearly.

Make Probes Consistent with the Purpose of the Question. The importance of choosing a probe that is appropriate for the particular kind of inadequate answer given cannot be stressed enough. Think through each response, evaluate it for relevance and clarity, and choose the right kind of probe. Any probe that does not suggest answers and is non-threatening is acceptable, provided it is appropriate to the particular interviewing problem.

Watch for Irrelevant Answers. Irrelevant answers can be interesting, but interviewers must bear in mind what information is being sought. Acknowledge the response and make it clear that you have been listening; also make clear your frame of reference before repeating the question. Repeat the question word-for-word, but preface it in such a way that you now need additional information. Consider saying, "I appreciate you sharing that information with me but I'd like to know more about 'X'", and then repeat the question as written on the form.

Watch for Vague, Incomplete Answers. A probe such as "tell me more about. . ." is effective.

Monitor for Inappropriate Responses. If the participant provides an inappropriate response to a question (e.g., uses the wrong response category), the interviewer may repeat the question *and* the response categories. Example: If the interviewer asks a question that requires the participant to provide their degree or level of agreement and, instead, the participant states, "That's true," the interviewer may respond "Would you say you strongly agree or agree?" If the participant provides an ambiguous response to a question, the interviewer should solicit an elaboration of the response without directing the response.

Avoid "Depends" or Qualified Answers. When the participant gives a response of this nature, it is advisable to use probes such as repeating the question; preface the question with a phrase such as "Well, in general . . ."

Record and Document Fully and Clearly. If a participant is having difficulty choosing a response between two or more of the response choices, a non-leading technique should be used, such as: 1) repeating the entire response set, or, 2) "Would you say it is closer to A or to B?" in a case where the subject has narrowed the choices.

Self-Administered Questionnaires

Most of the forms in SEARCH 4 may be self-administered.

Many of the general rules governing interviewer administered questionnaires are also applicable to self-administered questionnaires. Generally, these questionnaires will be self-reported by the participant or the parent/guardian. It is important to provide clear, concise instructions for completing these instruments and for study staff to be available to answer questions about the forms. If the form is being completed at the visit, staff will give instructions and answer questions in person. However, if the form is being completed at home, written instructions which include the following points should be mailed to the participant:

1. A summary of the content of each questionnaire;
2. Specific instructions regarding what to write with when completing the questionnaire, e.g., black ink pen;
3. A statement explaining that "There are no right or wrong answers. Please answer the questions to the best of your ability. Your answers are confidential;"
4. An invitation to call a staff member if the participant needs further clarification or has questions.

While the self-administered questionnaires are designed for ease of administration, the possibility exists that respondents, particularly children, may have difficulty completing the self-administered questionnaires based on their developmental age. According to the US Department of Education, in 1993 between 23 and 51% of the US population were either functionally illiterate or had limited literacy equating to having completed fewer than four years of schooling. This rate may be underestimated and has implications for questionnaire completion. In addition

to literacy, some respondents may have disabilities or impaired visual acuity that may impact their ability to respond to questionnaires. If any of these conditions exist, the forms should be interviewer administered.

Once completed, study personnel should evaluate the questionnaires for completeness, being certain not to be perceived as being judgmental of the responses. Questions regarding omissions should be clarified at this time.

How to Record the Interviews

The following guidelines are recommended for recording participant responses during an interview:

- Periodically establish eye contact with the participant while you read questions and write responses.
- Interviews should be recorded in black ink and in legible handwriting.
- Use abbreviations to help you record as much as possible.
- Always repeat a response using the participant's exact words.
- Always record verbatim the response to a probe.
- If you question whether you circled the correct answer, be sure to verify the response with the participant and record the verbatim response.
- If you make a recording mistake, put a single line through the error – do not erase or black out the incorrect response. Write the date and your initials, and then circle or write in the correct answer.
- If a participant fails to respond to a question, use the -9 code to indicate the response is known to be missing.

If a response requires a date and the Month or Day are unknown, enter **[-9]**. If the Year is unknown, enter **1800.** Unknown values are NOT acceptable for participant birthdates or visit/examination dates. The full date should be entered as Month, Day, and Year.

If a participant provides you with information that will help you unravel a confusing set of answers, take as many notes in the margin or at the back of the interview as you need. These will help you remember if a question arises at a later date.

Editing Study forms

Editing should be done as soon as possible after completion of the forms, preferably while the participant is still in the clinic. Editing should be completed both for forms completed at the study visit or forms completed prior to the study visit. It is easier to identify and correct a missed, unreadable, or confusing entry with the participant present. If a question arises once you no longer have face-to-face contact with the participant, you will need to decide if the information can be clarified over the phone or if it is best to record it as missing data. If it is

determined that the data can be captured by phone, contact should be made with the family as soon as possible after the visit since it is best to obtain/clarify all responses as close as possible to the time of the initial data collection.

One reason for many comments from editors and data entry staff is the illegibility of handwriting, both numbers and words. Be sure to RECORD RESPONSES AS CLEARLY AS POSSIBLE.

When editing look for: 1) completeness of the interview - no missing required data; 2) consistency - all the skip patterns should be observed and filled out appropriately; 3) clarity/legibility - clearly interpretable/readable data.

Interviewing non-English Speaking Participants

Interview forms are available in English and Spanish. Spanish versions of questionnaires will be used for Spanish-speaking participants. When interviewing non-English speaking participants, the interview should be conducted in the primary language of the participant with the assistance of a certified interpreter as indicated by the local IRB or other policies and regulations.