HALT-C Trial Quality Control and Quality Assurance Plan

I. Introduction

The goal of the Quality Control/Quality Assurance (QC/QA) Plan for the HALT-C Trial is to ensure standard administration of all study protocols and procedures by all HALT-C Trial staff at every clinical center, central lab and repository. When properly implemented, the QC/QA plan protects the scientific integrity of the Trial by maximizing the reliability and validity of the data collected.

The main objective of the QC/QA plan is to ensure that complete and accurate information is gathered in the data collection process. The plan ensures that all study protocols and procedures are performed in a standardized manner, across all clinical centers and all data collectors.

Standard application of the protocol will be accomplished by the following methods:

- Trial Data Management System (DMS)
- Double Data Entry of a percentage of selected forms
- 100 % Double Data Entry of Pathology reviews and HCV RNA results
- Comprehensive Manual of Operations
- User-friendly data forms and detailed Question by Question (QxQs) instruction sheets for each data form
- Memoranda and Communications
- Central Training
- Annual Site visits to each Clinical Center
- Periodic Visits to Central Lab and Repository
- Certification of staff performing data collection by interview
- Certification of staff performing data entry
- Biannual scheduled meetings with Study Coordinators
- Conference calls with Data Managers/Study Coordinators when needed
- On-going monitoring of data collection activities via reports
- Website Updates– central website restricted to use by HALT-C staff and investigators

II. Interview QA/Certification

Interviewers must be certified by the Data Coordinating Center (DCC) prior to conducting interviews for the study. To achieve interviewer certification, interviewers must:

- Attend an interviewer training session;
- Review the interviewer protocol;
- Review study instruments with QxQs;
- Demonstrate knowledge of basic principles and concepts of interviewing by successfully completing the *Interviewer's Learning Exercises*;
- Conduct five practice interviews before submitting the mock audio taped interview (a minimum of one practice interview with the PI or Site Coordinator);
- Demonstrate competence in administration of the study's interview(s) in an audio taped mock interview.

As part of the certification process, all interviewers must submit a packet of the required materials as specified on the Interviewer Certification Checklist and must meet a minimum standard to become certified. Final certification will be provided by the DCC once the Checklist, Learning Exercises, Audiotape and original data form(s) have been reviewed, and a minimum standard has been met by the interviewer. The DCC will issue a Certificate of Qualification to each Interviewer that has met the study's standards and thus becomes certified.

A description of the required completed materials follows:

A. Interviewer Certification Checklist: The Checklist identifies the specific items that must be completed for an Interviewer to become certified.

B. Interviewer's Learning Exercises: The Exercises are specific questions asked of the Interviewer to help evaluate how much the Interviewer has learned in training.

C. Audio taped Mock Interview: After training and review of study protocols (including interviewing protocol and study data forms), each Interviewer will audiotape their administration of the study's interviews. Sites will be informed as to which specific interview forms to administer for the mock interview. The respondent for this mock interview should be a volunteer who can provide realistic responses for the study protocol, not a respondent who answers "NO" to everything. While conducting the mock interview, the Interviewer must record the respondent's answers and complete all necessary paperwork (including editing of the answers, if a mistake has been made) as required by study protocols.

   The DCC's preference is that the interview be tape recorded on a full size cassette tape, however, if a site prefers to use a micro-cassette, the smaller tape will also be acceptable. The tape should be labeled with the Interviewer's name. The tape recorder itself should be placed in an area that is conducive to picking up the voices of both the Interviewer and the respondent. However, it should not be in such a conspicuous place that the respondent is constantly reminded that the interview is being recorded.

   Interviewers must be familiar with the operation of the tape recorder to ensure a quality-taped interview. Inadequately recorded tapes that are submitted will be returned to the site without being reviewed. The original hard copy completed data form(s) and the cassette tape (identified with Interviewer's name) must be submitted to the DCC for review after the site Supervisor has reviewed all materials. A copy of the completed data form(s) should be retained at the site for use as a reference during the debriefing session (described below).

D. Certificate of Qualification: A certificate of qualification is required before data collectors are permitted to begin data collection. The DCC will issue a certificate for each interviewer that meets at least the minimum criteria demonstrating competence in the study protocol for data collection by interview.

Submission and Evaluation Process for QA Audio taping

Submission of a QA audiotape and respective coded data form(s) of a mock interview will allow evaluation of both the verbal and written components of the interview. The site PI or Study Coordinator prior to submitting to the DCC should first review the audiotape and data form(s). The audiotape and respective data form(s) must be submitted to the DCC within the established due date, via an overnight courier. The Reviewer will focus on adherence to the interviewing protocol and accurate recording of information. The Reviewer comparing the tape responses with the respective data forms will assess the tape-recorded interview. After the review, the Reviewer completes an Interviewer Evaluation Form. All NERI Reviewers are trained and standardized in the evaluation process.

Written feedback will be provided to the interviewer on the interviewer Evaluation Form. The Reviewer will provide verbal feedback to the interviewer at a debriefing session via conference call. A completed Evaluation Form with general comments is forwarded to the site prior to the debriefing call session.

The debriefing call session, led by the Project Reviewer, includes discussion of the details of the interview, based on the Reviewer's notes from the data forms. Generally, the Reviewer, Interviewer and the site Study Coordinator are in attendance on the call. Site Principal Investigators are encouraged to attend. If the interview was not conducted satisfactorily, then a second audio taped interview will be required after further practice and a review with the Interviewer has been completed.

The completed Evaluation Form and the study data forms reviewed (with Reviewer's comments) serve as documentation of this QA activity. The telephone debriefing process provides timely feedback to the Interviewer, allows for an open dialogue between the Reviewer and Interviewer, and allows this QA activity to serve as a teaching tool as well as an evaluation. The DCC will coordinate the specifics of this QA activity with Site Coordinators.

Submit the completed QA packet materials via an overnight courier to:

NERI
HALT- C Trial – Margaret Bell
9 Galen Street
Watertown, MA 02472
617-923-7747x522

III. HALT-C Data Entry Certification Program

The HALT-C data entry certification program was developed to ensure:

- Data are entered accurately into the HALT-C Data Management System (DMS);
- Users are familiar with interpreting and resolving edit reports, know how to correct data entry errors, and how to deal with missing or out of range information on data forms.
- Users are familiar with the features of the HALT-C DMS, including printing Visit Control Sheets, setting appointments, running reports, and monitoring visits and the status of data entry of forms.

HALT-C DMS Users

There are two types of HALT-C Data Management System user accounts:

- **Full User:** Full Users have access to all facilities of the data management system appropriate for their site. These users will be able to enter patient data forms, view data and resolve edits for their site, and run reports. In addition, users at clinical sites where patients are seen can schedule and modify appointments, print visit control sheets, and use the specimen shipping and tracking system.

- **Limited User:** Limited accounts are available to users who only need to run reports. Limited users are not able to directly view or modify patient data, schedule appointments, print visit control sheets, or use the shipping and tracking system. No data entry certification is required to become a limited user.

Data Entry Certification Process

All training and certification exercises are done in the Development & Training System only. **Never** use the Production System for training. The certification process involves the following steps.

Notifying the DCC: A participating site contacts the Data Coordinating Center (DCC) with the name and contact information of the person(s) to be trained and certified in data entry. The site should also include information about the person's role on the study (i.e. Data Manager, Coordinator) and request for access to any ancillary study forms or information s/he will need.

Preparing the Data Entry Certification Packet: An appropriate data entry certification packet is compiled and sent to the site. The following steps are taken to prepare the packet for the new user. Certification exercises differ depending on the type of site and data entry being done.

Clinical Sites
• A new user account in the Training & Development System is set up. The new user will be assigned to the site which corresponds to the patient ID assigned to the new user. For example, if the ID used for training belongs to Site 11, the new user should be set up as if s/he is doing data entry for Site 11. • The user name and password information is filled out in the Data Entry Certification Checklist included in the training packet. A print out of the confirmation message and password shown in the DMS after adding a new user will be included in the packet.
Virology & Central Lab Data Entry
• Only those exercises that are relevant to the data entry the user will be doing at the site will be included. For example, a user working on the LP Study will only receive training on Form 173. A user working on the Main Trial will receive training for Main Trial forms. • Each central lab form training module is set up differently. Follow the directions included in the master packet. • The user name and password information will be filled out in the Data Entry Certification Checklist included in the training packet. A print out of the confirmation message and password shown in the DMS after adding a new user will be included.
General Instructions for All Certifications
• A personalized memo is created for each DE certification and added to the top of the packet. • Often, a new user will not have started working at the site yet. In this case, a packet will be sent to someone already working on the study who has agreed to be responsible for receiving the training packet. Full contact information for a new user may also not be available at the time the packet is requested and DMS access is set up. This information is added to the user's profile in the DMS as soon as it becomes available by a DCC data manager.

Receipt and Review of Completed Data Entry Exercises: The new user will return the completed checklist with copies of the written exercises to the DCC.

The DCC evaluates the accuracy of the data that have been entered into DMS. If a large number of data entry errors are identified, the data entry exercises will need to be repeated. The DCC will also check that all required written exercises have been completed. If there are only a few minor mistakes the new staff member may still be certified but will be contacted via email or phone to discuss errors and problems with the certification exercises.

Once all exercises have been completed the DCC will notify the new user of the outcome.

- Certification → The user is added to the Production System and receives a new password in login URL to begin real data entry.
- Not certified → The user needs to repeat the certification exercises. The DCC will determine if the person had any particular problems or questions that need to be addressed in order to pass the certification.

Activation of User Account Production: Once the Data Manager has determined that a user has passed the certification exercises, the user's account will be activated in the Production DMS. A notification of successful completion of data entry certification will be sent by email. The email will contain login information for the Production System including the URL http://study.neri.org/haltc, the user name, and a randomly assigned password generated when adding the user to the Production System. It will also include useful information about the QC process and who to contact about problems and for questions.

Whenever a new user is added to the production DMS, s/he is also added to the QC/DDE system as a second step in order for the user to be able to perform data entry. A new data entry (DE) person experiences 100 % QC selection until 10 of each form have undergone double data entry (DDE). A DE person who has been consistently accurate on a particular form will notice that few are selected for QC (the minimum is 7%). Fewer forms will be selected if accuracy rate improves for a particular form over time, and more forms will be selected if accuracy rate decreases for that particular form over time. Useful information about the QC process and who to contact about problems and for questions will be included in the DE certification packet.

IV. Annual Site Visits to Each Clinical Center, Central Lab and Repository

The Data Coordinating Center (DCC) conducts annual site visits to the 10 clinical centers and one sub center, participating in the HALT-C project. The DCC also conducts visits to all laboratories and repositories that handle HALT-C samples. The monitors review compliance with the HALT-C Trial protocol by observing procedures, form completion, and data entry. The DCC staff compare source documentation to study forms and to data in the Data Management System (DMS) to determine whether the Clinical Center/Lab is accurately reporting data. Proper filing of all regulatory documents required by Good Clinical Practice Guidelines (GCP) is also monitored.

The purpose of these visits is to provide support and assistance to the sites in their responsibility of conducting high quality, accurate and timely scientific research. The procedures that will be assessed during the site visit are made available to the site in advance of these visits and minor errors or edits can be corrected by the site staff in advance of the DCC monitoring visit.
An evaluation checklist is completed at these site visits and included in the Site Visit Report. The site visit report is sent to the clinical center and to NIDDK for review.

V. Training/Re-Training

These site visits also provide opportunities for training new staff as well as any needed retraining or training updates/review. Reinforcement of standardization of procedures will be emphasized and individualized to meet the needs of the site.

Formal scheduled training conference calls is also implemented to ensure standardization of procedures for new staff at sites and to explain any changes in the protocol, forms or in procedures.

VI. Monitoring Reports from the DCC

The Data Coordinating Center is responsible for monitoring the quality of all data collected for the HALT-C Trial. The Quality Assurance Plan for the Trial includes regular Monitoring reports and reports for monitoring patient safety.

The types of data Quality Assurance and patient monitoring reports to be generated by the DCC are detailed below. NIDDK will receive copies of all of the reports.

<u>Patient Safety</u>-To DSMB, FDA and Clinical Centers (as appropriate):
15 day Letters as appropriate
Serious Adverse Events - to be reported monthly
Adverse Events by patient-Quarterly
Lab values out of range-monthly

<u>Data Quality Assurance:</u>
Clinical Centers to receive Data Management Monthly Review, which contains the following:

- QC Report: Forms selected for QC, not yet received by DCC
- Site Pending Edits Report
- Outstanding Forms Report
- Expected Endoscopy Photos Report
- Expected Biopsy Report
- Block Tracking Report
- Missed Visits (visits outside of window)
- Data Integrity Checks

<u>Clinical centers, Central labs, and Repository to receive</u>:

- Site Visit Reports

APPENDIX A

Data Collection By Interview Protocol

(1.) <u>The role of interviewing</u>

Interviewing—asking questions in-person—is a direct and effective way of getting the data needed for research. Interviewing begins after the study has been designed and approved, and after the instruments have been written and tested. Project staff rely on the Interviewers to obtain accurate and complete answers from each Respondent.

While collecting the answers to the survey research questions, Interviewers first and foremost have a public relations responsibility. Interviewers must leave the Respondent with a good feeling about having participated in the research. The Respondent should also be willing to participate further as the study requires, and should be encouraged to be involved in other research projects in the future.

Interviewers must communicate respect and neutrality to each and every Respondent. This may involve ascertaining a convenient time to speak with the Respondent, dealing with other household members tactfully, and listening fully as Respondents share information, which may be of a personal nature. Too much conversation will erode the Interviewer's professionalism and decrease an Interviewer's "control" of the interview situation. An interviewing style that communicates respect for the Respondent is of the utmost importance.

The success of the interview depends on the quantity and quality of the information exchanged between the Interviewer and the Respondent. This flow of information depends upon four interacting parties and conditions:

1) the Interviewer;
2) the Respondent;
3) the topic; and
4) the immediate interviewing situation.

The Interviewer must communicate the question, motivate the Respondent to cooperate, probe for additional information when necessary, train the Respondent to answer within the framework of the questionnaire, and record the information obtained accurately.

The communication process may become distorted or biased at any of these points. Similarly, the Respondent contributes his or her part by accepting the role of information-provider and by giving answers, which are complete, precise, true, and relevant to the questions asked.

The Interviewer will ask the Respondent a series of questions that are very specific and often personal. The general guidelines outlined in this section will help the Interviewer maintain control of the interview and collect meaningful data.

It is important for the Interviewer to understand the social and cultural issues as well as the personal sensitivities at work in any interviewing situation and the effect the Interviewer may have with them.

(2.) Face-to-Face Interview Setting

In a face-to-face interview, qualified/certified staff member must conduct interviews with the Study Participant (Respondent) in private. The interview setting needs to be a comfortable space to encourage the Respondent to speak freely. The room should contain a table or desk for the Interviewer and the Respondent to record the data, and at least two chairs. The interview setting should also be a quiet space since interruptions or distractions could negatively affect the quality of the data being collected. The Interviewer and the Respondent should be seated facing each other whenever possible for the following reasons:

(a) The Respondent should not directly see the Interviewer recording his/her responses;
(b) The Respondent should not see the printed questions;
(c) The Respondent should not become distracted by the recording process.

(3.) Confidentiality

Since Respondents are rarely anonymous to the project staff, procedures must be developed to protect their identity and to assure that the data collected from or about them cannot be associated with them. Not identifying or associating a Study Respondent's name with her/his answer is providing confidentiality of data to the Respondent.

Researchers, like counselors, lawyers, or clergy, have a responsibility of assuring Respondents' confidentiality. A Respondent's identity is **never divulged**. Unique ID numbers are assigned to Respondents' interviews (data forms) so those names are never associated with the completed study instruments. Complex data management systems are used to protect all Respondents' identities and to avoid having individual's names connected to their answers.

Interviewers communicate the commitment of confidentiality to the Respondent and preserve it by not discussing interviews with anyone, including other project staff, unless necessary. Interviewers promise those interviewed that their answers will be kept COMPLETELY CONFIDENTIAL.

Respondent's answers are combined with everyone else's in the study and the results are reported in percentages and totals in such a way that no individual Respondent's answers can be identified. 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 the Interviewers are to the Study Respondents.

It is the Interviewer's obligation to keep the pledge of confidentiality. The Interviewer never divulges names, tells facts about or reveals the opinions of any respondent that is interviewed. Failure to comply with this will be viewed as a serious violation by the study principal investigators.

During each interview, Interviewers will be asking Respondents a number of questions that may be of a personal or sensitive nature. Most Respondents will accept the Interviewer's assurance of confidentiality and will answer these questions and all other information required during an interview. An Interviewer's pledge of confidentiality applies whether the information is given in direct response to a questionnaire item or is volunteered in other comments or conversation during the interview.

(4.) Instrument (questionnaire) design

The study instruments that are used to collect data in an interview are designed very carefully. The specific words, the word order, and the progression of the questions have all been chosen because they will produce the most accurate answers possible without introducing bias.

Instrument design is concerned with finding a series of questions that will provide reliable and valid answers. A reliable instrument will collect the exact same information each time it is used. A valid instrument will produce data that is accurate and measures what it is designed to measure. For example, a scale that routinely measures a 100-lb. weight as 100 pounds is a reliable measurement. However, a scale that routinely measures a 100-lb. weight as 80 pounds is not valid, although it behaves reliably.

To make sure that the instrument is reliable and valid, instrument designers rely heavily on previously used and tested questions. If designers have to develop new questions, they “pretest” the questions before the study begins. The pretest data is analyzed for reliability and validity, and adjustments are made to the instrument.

(5.) General principles of interviewing

Of all the methods used to gather information needed to compile statistics, the personal interview conducted by well-trained staff is one of the most effective. The standardized interviewing techniques outlined here are based on sound principles governing communication between individuals and, therefore, between an Interviewer and the Respondent. All Interviewers at all study sites must follow standardized interviewing techniques and methods to insure the quality of the data collected.

(a.) The role of the Interviewer

The Interviewer serves as a critical link between the researchers who are seeking to understand the characteristics or problems of a population and the Respondents whose individual answers provide data for the researchers to study. The Interviewer is a necessary and valuable member of the research team.

The art of interviewing involves special skills, e.g. the ability to cope with unexpected events, to focus on the Respondent and to be non-judgmental. Interviewing requires warmth, discipline and patience. An Interviewer’s main responsibility is to obtain and record the Respondent’s answers accurately.

Interviewers must focus on the Respondent and concentrate on the importance of obtaining a valid interview. Interviewers must refrain from expressing opinions if in disagreement with the Respondent’s views and must not offer advice to the Respondent. Interviewers must control the interview and be as neutral as possible. This is especially true if the Interviewer “wears more than one hat.” For example, in the situation where an Interviewer is also a clinician or other health care provider to the Respondent. A Respondent may be more apt to ask for advice from a clinician, forgetting that the clinician is in the role of an Interviewer. This same situation could also cause the Interviewer to use previous information about the Respondent while asking the questions. During the interview, the Interviewer must never use previous knowledge about a Respondent that has been obtained outside the interview, even if the Respondent’s answers conflicts with what the Interviewer knows to be true. If an Interviewer uses previous knowledge, the interview becomes biased. Anything the Interviewer says or does may influence the Respondent and her/his response, which, in turn, may bias the interview. Always remember, an interview is based upon the Respondent’s self reporting of information.

(b.) Interview preparation

Interviewers must review all study materials and protocols until they fully understand and know all aspects of their job. Interviewers must become certified as outlined by the Study’s Quality Assurance Plan. This includes becoming comfortable asking the questions, following skip patterns and knowing the detailed specifications (Q by Q’s) for all of the questions. The ability to work comfortably with the study instruments will help keep the Respondent interested in the interview and will greatly facilitate the interview process.

Before an Interviewer begins an interview, s/he must check to be sure that s/he has sufficient quantities of all necessary interviewing materials and that all materials are organized in an orderly fashion.

(c.) Promoting participation

Once an eligible Respondent has consented to participate in the Study it is within the scope of the Interviewer's job to promote participation. In the first few minutes of the initial contact, the Interviewer must convince the Respondent of four things:

1. S/he is a professional Interviewer;
2. S/he represents a legitimate and reputable organization;
3. The Respondent will be engaged in important and worthwhile research and;
4. The Respondent's participation is vital to the success of the research.

An Interviewer's manner of speaking and, for in-person interviewing, his/her appearance must convey credibility. (Professional attire is expected at all times when conducting an in-person interview.) Interviewers must be professional by displaying that they are serious, pleasant, self-confident and neutral. If an Interviewer's approach is uncertain, this feeling will be communicated to the Respondent, who may then act similarly.

(6.) Conducting the interview

(a.) Asking the questions

Any differences found in the data collected must be differences discovered among Respondents; not differences among Interviewers. It is the Interviewer's responsibility to make certain that questions are always asked in the same objective fashion, so as not to affect a Respondent's answers. When asking the questions, the use of a "natural" speaking voice will reflect the Interviewer's interest. The Interviewer must ask each question exactly as worded on the study instrument. The same questions must be asked of each Respondent. Interviewers must not change, add to, or vary the wording of any question in the protocol**.** The following are some general techniques for Interviewers when asking questions.

Always remain neutral: During an interview, the Interviewer must always maintain a completely neutral attitude. The Interviewer must never allow anything in words or manner to express criticism, surprise, approval, or disapproval of the questions, or of the answers Respondents may give the Interviewer.

An important part of the Interviewer role is to actively involve the Respondent in the interview. Allow the Respondent to talk comfortably and freely in response to the questions. While encouraging the Respondent to talk freely, however, the Interviewer must carefully avoid saying or doing anything to influence the content of the Respondent's answers. No matter what topics the Interviewer asks about, no matter how strongly the Interviewer agrees or disagrees with the Respondent's answers, and no matter how interesting or discouraging the Interviewer might find those answers to be, the Interviewer must always maintain the same neutral and professional stance during the interview. The Interviewer is there to ask for and record the Respondent's answers, not to influence them in any way.

An effective Interviewer must be comfortable with the questions s/he asks. If the Interviewer feels uncomfortable with certain questions, it is likely that the Interviewer will transmit some of that feeling to the Respondent and influence the answers the Interviewer receives. If the Interviewer is uneasy with some questions, the Interviewer should practice them repeatedly until the Interviewer can ask them in a simple, straightforward, matter-of-fact way. Occasionally, the Interviewer will find a Respondent, who refuses to answer some questions, but usually the Interviewer will find that so long as all questions are handled in the same relaxed and professional manner, Respondents will answer without hesitation. If the Interviewer's feelings about any topics in the questionnaire are so strong that they cannot be hidden from Respondents, the Interviewer should not be conducting interviews for the study.

<u>Ask all questions in the order in which they appear in the study instrument</u>: When questionnaires are designed, the order in which questions are to be asked is always given careful attention. Questionnaire developers repeatedly review the questions in order to make sure that all questions are asked in a logical sequence and to lessen the chance that a Respondent's answers to one question will improperly influence her/his answers to another. Given the care with which the questions have been arranged and the importance of ensuring that all Respondents hear <u>exactly</u> the same question in the same exact order, it is essential that Interviewers strictly follow the order in which the questions appear.

At times, particularly if the Respondent is talking freely, the Interviewer may feel that s/he has already answered a question before the Interviewer gets to it. If a Respondent becomes annoyed or says something like "I just told you that", the Interviewer can acknowledge the repetition, but explain that s/he is required to ask all of the questions exactly as they appear on the questionnaire. The Interviewer might say something like:

> "I need to make sure I have your full answer on that." Or,
> "I thought perhaps you might have more to say about that."
> Sometimes it may be helpful to anticipate the Respondent's reaction to the repetition by saying something like:
> "You may already have mentioned this, but I need to make sure I am collecting accurate information here." Or,
> "You may have told me about this before, but let me ask this question to make sure I have the right answer."

There is only one exception to the rule that the Interviewer must always ask questions exactly as ordered in the questionnaire. If, during an interview, the Interviewer discovers that s/he has accidentally skipped one or more questions that s/he should have asked, the Interviewer should go back to ask the omitted questions. In this situation, the Interviewer should be aware that questions asked out of order may not obtain the same information since they are taken out of context. This will require the Interviewer to re-focus the Respondent to the omitted questions. [The Interviewer must make a note in the margin so there will be complete documentation of this event].

<u>Ask all questions exactly as worded</u>: The Interviewer must read each question completely and exactly as it is printed on the study instrument. The Interviewer should not change even a single word, since even the smallest change can affect the entire meaning of a question. For the answers obtained by Interviewers to be combined, there must be no doubt that each Respondent heard <u>exactly</u> the same question before responding. If the Interviewer must repeat a question if the Respondent did not hear it the first time or did not understand the question, The Interviewer should re-read the <u>entire</u> question.

All Respondents must receive the same information with the same inflections prior to answering. The Interviewer must emphasize only those words that are underlined or are otherwise highlighted within the question, pausing only at commas or, when answer categories are included in the question.

At times, Respondents may ask the Interviewer to define words or to explain some part of a question. If a definition or explanation is provided on the form in parentheses, the Interviewer may give that explanation to the Respondent. Or, if the Question-by-Question Specification (Q by Q's) provides a definition or further explanation, the Interviewer may use that. The Interviewer must not provide his/her own explanation. The Interviewer should simply ask the Respondent to answer the question to the best of her/his ability with the standardized information provided. The Interviewer might say, "Whatever it means to you" or "However you understand that word".

Do not read answer categories to the respondent unless they are part of the question: Material contained in the answer column is not to be read to the Respondent unless the Interviewer is specifically instructed to do so. Everything printed in "lower case type" should be read to the Respondent. Instructions, which are not read to the Respondent, are occasionally included with the question, and are always printed in "ALL CAPITAL LETTERS." These are intended to be a directive to the Interviewer.

(7) Controlling the interview

There are many different situations that may occur during an interview where the Interviewer will need to take control in a professional manner. Controlling the interview will reduce the time it takes to ask the questions, maintain the Respondent's interest and thus, result in collecting accurate data.

The following methods should be used to help control an interview:

Maintaining rapport: Interviewers begin the rapport-building process with their initial contact with the Respondent. Through accepting and understanding behavior as well as sincere interest in the subject, the Interviewer can create a friendly atmosphere in which the Respondent can talk freely and fully. The Interviewer will then find that there is less hesitation on the Respondent's part to answer difficult and sensitive questions. Occasionally rapport may be broken during the interview because the Respondent finds a particular question "too personal" or for other reasons. If this happens, The Interviewer should reassure the Respondent that s/he may speak freely without fear. Re-stating the confidential nature of the study or explaining why the question is asked may accomplish this. For example, many times Respondents find some demographic questions (income, race or ethnicity) "too personal." The Interviewer should explain that all study participants are asked the same questions and that these questions help the Investigators to better understand the population that is being included in the study. Interviewers must be very careful not to divulge any study hypotheses when providing explanations.

If a Respondent refuses to answer a question after an Interviewer has provided a reassurance of confidentiality or the rationale for the question, (if applicable) the Interviewer should not force the issue. The Interviewer should go on to the next question. The Interviewer does not want to irritate the Respondent and provoke a refusal to complete the rest of the interview. If a Respondent refuses to answer a question, the Interviewer should note the refusal on the questionnaire. If a Respondent refuses to answer a question early on in the interview, the Interviewer should use his/her judgment as to whether or not to go back at the end of the interview to re-ask the refused question. Sometimes by the end of the interview, a better rapport with the Respondent may be established.

Discourage unrelated conversation while asking questions: Occasionally a particular question may cause the subject to reminisce or relate a lengthy story illustrating the point just made. An effective Interviewer will discourage such irrelevant conversation and keep the discussion focused on the questions in the study instrument. In some ways, that requires that Interviewer gain control of the interview situation by subtly teaching the Respondent how to be a cooperative Respondent.

- If the Interviewer maintains a business-like demeanor, and acknowledges appropriate answers with neutral comments such as: "I see", "OK", or "Hmmm", s/he will offer "positive feedback" to the Respondent and begin to reinforce the positive behavior.

- If the Interviewer tactfully interrupts rambling and irrelevant answers and brings the conversation back to the original question, the Interviewer will offer "negative feedback" on the Respondent's performance, thereby gently discouraging such behavior.

- At the same time, the Interviewer must be careful not to offend the Respondent, though the Interviewer may find that talkative persons are the ones who least mind being interrupted. The Interviewer can politely use comments such as:

  "That sounds very interesting, but what I need to ask is..." or,
  "I see what you mean, but let me repeat the last question..." or,
  "Let me make a note of that and we can discuss it after we have completed the interview."

Keeping the respondent focused: Respondents may not understand a question or may respond in such a manner that is evident that they misunderstood the time frame of the question the Interviewer has just asked. To help keep the Respondent focused, Interviewers are provided with "Introductory Statements" before a specific question or set of questions. Interviewers should always read these "Introductory Statements" to the Respondent.

Another way to keep the Respondent focused and to help ensure that the Respondent will give accurate responses to the questions is to emphasize the time frame (if there is one) for the question or set of questions. To assist the Interviewer with the specific time frames within a question, the time frame reference, in many cases, will be underlined or highlighted.

Tone and pace of the interview: The Interviewer's tone of voice and the pace the Interviewer sets are essential for a successful interview. If an Interviewer sounds too mechanical or stilted, the Respondent can lose interest quickly. With a lengthy protocol, pace becomes extremely important. An effective Interviewer must be able to adapt to the requirements of each individual Respondent. The pace the Interviewer sets should be comfortable for both the Interviewer and the Respondent. It should be fast enough to keep the Respondent's interest, yet not too fast that the Respondent becomes frustrated and misunderstands the questions. The Interviewer needs to control the pace. Do not allow the Respondent to set the pace. The Interviewer is conducting the interview and should set and control the pace of the interview.

All of the above methods for controlling the interview, especially if utilized early on in the interview, will promote both cooperation and collection of accurate data.

(8.) Probing

The main task for every Interviewer is to take every precaution to get a statement of the Respondent's ideas, which is clear, complete, and unambiguous. Before an Interviewer can confidently circle a pre-coded response (a question that has several answer options) or leave an open-ended question (where any response is acceptable), it must be determined whether the Respondent has given a clear and complete answer. Unclear or vague answers that do not answer the question objectives are not acceptable.

Probing is a technique used by the Interviewer to obtain information when the Respondent's answer does not adequately answer the question. Probing motivates the Respondent to clarify her/his answer and serves to eliminate unnecessary information. The quality of the interview will depend a great deal on the Interviewer's ability to use probing techniques successfully. Successful probing requires that the Interviewer immediately recognize just how the Respondent's answers fail to meet the objectives of the question. The Interviewer then must be able to formulate a "neutral probe" to elicit the information needed.

(a.) Principles of probing

- The probe should in no way change the frame of reference of the question.
- The probe should never indicate that one answer is expected over another.
- The probe should never indicate that one answer is more socially acceptable than another is.
- The probe should motivate the Respondent to meet the question objective.

(b.) Kinds of probes

An expectant pause
- The pause conveys to a Respondent that the Interviewer knows the Respondent has begun to answer the question, but has more to say. This allows the Respondent time to gather her/his thoughts.

Repeating the question
- When the Respondent does not seem to understand the question, misinterprets it, seems unable to decide, or strays from the subject, The Interviewer's best probe is to repeat the entire question. Many Respondents, when hearing the question for the second time realize what kind of answer is needed.

Repeating the respondent's reply
- The Interviewer's repeating the response just given often stimulates the Respondent to further thought.

Re-formulating the respondent's reply in the form of a question
- When a Respondent hears the answer phrased in the form of a question, s/he often provides further information.

A neutral question or comment
It is very important to always use neutral probes. That is, an Interviewer should not imply to the Respondent that s/he expects a specific answer or is dissatisfied with an answer. Some neutral probes include the following:
Clarifying
"What do you mean exactly?"
"What do you mean by...?"

Specifying
"Could you be more specific about that?"
"What in particular do you have in mind?"

Completeness
"What else?", "Any others?"
"What else can you think of?"
"What other reasons/things/examples etc. can you think of?"
"Can you tell me more?"

The "I Don't Know" response
A Respondent may answer "I don't know" for a number of reasons:

1. The Respondent doesn't understand the question and says, " I don't know (DK)" to avoid saying s/he doesn't understand.
2. The Respondent is thinking the question over, and says "DK" to fill the silence and give her/himself time to think.

3. The Respondent may be trying to evade the issue because s/he feels uninformed or is afraid of giving a wrong answer.
4. The Respondent may really not know.

The Interviewer should decide which is the best approach based upon their assumption regarding the above. A “DK” response must be probed at least once. Sometimes if the Interviewer sits quietly and expectantly, the Respondent will usually think of something to say.

The qualified response
When a Respondent answers “it depends” or gives a qualified response, The Interviewer should get a commitment to the either/or situation and ask the Respondent to make a selection of one of the responses provided.

(c.) Problem questions requiring probing

The following are examples of particular question types that often require probing. It is important to remember that probing serves as a teaching tool for the Respondent. It indicates to Respondents the need for accurate and complete information and it helps them to see the criteria used (within certain types of questions) to determine when their response is complete. For example, an Interviewer who successfully probes a Respondent’s answer on the first of several scale questions (such as the one illustrated below) may find any successive scale questions answered more smoothly than the first time around.

The scale:
Example: In your current job(s) how often do you sit? Would you say?

Never,	1
seldom,	2
sometimes,	3
often, or	4
always?	5

The Respondent may give an answer that does not fall on the scale at all. For example, the Respondent may say: “Oh, I’d say usually or most of the time I sit on the job.” In this example, the Interviewer should probe by repeating the question, asking the Respondent to choose from one of the scale categories. It is important to remember the complete scale must be repeated.

(I): “I see, so based on what you’ve said, which choice comes closest when I ask: “In your current job, how often do you sit? Would you say: never, seldom, sometimes, often, or always?”

By using this format, the Respondent is instructed on how to answer the remaining questions.

Non-directive probing is least likely to influence either directly or indirectly her/his response on this or future scale questions.

An example of an **incorrect**, directive probe:

(I): “Usually or most of the time? Would you say that’s often or always?”

In this example, the Interviewer has only offered the Respondent two choices; based on the Interviewer’s assumption of where s/he feels the Respondent’s original response should fit.

Close-ended factual questions
In the following example the Interviewer is seeking specific information such as, 'how long', 'how much', 'when', etc.

(Q): "For how long have you taken it this time?"
(A) "Oh, for a few years now."

This response will need to be probed to obtain the specific number of years and/or months.

Correct, neutral probe
(I): "So how many years or months is that? I need your answer in the number of years and/or the number of months."

Incorrect, directive probe:
(I): "So should I put down three years?" or the Interviewer merely assumes three years.

Interviewers should take their time when asking Respondents to give specific times, numbers, dollar amounts, dates, etc. Sometimes it may take the Respondent a while to think back.

Open-ended questions (Q): In open ended questions - questions where the Respondent is asked to answer in their own words and the Interviewer records verbatim what is said—there are several ways in which answers can be inadequate and require further probing.
Example:
(Q): Did a doctor give you a reason why you were not getting pregnant?
NO. 1 (GO TO Q28)
YES 2
(Q): What was the reason? ________________________________

In this example, the Respondent gives a totally irrelevant answer to the above question.
(A): "Well, I'm not sure I want to get pregnant."

Although the Respondent is on the general topic of pregnancy, she has not met the question objective which is to identify the specific reason the doctor told her why she was not getting pregnant.

Proper probe:
(I): "I see, well let me repeat the question..."

Maybe the Respondent didn't hear or understand the question or maybe she was just thinking of something else. The Respondent needs to be brought back on track and the question objective must be made clear to her by re-asking the question.

The following is an example where the Respondent has given an unclear answer.

(A): "Well it's because of my health insurance."

Neutral probe:
(I): "Can you tell me more about that? OR How so? OR What do you mean by that?"

In this example, the Respondent has given an answer which may seem perfectly clear to her, but is not clear to anyone else including the Interviewer who knows the question objective. The Interviewer might think s/he knows what is meant, but must never guess or make assumptions about an answer. Therefore the Interviewer probes (non-derivatively) for clarification.

<u>Open-list questions:</u> Lists often require the use of <u>exhaustive</u> probes where Respondents are asked to give all possible answers. In an example like the one above, the Respondent's answer is probed to be sure she has included all possible responses.

Probe: "Are there any others?" OR "Is there anything else you can think of?
Usually when the Researcher requests that the Interviewer exhaustively probe the Respondent's answer, the exact probes to use will be provided on the form immediately following the question. For example:

[PROBE: "Any others?"]

The Interviewer continues to evoke additional answers by probing, "Anything else?" OR "Any others?" until the Respondent indicates that s/he has no additional information to offer.

(d.) <u>Probing factual verses opinion questions</u>

There is a difference between factual questions and questions of opinion. Factual questions ask about actual information or events, e.g., time/dates, income, locations, amounts, marital status, etc. Opinion questions are subjective and ask about feelings, impressions/perceptions, etc.

When probing factual questions, the Interviewer has some latitude. If a Respondent answers "yes" to the question: "Was there a time when you were unable to pay your rent for a month or more?" An appropriate probe would be "When was that?" If the Respondent can't remember the date, it is appropriate for the Interviewer to help jog the Respondent's memory. The Interviewer should never suggest a time, as that would be leading or directing the Respondent's answer. However, the Interviewer might probe with, "Do you remember what time of year (or season) it was, or what else was happening at the time?" This type of probing may help the Respondent focus in on an event that may trigger the date or time asked for.

<u>Inconsistent statements:</u> Respondents can be contradictory in their opinions and perceptions. For example, at the beginning of an interview the Respondent may give a very negative opinion about health care. In another context, later in the interview, the Respondent may praise health care. The Interviewer should never attempt to reconcile opinion questions. However, the Interviewer should reconcile factual inconsistencies within the context of the interview. For example, if the Respondent says at the beginning of an interview that s/he has lived at an address for 10 months and later indicates that she/he moved 18 months ago, the correct (factual) response must be determined. However, the Respondent should not be challenged. An example of an appropriate probe would be, "I may have misunderstood. I thought earlier you said that you've been living at the address for 10 months." The Interviewer should continue to probe by going back and re-asking the question. This way, the Interviewer is the one who made the mistake or misunderstood, not the Respondent. Respondents are usually glad to correct the discrepancy.

(9.) <u>Ending the interview</u>

All people who give their time and energy for an interview are entitled to courteous and tactful treatment. After the study visit has been completed, Respondents must be thanked, indicating appreciation. Respondents must be made aware that their contribution has been most helpful in providing important information to the study. The Interviewer may spend a few more minutes answering any questions the Respondent may have and then the interview is closed.

(10.) Recording the answers

The Interviewer should always record answers in black pen. The Interviewer must always have an extra pen accessible.

(a.) Pre-coded questions

Answers to pre-coded questions are easy to record. Ordinarily, the answer categories will be clearly shown on the study instrument. The usual way to indicate answers is to circle the appropriate number that corresponds to the Respondent's answer.

Would you say your health in general is…?

excellent, 1
very good, ②
good, 3
fair or, 4
poor? 5
DK………………………………………………………………..-8
REFUSED -7

In the above example, the Respondent answered "very good" and the Interviewer circled the number 2. In addition to the answer categories contained in the question, sometimes there will a "DK" (don't know) and "REFUSED" choice included in capital letters in the list of answer possibilities. The "DK" and "REFUSED" responses are not read to the Respondent. If the Respondent's final answer is "don't know", the Interviewer should mark the response for "DK " as you would for the other answer categories. If a "DK" category has not been provided and the Respondent's final answer is "don't know", the Interviewer should record "DK" in the answer space. An Interviewer should always indicate that s/he has probed a "don't know" response at least once.

Sometimes, a pre-coded question will include an "OTHER" category. This is for an answer that cannot be classified in any of the listed categories. In addition to circling the appropriate number, the Interviewer is required to write the actual response on the "specify" line or in the space provided. In these cases, it is especially important to faithfully record the response verbatim.

On pre-coded questions, the Interviewer should be careful to record only one answer (unless the question calls for or permits more than one answer). It is unacceptable to lose data because the Interviewer, in a hurry or in a sloppy fashion, drew a circle that covered more than one answer or marked more than one answer when the question only calls for one. In such cases, the correct answer may not be able to be determined. Interviewers must edit their study instruments immediately after completing the interview.

(b.) Short open-ended questions

The following is an example of a short open-ended question. A line(s) is provided for recording the Respondent's answer.

(Q): What is the name of the medication?

____
(SPECIFY)

The Interviewer should carefully record the answer legibly wherever a write-in space is provided. The Interviewer should also ensure the answer conforms to whatever unit of measure is specified in the question (i.e., if the question asks for "days", do not record the answer in "weeks").

(c.) Error in recording

If it is necessary to change an answer, a reason must be given. If the Respondent changes her/his mind after the answer is coded, a single slash line is drawn through the wrong answer and R.E. should be written next to it is meaning "Respondent error". The Interviewer should never erase if the wrong answer was marked by mistake. The Interviewer should draw a single slash line through the wrong answer and note M.E. meaning "my error." The Interviewer should always re-code the correct response. Initial and date the time the answer was recoded.

(d.) Refused answers

If a Respondent refuses to answer any given question, it is important to record in the margin verbatim what s/he said when refusing that question, and any observations of, as to why the Respondent refused. The Interviewer should place parentheses around those comments distinguishing them from the Respondent's. As discussed above under "Maintaining Rapport", the Interviewer should use his/her judgment as to whether or not to go back at the end of the interview to re-ask the refused question.

Write legibly:
Always be sure to write legibly so that the person coding or data entering the study instrument does not misinterpret what the Respondent intended.

(e.) Editing one's own instrument

Immediately after the interview has been completed and the Respondent has left, Interviewers should edit (review) the data forms for completeness, accuracy and legibility. This again will help prevent missing and inaccurate data collection.

(11.) Self-administered questionnaires

These instruments are designed so that the Respondent can complete them her/himself without the Interviewer asking the questions. However, it is very important to understand that not all Respondents will want or be able to complete the questionnaires themselves. In the event, the Interviewer must be prepared to administer the questionnaires using the standard interviewing conventions discussed above.

(a.) Introducing self-administered questionnaire

The following general introduction to a Self-Administered questionnaire should be given to each Respondent at the start of this portion of the interview:

> *"This questionnaire is designed so that you can fill it out yourself, as there are personal questions that some people may prefer to answer privately. However, if you prefer that I read the questions and you give me the answers to record, that is all right too."*

The respondent gives her/his preference followed by the appropriate suggested script below.

"If you would like to fill out this questionnaire by yourself, please answer all questions to the best of your ability. There are no right or wrong answers, simply choose the most appropriate response that comes closest to how you feel about each question. After you have selected your response, circle the number next to the answer you have chosen. Please note there may be an instruction in parentheses (all in capital letters) next to a specific response category. These are directions to you as to where to go if you choose that response. If there is no instruction in parenthesis next to the response category you chose, then go to the next question that follows. Please remember that all your answers will be kept confidential. I will be here to respond to any questions you may have."

(b.) Specific situations affecting self-administered process

The following procedures are provided for handling some situations that may occur during the self-administered process.

(1.) Respondent completes questionnaires her/himself during visit

While the Respondent completes the Self-Administered Questionnaire(s), the Interviewer will be present to answer any questions s/he may have. The Interviewer should only provide assistance when asked for by the Respondent. If asked about the meaning of a word or what is meant by a question, the Interviewer should follow the same rules and guidelines for Interviewer-Administered questionnaires described above. In other words, the Interviewer must not introduce bias to the Respondent. Administrative questions should be clearly answered.

After the Respondent has agreed to complete the form(s) her/himself, the Interviewer affixes a study ID label and completes all of SECTION A (administrative information) before giving the form(s) to the Respondent. Once the Respondent has completed the form(s), the Interviewer should review the questionnaire for completeness. If the Interviewer identifies "gross omissions", the Respondent should be requested to complete the missing information. Gross omissions should be defined by each project. This process is not a check for content, but a check that the questionnaire was completed.

(2.) Respondent has difficulty

On rare occasions, the Respondent may choose to complete the questionnaire(s) her/himself, but then finds that s/he has difficulty in doing so. If the Respondent appears to be slow in completing the questionnaire or is asking the same questions repeatedly, the Interviewer should repeat the offer to complete it orally. If the Respondent accepts the offer, the Interviewer should begin the questionnaire again using a new set of questionnaires if needed. The Interviewers should not write over the Respondent's responses or assume that the Respondent's responses are correct. The Interviewer should document that this instrument was "Interviewer-administered" in Section A and follow procedures for Interviewer-administration.