Chapter 4

Informed Consent, Proxy Procedures, Interview Feasibility, Contact Information, and Order of Examinations

Several terms used in this chapter refer to individuals other than the participant who may be involved in some aspects of the study. These terms are related but not synonymous and are defined below. In most but not all cases, the contact person will fulfill the other roles defined, serving as the participant's informant, and if needed, as the interview proxy and consent proxy.

Term	Relevant To	Definition
Contact Person	All participants	An individual listed by the participant as someone "who you would want us to ask to provide information and answer questions for you in the event that you are unable to answer for yourself".
Informant	All participants	An individual chosen by the participant to provide information about him or her from an outside perspective (*not* on behalf of the participant). THIS APPLIES ONLY TO THE DQ and CDR.
Interview Proxy	Individuals with significant cognitive impairment, including but not limited to all participants without capacity to consent.	An individual who completes study interviews *on behalf of the participant* when there is concern about the validity of the participant's self-report.
Consent Proxy	Individuals without capacity to consent	An individual who provides informed consent on the behalf of the participant. This person may be the LAR, the next of kin, or may be appointed by the participant depending on local IRB regulations.
Legally Authorized Representative (LAR)	Individuals without capacity to consent	An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

1. INFORMED CONSENT

A. BACKGROUND AND RATIONALE

Completing the 'informed consent' process is the first and most important requirement for conducting a research project. All staff should be trained and certified according to regulations mandated by their local Institutional Review Board (IRB) for conducting research with human subjects, including procedures for administering informed consent. These required procedures are typically similar across American institutions.

Before any assessments or interviews can be conducted on a human being as a subject in research, the investigator or his/her staff must first obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). This procedural requirement is known as "obtaining informed consent" and is met after the potential participant carefully reviews all study related information summarized on a consent form and then signs his/her name on the document to indicate s/he has read and understands the details outlined in the consent form, and agrees to participate. Such consent shall be sought only under circumstances that provide the prospective subject or the LAR 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 LAR shall be in language understandable to the subject or the LAR. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

For each home visit, this study plans to obtain consent through a written consent document that embodies the elements of informed consent required by each field center's local IRB. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator/study staff shall give either the subject or the LAR adequate opportunity to read it before it is signed. Please address any concerns the participant may have in clear, concise language without coercion. If the subject agrees to participate after any questions have been addressed, s/he or his/her legally authorized representative must sign the consent form on the line provided along with the witness (i.e., the research staff member obtaining consent). A copy of the consent form shall be given to the subject or the LAR while the original consent form must remain in the participant's charts as a source document.

Additionally, many IRBs will require documentation of continued consent before the annual phone follow-up surveys are administered and if the data collection forms are mailed to the participants before the home visit. See section below - **OBTAINING AND ACCESSING CAPACITY TO CONSENT FOR ANNUAL PHONE FOLLOW-UP SURVEYS**.

In addition to the participant informed consent, field centers should investigate the regulations within their institution for consents to contact interview proxies or informants when participants are unable to complete the information (see p.4 – Interviewing Guidelines for Proxy Administration below), and for telephone consent to obtain study information during the annual phone follow-up interviews or when an in-person visit cannot be completed.

B. COMPLETING THE INFORMED CONSENT FORM

Under the page header, mark the appropriate box to indicate whether the consent form was administered in person or by phone.

Once informed consent is obtained, check the appropriate box under Q1 to indicate that informed consent was obtained by the participant. If the participant is unable to provide informed consent, the examiner should proceed according to their local IRB regulations for obtaining consent by proxy (described below).

For **Q2a**, document the date the participant signed the consent form. Please be sure to use the convention for dates (i.e. June 5, 2006 is 05/JUN/2006).

Q2b requests the Version Number and Date of the consent form that the participant signed. Complete **one** of these fields by **either** jotting down the Version Number or Version Date listed on the consent form. Use the date convention mentioned above.

For **Q2c** and **Q2d**, place an X in the box to indicate whether the participant provided permission to share data/samples, allow samples to be stored, etc. Please note: The number/type of questions in this section may vary by site depending on the required checkboxes inserted onto each FC's consent form as required by the local IRB.

For **Q3**, record the date the participant signed the HIPAA Authorization Form. This is not applicable for the Pittsburgh Field Center.

C. OBTAINING AND ACCESSING CAPACITY TO CONSENT FOR ANNUAL PHONE FOLLOW-UP SURVEYS

Continuing Documentation of Consent

Before the annual phone follow-up surveys are administered, many IRBs will require documentation of continuing consent among previously consented participants who have been initially seen during the baseline home visit. This may also apply to the plan to administer a portion of the home visit by phone or mail to reduce participant burden during the actual home visits. Across field centers, the baseline consent form summarizes the plan to annually contact each participant to administer telephone surveys and other data collection forms by mail. Before commencing the telephone interview or mailing data collection forms to the participants, staff will remind the participants of these planned surveys upon their initial phone contact. Participants are then asked if they continue to agree to undergo the surveys before commencing the annual telephone interview. Any participant not wishing to participate in the annual phone interview is offered an opportunity to complete the surveys by mail (i.e. self-completion as an alternative to completing them by phone, especially practical for the hearing impaired). If the participant agrees, s/he is mailed a self-addressed stamped envelope into which the participant will insert and return the completed surveys to the field center. The same procedures will be followed for any data collection forms mailed before the home visit to reduce participant burden. Participants who refuse participation of the annual phone follow-up surveys are entered as "refusal" into the study database. Some IRBs will require that a dated note be jotted down on the bottom of each participant's original consent form documenting either his/her refusal or continued consent for this annual phone follow-up interview.

Documentation of Continued Capacity

Among members of this cohort, it is necessary to assess capacity to provide consent before the phone interviews are administered or surveys are mailed to the participant's home. Some IRBs will also require that this process be documented. Some IRBs may require that a dated note on the bottom of their original consent form is jotted down by the RA administering the interviews to indicate whether or not the participant has demonstrated the capacity to provide consent and whether or not the consent proxy or LAR is used. A box

appears in the header of each attached survey for the RA to indicate whether an interview proxy, informant, or the participant completed each survey.

D. OBTAINING CAPACITY TO CONSENT FOR IN-PERSON FOLLOW-UP

This section contains guidelines for obtaining informed consent in participants, consent proxies, and informants.

i. Assessing Capacity to Provide Informed Consent:

Capacity to provide informed consent will be assessed by first reviewing the consent form with each participant. Then, the Assessment for Capacity to Provide Consent instrument will be used to determine whether s/he has the cognitive capacity to provide informed consent (See Appendix 1). This instrument involves four, open-ended questions which attempt to measure the individual's understanding of the study (i.e. describe study purpose, risks and benefits, study activities and alternatives to participation). Based on the responses to these questions, the interviewer will determine whether the individual has sufficient understanding to provide informed consent.

ii. Procedures for Obtaining Consent by Proxy

Consent by proxy will be obtained if there is significant concern that the person does not comprehend basic aspects of the study during the capacity assessment. Under these circumstances, interviewers will acquire informed consent from a proxy (either a legally authorized representative (LAR) or consent proxy), if possible, as long as the family member demonstrates assent to participate in the study.

Individuals with severe cognitive impairment at the last telephone follow up who are highly unlikely to demonstrate the capacity to provide informed consent at the second home visit will be flagged to assist field centers in preparing for consent by proxy procedures. These individuals will be identified on the basis of criteria described in Chapter 2: Recruitment. However, participant consent will always be sought first.

Most IRBs will require that the proxy be the person officially designated by the participant on the Participant Contact Information Sheet, during the baseline visit, as his/her contact person. However, each site will likely have procedures specific to their respective IRBs for assigning a consent proxy.

(insert information for each site)

Once a consent proxy is selected, s/he will complete the 'consent by proxy' section of the participant's consent form. The participant's name will be printed on the consent form in this section (under 'name of participant') and the chosen consent proxy will sign his/her own name on that line instead of the participant. The consent proxy will then sign his/her name again in the 'consent by proxy' section along with printing his/her name and dating the document. Assent will be documented by writing a statement on the consent form to indicate that the participant demonstrated his/her willingness to participate (i.e. participant extended her arm, smiled and nodded, etc.) before any study procedures begin. The minimum data set will be collected via proxy interview (Please see *Appendix C* at the end of this MOP). In most cases, it is expected that the proxy interview will be completed by the same individual providing proxy consent.

If a consent proxy is unavailable, the participant will not be able to participate in the study.

2. Procedures for Proxy Interviews

A proxy interview is defined as the administration of surveys to an individual that is not the participant when there is concern regarding the accuracy of a participant's self-report due to significant cognitive impairment. By default, proxy interview would be completed by a named contact person who has been listed by the participant as someone "who you would want us to ask to provide information and answer questions for you in the event that you are unable to answer for yourself". Obtaining an interview by proxy is different from obtaining consent by proxy.However, proxy interviews will be conducted in all instances in which consent by proxy was obtained.

Importantly, proxy interviews will also be conducted in individuals who have capacity to provide informed consent but who demonstrate significant cognitive impairment and therefore may not provide accurate information about their history. These individuals will be identified according to the following criteria: 1) the participant scores 24 or below on the MMSE and this is not due primarily to sensory impairment; OR 2) there is significant concern regarding the participant's ability to provide accurate self-report, regardless of MMSE score. (Please refer to Flow Chart contained in *Appendix 1* to this chapter.)

The modified interview for surrogates is outlined in the Data Collection Forms section below. It is important to note that all performance and cognitive measures will be administered directly to the participant without the aid of the surrogate regardless of the participant's cognitive status. These measures will be eliminated if participants are unable to comprehend instructions.

Instructions for Mailing Questionnaires to Participant versus Proxy

As several questionnaires will be mailed to the participant in advance of the visit, it is important to try to determine whether the participant is able to provide accurate information on his or her own behalf, or if it is necessary to collect the information via proxy. Field staff can use information from the most proximal phone follow-up, as well as information gathered at the time Visit 2 is scheduled, to determine whether it is necessary to collect the information via proxy. Indications that proxy interviews may be necessary include:

- Proxy interview was conducted at baseline
- Most proximal TICS score was < 27 (this is equivalent to an MMSE score of 24, and is a rough guideline to be used in conjunction with clinical judgment)
- Examiner has information from the participant or his or her family indicating that the participant has significant cognitive impairment that may interfere with providing accurate information

There will be instances in which none of these indicators is present but it is determined at the time of the in-person assessment that proxy interview is needed (based on Panel 1B). Under those circumstances, field staff should request that a proxy fills out the relevant questionnaires (that have already been filled out by the participant), and the proxy based forms should be considered the final data to be entered into REDcap.

3. INTERVIEW FEASIBILITY

From the informed consent process alone, please use your judgment based on that interaction to complete **Q4a-d**. Then, follow the instructions on this panel by using your best judgment to determine whether any visual, auditory or cognitive impairments will make it impossible for the individual to participate in this study. Please check the appropriate box provided if this person is too impaired to participate and then jot down the specifics of the impairment on the line provided.

Respond to **Q6** by placing an X in the correct box to indicate whether the participant is confined to a bed. For purposes of this study, "confined to a bed" includes someone who rises from the bed when going to the toilet and taking a bath.

4. PARTICIPANT CONTACT INFORMATION

The Participant Contact Information Sheet provides an opportunity to collect complete and accurate contact information, thus helping to minimize missing data and losses to follow-up. An attempt will be made to collect full contact information on the participant, at least three other individuals who know the participant well, and the participant's health care provider. Please use the appropriate fields on this Sheet to document the contact information first for the participant and then for his/her proxies. As directed, indicate whether the proxy is also enrolled in this study and select the appropriate category to indicate the relationship between the participant and each proxy.

To maintain current records on all active proxies per participant, the form is designed to capture updates on whether or not a previously-listed contact person remains a viable proxy for the participant. If you learn, during an annual phone follow-up interview or at a home visit, that the contact person is no longer able to be a viable proxy for the participant, select "no" to the question which asks whether that contact person's name should remain in our system. Doing so will remove that contact person's name from our system without further modifying these fields. IMPORTANT: In other words, in spite of any changes to the contact people listed on the form, be sure to leave that person's name and contact information in the original fields exactly as the information was first entered even though that contact person may no longer be a valid proxy. None of this information should ever be deleted on this form. Towards the end of this section, additional fields have been included so that the contact information and details for any new proxies can be added over time.

Q9a-9c provides several fields to document whether or not the participant has a primary care physician (PCP), the location they have chosen to obtain healthcare and the primary care physician's contact information. After checking the appropriate box for **Q9a** to indicate whether the participant has a PCP, then check **only one** box for **Q9b** to document where the participant goes to obtain actual health care or advice regarding his/her health. Then use the lines provided in **Q9c** to collect contact information details on the participant's PCP if one exists. Please try to collect as much information as possible and carefully document all details on the lines provided so that the participant's PCP can be easily contacted if necessary (i.e. medical alerts arising during data collection).

Study Documents Referred to in this Chapter

- Informed Consent
- Consent Tracking and Interview Feasibility Form
- Participant Contact Information

EXAMINATION ORDER:

The sequence of procedures at a home visit is not mandated and may be administered at the discretion of the individual Field Centers in an order which would best build rapport with the participant.

Physical/Cognitive Measures

- Phlebotomy (or on a separate visit)
- BP/HR
- Medications
- Performance Measures
- Cognitive Tests (with exception of long-term recall)
- WT/HT & Waist Circumference (please do as many of these measures as possible during the 40 minute wait for long term recall)
- Long-term recall
- Carotid ultrasound
- Finish any WT/HT and Waist Circumference Measures not completed during 40 minute break
- Spirometry
- CES-D

Questionnaires/Other Instruments

- Socio-demographics
- Medical History
- Physical Function and Activity
- Personal History

The above list created keeping in mind that some questionnaires can be administered over the telephone with the participant or left with the participant to complete and return mail to the Field Center. In some situations, the participant may be unable to complete some or all of the examinations due to either physical or mental impairment. In these cases, some of the forms may be administered to a proxy.

Because the blood sample must be fasting, it may be preferable to schedule the phlebotomy as a separate visit. **If so, the blood sample should be collected within four weeks AFTER the exam.** Do not arrange for the blood sample collection before the exam is completed because informed consent is part of the exam.

DATA COLLECTION FORMS/ASSESSMENTS

Sociodemographic Interview: If this panel is being completed by proxy interview, check the appropriate box at the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8e, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

For this panel, all questions should be asked via an Interview Proxy **WITH THE EXCEPTION OF**

Questions 5, 11a-11b, 12b-12c, 14a-15d and 16b-17. Note that all the questions should be rephrased so as to ask about the participant. Generally speaking, you should substitute the word "you" with the name of the LLFS participant. For example, Question 1 should be rephrased as follows: "Was (name of LLFS Participant) born in the US? If the Proxy does not know the answer to any questions or if s/he refuses to answer a question mark, "Don't know" or "Refuse" wherever applicable. Therefore, the same instructions apply here to following conventions as description in the General Instructions of the Introductions to Visits Chapter.

Physical Function And Activity Evaluation: If this panel is being completed by a proxy interview, then check the appropriate box at the top of the form. Then, for US sties, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

For this panel, all questions should be asked via an Interview Proxy **WITH THE EXCEPTION OF** Questions 5, 11a-11b, 12b-12c, 14a-15d and 16b-17. Note that all the questions should be rephrased so as to ask about the participant. Generally speaking, you should substitute the word "you" with the name of the LLFS participant. For example, Question 1 should be rephrased as follows: "Was (name of LLFS Participant) born in the US? If the Proxy does not know the answer to any questions or if s/he refuses to answer a question mark, "Don't know" or "Refuse" wherever applicable. Therefore, the same instructions apply here to following conventions as description in the General Instructions of the Introductions to Visits Chapter.

Personal History Questionnaire: If this panel is being completed by a proxy interview then check the appropriate box at the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

For this panel, only Questions 1a-1d and 2a-2e should be asked via an Interview Proxy. Note that all the questions should be rephrased so as to ask about the participant. Generally speaking, you should substitute the word "you" with the name of the LLFS participant. For example, Question 1a should be rephrased as follows: "Has (name of LLFS Participant) smoked more than 100 cigarettes in his/her lifetime?" Similarly, Question 1b, should be rephrased as "In what year or how old was (name of LLFS Participant) when he/she started smoking cigarettes on a regular basis". If the Proxy does not know the answer to Questions 1a, 1c, 2a and 2c mark "Don't know" or if they refuse, mark "refused" and move on to the next question until you complete the panel. If the Proxy does not know the answer to Questions 1b, 1d , 1e and 2b, 2d and 2e (how old and how many), then use the standard LLFS convention of D.

Medical History Questionnaire: If this panel is being completed by a proxy interview, then check the appropriate box at the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in

the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

For this panel, Questions 2, 4a-4b, 8a-8d, 9, 10a-10c, 11, 12a-12e and 13a-13c can be administered to a surrogate (Interview Proxy/Legally Authorized Representative, LAR/Informant). Note that all the questions should be rephrased so as to ask about the participant. Generally speaking, you should substitute the word "you" with the name of the LLFS participant.

Medication Inventory: This panel can be attempted with a proxy interview . If so, then check the appropriate box at the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

If the Interview Proxy does not know about the prescription or over-the-counter medications the LLFS participant has taken in the past two weeks, check the box "don't know", or if they refuse to provide this information, check "refused" on the study form.

Cognitive Assessment: All cognitive measures should be administered directly to the participant without the aid of the interview proxy. These measures should be eliminated if participants are unable to comprehend instructions. It is not appropriate for the proxy to assist the participant in performance or cognitive measures. The IADL scale, however, should be completed by proxy when there is concern regarding the participant's cognitive status.

Performance Measures: This panel is a physical measure and requires that the participant follow the interviewers' instructions for completing maneuvers. These are physical measures and cannot be completed by Proxy. All measures in this panel should be attempted. If the participant is unable to complete any of the procedures because they were unable to sufficiently follow instructions to complete the measurement, there are check boxes on the form to document this for each measure that cannot be completed.

Blood Pressure, Heart Rate, Height, Weight And Waist Circumference: This panel is a physical measure and requires that the participant follow the interviewers' instructions for positioning purposes. These are physical measures and cannot be completed by Proxy. All measures in this panel should be attempted. If the participant is unable to complete any of the procedures because they were unable to sufficiently follow instructions to complete the measurement, there are check boxes on the form to document this for each measure that cannot be completed.

Spirometry: If this panel is being completed by proxy interview , then check the appropriate box at the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B(Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the

proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

Questions 1-4 can be administered to a proxy in all cases. If Spirometry is to be attempted on the participant (i.e. if the participant agrees and seems able to follow the instructions), questions 5-12 should also be administered to the proxy and then attempt to proceed with the Spirometry procedure on the participant. The plan is to attempt Spirometry for all participants. Participants who are disoriented and have no recall but who can follow 2-3 step instructions will likely do well; participants who cannot follow instructions will, more or less, be unlikely to complete this procedure.

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CES-D**.** All questions on this panel must be asked of the participant only.

Venipuncture & Blood Collection: If this form is administered on the proxy, check the appropriate box on the top of the form. Then, for US sites, refer to the question numbers of each contact person on the PCI Form to complete Section B (Proxy Tracking) by jotting down, on the line provided, the corresponding question number (e.g. Q6a, Q6e, Q6i, Q8a, Q8d, Q8i, etc.) of the listed contact person who acted as a proxy for this interview. Please note: These question numbers will also automatically populate in the corresponding REDCap data entry field for ease and accuracy of data entry. In Denmark, indicate the relationship of the proxy to the participant. Finish Section B by selecting as many reasons that apply for reason(s) this form was completed via proxy instead of via the Study Participant.

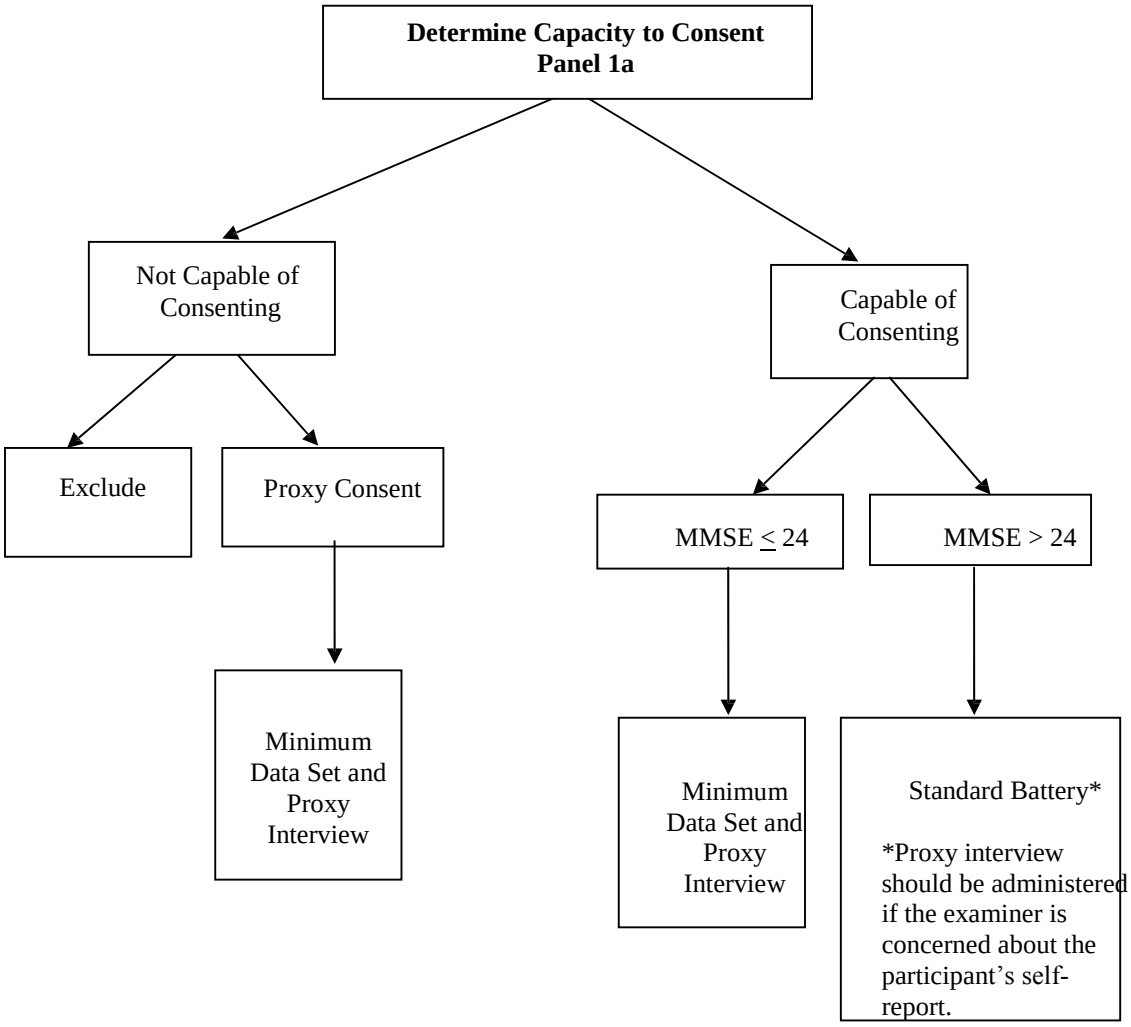
Once you have followed your IRB's guidelines for obtaining consent to draw blood from a cognitively impaired individual and she has not provided consent, you can conduct the Phlebotomy Screening survey (p2 Qa-e) on the proxy by replacing "you" with the study participant's name. Next, Questions 1- 3 can be asked of the proxy, again by replacing "you' with the participant's name. This completes the questions for the proxy on this form. Please continue to complete the rest of the fields involving blood processing and shipping information for this sample.

Chapter 4 – Appendix 1

Process for Determination of Inclusion of Cognitively Impaired Participants (Extended Family Members)

Inclusion of cognitively impaired participants involves several steps. The outline below details our approach to including these participants.

1. Evaluation of Capacity to provide informed consent (See following page for sample form).
2. MMSE evaluation
3. Administration of Proxy-based interview for cognitively impaired participants.



Chapter 4 – Appendix 1 (cont)

'Sample' of Assessment for Capacity To Provide Informed Consent

After reviewing the consent form, please read the following:

Interviewer Script: *"I'm going to ask you a couple of short questions. Please feel free to refer to the consent form we just reviewed."*

1. In your own words, please explain the general purpose of this study. _____

   _____

   _____

2. In your own words, please explain the potential risks and benefits of participating in this study. ___

   _____

   _____

3. In your own words, please describe the activities you will participate in during this study. _____

   _____

   _____

4. In your own words, please explain your options if you do not want to participate in the study, or in certain parts of the study. _____

   _____

   _____

Interviewer Note: ***Based on the participant's responses to the above questions, the interviewer determines whether or not the person has sufficient understanding to provide informed consent. It is important to note that this is not a memory test, and participants can use the consent form to help them answer these questions and/or request clarification from the examiner.***

Based on the responses to the questions above, is it your opinion that this participant is adequately able to provide informed consent to participate in this study?

☐[1].....Yes
☐[0].....No

'Sample' of Criteria for Proxy-Based Interviews (Panel 1b)

Interviewer Note: The following table outlines four scenarios based on the initial cognitive screen (MMSE) and the examiner's impression of the participant's self-report. Indicate the scenario that applies by checking the appropriate box in the left column. Proceed as indicated in the right column. Note that these categories are mutually exclusive, so only one scenario should be marked as "Yes" and all others should be marked as "No".

	Results of Cognitive Screen	Administration Procedure
☐ 1 Yes ☐ 0 No	Participant scored above 24 on the Mini-Mental State Examination and there is no significant concern regarding the participant's ability to provide accurate self-report.	Proceed with interview. Proxy-based interview not necessary.
☐ 1 Yes ☐ 0 No	Participant scored above 24 on the Mini-Mental State Examination but there is significant concern regarding the participant's ability to provide accurate self-report.	Administer proxy-based interviews.
☐ 1 Yes ☐ 0 No	Participant scored 24 or below on the Mini-Mental State Examination and this impaired score is not due to a sensory impairment.	Administer proxy-based interviews.
☐ 1 Yes ☐ 0 No	Participant scored 24 or below on the Mini-Mental State Examination; however, this impaired score is due primarily to a sensory impairment; cognitive abilities appear intact.	Proceed with interview. Proxy-based interview not necessary.