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ACTIVE (Advanced Cognitive Training for Independent and Vital Elderly), 1999-2001 [United States]

Sharon Tennstedt
New England Research Institutes

John Morris Hebrew Senior Life-Boston

Frederick Unverzagt Indiana University

George Rebok

Johns Hopkins University

Sherry Willis
Pennsylvania State University

Karlene Ball University of Alabama-Birmingham

Michael Marsiske University of Florida

Third Annual Post-Test Measurement

Inter-university Consortium for Political and Social Research P.O. Box 1248 Ann Arbor, Michigan 48106 www.icpsr.umich.edu

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Question by Question Specifications Guide for Administration of the **Abbreviated Testing Batteries for the 3rd Annual Post-Test Measurements**

I. Purpose

At the time of enrollment, ACTIVE study participants are 65 years of age or older, living in non-institutionalized settings but at risk of loss of functional independence. Because of the potential for a change in health status, functional status or residence, it is prudent to prepare for the possibility of follow-up testing with disabled/institutionalized participants or participants who re-locate prior to completion of the study protocol.

In anticipation of these possibilities, ACTIVE Investigators have developed a two-tiered Abbreviated Testing Battery that can be used at the time of annual post-test visits.

II. Overview

When a participant cannot/will not agree to <u>full</u> participation at the time of an annual study assessment, the Field Site Staff must determine which measures, if any, can be completed. To allow for appropriate planning, Testers must first gather as much information as possible about the participant's current situation. A standardized Testers' Guide is provided here as Attachment A. Field Sites' senior staff (i.e. Principal Investigator, Site Coordinator or Designated Specialist) will use this information to determine the most appropriate plan for the follow-up visit.

In some instances, special accommodations may be instituted to allow the subject to complete the **full Annual Post-Test Battery**, e.g. transportation may be provided, testing may be conducted in the participant's home, etc. In other cases, an abbreviated testing protocol will be required to conduct as many follow-up measurements as possible.

A two tier abbreviated testing protocol has been designed. Measures included in **Level I** (the minimal data set) can be administered in approximately 75 minutes either in-person or as a telephone interview. Level I tests include the MDS-HC, Mobility Questionnaire (Mobility, Life Space, Falls), Driving Habits, Health Conditions, Health Services Utilization, SF-36, Medication Audit and the EPT.

The **Level II** battery includes all Level I measures <u>and</u> the AVLT Recall, Letter Series, AVLT Recognition, MMSE, Timed IADL and UFOV. It takes approximately 2 hours and forty-five minutes to complete all Level II measurements, i.e. 75 minutes for Part 1 plus 90 minutes for Part 2. At least two sessions are required, although several sessions may be necessary.

A few of the measures can be completed in a **Proxy Interview**. The following measurements may be completed with a proxy: MDS-HC, Mobility Questionnaire, Driving Habits, Health Conditions and Health Services Utilization and the Medication Audit. It takes approximately 40 minutes to complete the Proxy Interview.

III. Eligibility

When an ACTIVE participant cannot or will not complete a full post-test assessment during the prescribed study visit window, Field Sites will use the Abbreviated Battery protocol to gather a minimal amount of critical outcome data from the participant.

The most common reasons for non-participation include:

- The participant is suffering from a serious or debilitating illness and/or they are institutionalized.
- The participant moved too far away or they are living in another location during the entire study visit window.
- A close family member is suffering from a serious illness, or there has been a major change in an alternate obligation preventing full participation.
- The participant simply refuses to participate stating reason such as, "I just am too busy to continue.", "It just takes too long.", "I can't go through that again.", "Please don't ask me to do that again.", etc.
- A household member reports that the participant has died.

A. Eligibility for completion of the full Annual Post-Test Battery

To be eligible to participate in the full Annual Post-Test Battery the participant must:

- With special accommodations, be willing/able to complete all the measures in the full Annual Post-Test battery including Individual Parts 1 and 2 and Group. Each session lasts as long as 2 hours. If necessary, sessions can be split per the current protocol. Additional breaks may be added to accommodate a participant with a debilitating condition.
- Have the general physical strength/stamina to tolerate three, 2-hour sessions, or several 1-hour sessions.
- Be capable to complete all measurements in the battery.
 - ✓ Can/will the participant travel to the testing site or can a tester travel to the participant's home or alternate location?
 - ✓ Can the participant read? Are there changes in the participant's vision? Changes in comprehension?
 - ✓ Can the participant write? Is there paralysis or significant weakness in dominant hand?

B. Eligibility for completion of the Level I Abbreviated Battery

To be eligible to participate in the **Level I Abbreviated Battery** the participant must:

- Be willing/able to complete a 1-hour interview in-person or on the telephone. The interview can be split into more than one session.
- Have the general physical strength/stamina to tolerate at least a 15-minute telephone interview.
- Be willing/able to complete the EPT either in-person or at home. The EPT takes approximately 15 minutes. A Tester, a proxy or another person may record the participant's responses on the data form if s/he cannot write her/his own responses due to a debilitating condition.
- Be capable to complete the measures in the battery.
 - ✓ Can the participant understand the questions? Are there changes in comprehension?
 - ✓ Can the participant write? Is there paralysis or significant weakness in dominant hand? (An ACTIVE Tester may record the participant's responses on the EPT form.)

C. Eligibility for completion of the Level II Abbreviated Battery

To be eligible to participate in the Level II Abbreviated Battery the participant must:

- Be willing/able to complete all measures in the Level I protocol (see above).
- Be willing/able to meet with a Tester <u>in-person</u> to complete Part 2 of the Level II battery. If completed in one session, Part 2 lasts approximately 90 minutes (not including the break) or it can be split into more than one session. A break can be taken after any test in the battery.
- Have the general physical strength/stamina to tolerate a 60 − 90 minute testing session
- Be capable to complete all tests in the battery.
 - ✓ Can/will the participant travel to the testing site or can a tester travel to the participant's home or alternate location?
 - ✓ Can the participant read? Are there changes in the participant's vision? Changes in comprehension?
 - ✓ Can the participant write? Is there paralysis or significant weakness in dominant hand?

D. Eligibility for completion of the Proxy Interview

To be eligible to complete a post-test battery with a **proxy**, the participant must:

- Be too weak to tolerate at least a 15 minute in-person or telephone interview.
- Be too disabled to complete the tests in the Level I battery.
 - ✓ Cannot read? Cannot see? Cannot understand?
 - ✓ Cannot write? Has a paralysis or significant weakness in dominant hand?

IV. Administration Protocol

The Abbreviated battery has been divided into two parts to meet both administrative and scientific objectives. All Level I measurements are included in the Part 1 battery. The measures included in Part 1 constitute the minimal data set and must be completed first, in their prescribed order, for both Level I and Level II subjects. The Part 2 battery should always be completed <u>after Part 1</u> for Level II participants. A description of Parts 1 and 2 of the Abbreviated Battery appears below.

A. Part 1 of the Abbreviated Battery for both Level I and Level II participants

The Part 1 instrument, **Form #706** has been developed for use in 3rd Annual PT. Part 1 of the Abbreviated Battery is considered the minimal data set. Measurements included in the Part 1 battery should be completed for both Level I <u>and</u> Level II subjects. Ideally, the Part 1 measurements will be conducted during an in-person session, although most can be conducted on the telephone if necessary. The only exception is the EPT, which must be completed as a self-administered measurement at the end of an inperson session or at home with mailed return. In-person testing may be conducted at the established testing site, at the participant's home or at an alternate location. Testing sessions that occur at a health care institution (hospital, nursing home, etc.) may require special authorization from the institution, family member, an appointed guardian, or someone else.

1. <u>Materials / Equipment Needed</u>

The following items should be assembled in advance of the subject's appointment time.

- Abbreviated Battery, Part 1, 3rdAnnual Post-Test, Form #**706** with ID label
- EPT Form #617 for in-person administration OR EPT Form #717 with a self addressed stamped envelope for take-home or mail-home administration
- Pencils for subject's use

2. Preparation

- a. Only certified ACTIVE Testers are qualified to complete this session.
- b. Ideally, this session will be completed as an in-person interview, but it may be completed as a telephone interview.
- c. An appointment should always be negotiated/established with the participant in advance of the session. If completed in one sitting, the session may take as long as seventy-five minutes including the EPT and a break. It may be completed in two or more sessions.
- d. In advance of the testing session, the tester should assemble all the forms necessary to complete the battery.
- e. The area selected to complete the interview must allow for the conduct of a private, confidential interview. A flat writing surface must be available to complete the EPT. If completing the interview on the telephone, remind the participant to be seated in a comfortable chair.

3. Order of Administration

The ACTIVE Steering Committee has prescribed the order of test administration for the Abbreviated Battery. The order of administration for the Part 1 battery should be as follows:

- MDS (15 minutes)
- Driving/Life Space/Falls (10 minutes)
- Health Conditions (5 minutes)
- Health Services Utilization (5 minutes)
- SF-36 (10 minutes)
- EPT (15 minutes) (either in-person or as a mailed/take home questionnaire)

Part 1 can be completed in a single session if the participant can tolerate a 1-hour testing session, or it can be split into more than one session at any point in the testing battery. Likewise, a break can occur at the end of <u>any</u> test. Part 1 should last approximately 60 minutes, not including a break or completion of the EPT.

4. Section by Section Review

- a. Section A. Identifying Information for Form # 706, Part 1 of AB,
- **A1.** Study ID: Affix the subject's ID label in the space provided.
- **A2.** Visit #: This item will be precoded with various Visit #'s, e.g. the code for the **3rd** Annual Post-Test is Visit # **ABB3**.
- **A2a**. Level: Code the correct Level of this assessment. The Site PI, Coordinator or Designated Specialist will determine the appropriate Level for the Abbreviated Battery.
- **A3.** Form Version: Be sure the form version on the form matches the current approved version. Note the year appears as a 4-digit number.
- **A6.** Time started: Record the exact time you begin the General Introduction in A6. Use a 12-hour clock; circle **AM** or **PM** as appropriate.

b. Sections Preceding Each Measure, Sections B, D, I, L, N, P

A standard set of questions has been added to the beginning of each of the measures in Part 1 of the Abbreviated Battery. A description of these questions follows here:

- Q1. Was the measurement completed at this follow-up? If the measurement was completed, code 'yes' and complete the rest of the questions in this section. If the measurement was not completed, code no and skip to the next measurement.
- Q3. Indicate the mode of the interview. Only modes allowed for the measure are included in the coding scheme for each respective measure. For example, it is not allowed to complete the EPT as a telephone interview, so telephone interview does not appear as a category for this measure.
- **Q4.** Indicate with whom you completed the interview. Only allowable codes are listed for each respective measure. For example, it is not allowed to complete the SF-36 interview with a proxy so the proxy categories do not appear for this measure.
- **Q4a**. If a proxy is interviewed for any of the items in the measure, record a proxy code in this data field.
- **Q6.** Record the start time for the measure. Follow the standardized convention for coding times described elsewhere.

c. Section C: The MDS

No changes have been made to the procedures for administration of the MDS. Follow the procedures for administration of the MDS described elsewhere. This measure **may** be administered to a **proxy**.

d. Sections E, F, G and H: Life Space, Falls, and the Driving Questions

The Mobility Questionnaire is a questionnaire designed to assess the extent of the subject's usual mobility and driving habits. Specifically, the questionnaire assesses:

- a) the range of a person's life space
- b) the extent to which they have trouble with falls
- c) a person's **driving** habits

The instrument is particularly suited for assessment of these mobility-related behaviors in older individuals. Functional independence and mobility are critical elements of an older person's quality of life and therefore represent important outcome measures.

Please note, Version A does not have any changes to the procedures for administration of these measures. <u>Changes have been made to the Version B (08/16/01) Section E</u>, <u>question, E1, in Life Space, as noted below.</u>

The remaining sections are unchanged. Follow the procedures for administration of these measures described elsewhere. The Life Space and Falls questions may be administered to a proxy but the Driving Questions may **not** be asked of a **proxy.**

Section E.

E1: This question collects information about household composition, how many persons live with the subject and the relationship of these persons to the subject.

There are four response choices listed:

٠.	E1, E5 11E01, E1, 110 05E/11 1
2.	LIVES WITH OTHERS IN HOUSE/APT
3.	LIVES IN ASSISTED LIVING/CONGREGATE HSG3 (E2)

4. LIVES IN NURSING HOME...... 4 (GO TO SECTION F)

Response choices (1) and (2) refer to residence in a house or apartment (including independent senior housing). If the subject reports living alone, code (1) and skip to E2. If the subject reports living with others, code (2) and ask E1a and E1b. If the subject reports living in assisted living/congregate housing setting, code (3) and skip to E2. If subject reports living in a nursing home setting, code (4) and skip to the next section. When you ask how many people live with the subject, s/he will often give you the answer to E1b without you having to ask the question. You can use the questions for E1b as probes if the subject does not offer the information. Record the number reported for each

category. Record 0 if none (e.g. children) are mentioned. If the number/s reported for E1b <u>do not</u> equal the number in E1a, probe to correct the inconsistency.

e. Section J: Health Conditions Ouestions

The purpose of questions **J1** (a-p) is to obtain a listing of chronic diseases diagnosed since the time of the last participant's interview. Therefore, the time frame for these questions assumes an approximate **1-year** interval from the last Annual visit. The month and date of the **last Annual Post -Test contact** should be used to orient the participant to the time frame. Before the interview, be sure to determine the date you will use here. Take the date from the upper right hand corner of the participant's VCS labeled, e.g.," Annual Post-Test I4 Date". Only the month and year of the date should be used to orient the participant to the questions.

For example, if the participant responds 'yes' to a condition and the Post-Test date is 06/12/2000, the Testers can probe "Is that since June, 2000?".

The questions may be administered by proxy.

The stem question, "Since your first visit in _____ (MONTH/YEAR_OF ANNUAL Post Test FROM THE VCS) has a doctor/nurse told you that you have.:", is specifically worded so that the participant does not make up diagnoses. For example, the participant may have some difficulty seeing and think s/he has cataracts, but if s/he has not been told this by a doctor (nurse or Physician's Assistant), it should not be coded as 'Yes'.

f. Section K: Health Services Utilization Question

The use of health services is an outcome of major interest. The purpose of the questions in this section is to determine the type, amount, and reasons for use since the participant's last study visit.

Please note, Version A does not have any changes to the procedures for administration of these measures. Several changes have been made to Version B (08/16/01); the directives for questions 13, 14 and 16 are noted below.

Follow the procedures for administration of the remaining measures described elsewhere. These measures **may** be administered to a **proxy**.

K13-14: These questions ask about use of nursing home services. If none, skip to K15. These questions are similar to those for hospital stays.

K13: Asks how many times subject has been a resident in a nursing home since their last visit? If subject currently a full time nursing home resident, record # of times as 1 and make a comment in the margin to that effect.

K14: Record the total number of days the subject spent in the nursing home for all nursing home stays since the subject's last visit.

K16: This question asks about the frequency of use of several types of Community-based health or supportive services. Do <u>not include</u> these services if received in a <u>nursing home</u>.

g. Sections M: The SF-36 Questions

Administration of the SF-36 is different in the Abbreviated Battery. In this battery, it is administered as a tester-administered interview. Otherwise, no changes have been made to the questionnaire. It should **not** be administered to a **proxy**.

i. Section Q: The EPT

A few minor changes have been made to the EPT procedures. For the Abbreviated Battery, it may be taken home or mailed to the participant's home to be completed independently. Ideally, it will be completed during an in-person session. It should **not** be administered to a **proxy**. Testers should have the participant use Form # 617 for inperson administration of the EPT. A new form, #717, has been developed for use when the EPT is sent home with the participant or mailed to the participant's home and completed independently. In addition, it is now permissible for the participant to receive physical assistance in recording responses to the questions in the EPT. Such assistance may be required for participants who otherwise may be unable to write their responses due to limited physical strength or stamina or limited motor control secondary to a paralysis or paresis.

The following changes have been made to the new EPT form # 717 for use in independent or at-home administration.

- 1) Changes have been made to Section A to capture the date of distribution and the date the form was returned.
- 2) A written introduction to Participants has been added and appears as page 2.
- Participants are asked to record the date and time they start the test, items A8 & 9
- 4) Participants are asked to record the time they complete the test, item B30.
- 5) Participants are asked to record any break time, item B31.
- 6) Participants are asked to 'certify' that they completed the test on their own. Physical assistance in writing responses is allowed.
- 7) Finally, participants should be provided a self-addressed stamped envelope to return the EPT.

The following points should be included in a script or cover letter when distributing Form #717 to participants.

- 1) Thank the participant for agreeing to complete the EPT at home.
- 2) Provide the participant with a site contact name and phone number for use if s/he has questions.
- 3) Remind the participant that s/he should complete the EPT independently. Someone may provide physical assistance in writing responses if the participant

- is unable to write their own responses but no assistance is permitted for the actual content of the responses.
- 4) Provide the participant with a self-addressed stamped envelope and instruct them in how and when to return the completed EPT to the Study Center.
- 5) Set a date for the expected return of the EPT and continue to track all distributed tests until they are returned.

C. Abbreviated Battery Part 2, only used for Level II participants

A unique form has been developed for administration at each Annual Post-Test visit. The **Form # 713** has been developed for administration at the 3rd Annual PT only. The measurements in Part 2 of the Abbreviated Battery <u>must</u> be conducted **in-person**. **None may be completed with a proxy**. Part 2 may be conducted at the field site's testing site, in the participant's home or an alternate location requested by the participant or determined by the study staff. Testing sessions that occur at a health care institution (hospital, nursing home, etc.) may require special authorization from the institution, family member, an appointed guardian, etc.

1. Materials / Equipment Needed

The following items should be assembled in advance of the subject's appointment time.

- Abbreviated Battery, Part 2 data Form # 713 with ID label attached
- AVLT Subject data forms packet #611a with ID label attached to all pages
- AVLT Post test coding Form #611 with ID label attached
- Letter Series data Form # 612 with ID label attached
- AVLT Recognition Form #613 with ID label attached
- The proper AVLT Audiotape
- MMSE supplies, i.e. wristwatch, 3 pieces of 8 ½ x 11 inch blank, white paper for completing directives, writing a sentence, and drawing shapes, 'Close Your Eyes' Show Card, pencil, and 'Intersecting Shapes' Show Card
- Useful Field of View supplies, i.e. computer, UFOV software
- Electronic timer
- Clock with digital display
- Ruler or 5 x 8 card for subject's use
- Sony Boom Box Model CFS-B15
- Pencils for subject's use

2. Preparation

- a. Only certified ACTIVE Testers are qualified to complete this session.
- b. This session must be completed as an in-person interview; it may be completed in two or more session.
- c. In advance of the session, the tester should assemble all the forms, supplies and equipment necessary to complete the measurements.
- d. The area selected must allow for private, confidential testing with minimal background noise.
- e. Ideally, all Part 2 measurements can be completed at 2 workstations. A table for two with a smooth working surface is needed for the subject and tester for

- recording and testing during administration of the AVLT, Word Series, MMSE and Timed IADL. A computer station is used for the UFOV.
- f. Prior to the start of the session, the tester should set up and test equipment to be sure that all equipment is in proper working order, including the audiotape player, electronic timer, computer and related software for UFOV. Spare batteries should be carried for all battery operated equipment.

3. Order of Administration

The order of administration for the Part 2 testing session should be as follows:

- AVLT Recall (25 minutes)
- Letter Series (10 minutes)
- AVLT Recognition (5 minutes)
- MMSE (10 minutes)
- Timed IADL (17 minutes maximum)
- UFOV (20 minutes)

Part 2 must be completed <u>after</u> Part 1 measurements during an in-person session in one or more visits. If completed in one session, Part 2 should take approximately 90 minutes, not including a break. Although a break may be taken at the end of any test, testers should not split the session prior to the completion of the AVLT Recognition.

4. Section by Section Review

- a. Section A. Identifying Information for Form # 713, Part 2 of the AB.
- **A1.** Study ID: Affix the subject's ID label in the space provided.
- **A2.** Visit #: This item is precoded. The code for the **3rd** Annual Post-Test is Visit # **ABB3**.
- **A3.** Form Version: Be sure the form version on the form matches the current approved version. Note the year appears as a 4-digit number.
- **A6.** Time started: Record the exact time you begin the General Introduction in A6. Use a 12-hour clock, circle **AM** or **PM** as appropriate.

b. Sections Preceding the Measures, Sections B, F, H, J

A standard set of questions has been added to the beginning of each of the measures in Part 2 of the Abbreviated Battery. A description of these questions follows here:

Q1. Was the measurement completed at this follow-up? If the measurement was completed, code 'yes' and complete the rest of the questions in this section. If the measurement was not completed, code no and skip to the next measurement.

Item number varies: Start and End Times: Record the start and end times for the measure. Follow the standardized convention for coding times described elsewhere.

c. Section C: AVLT Recall

No changes have been made to the procedures for administration of the AVLT Recall measure. Follow the procedures for administration of the AVLT Recall documented in the 3rd Annual Post-Test materials. This measure may **not** be administered to a **proxy**.

d. Section D: Letter Series

No changes have been made to the procedures for administration of the Letter Series measure. Follow the procedures documented elsewhere. This measure may **not** be administered to a proxy.

e. Section E: AVLT Recognition

No changes have been made to the procedures for administration of the AVLT Recognition. Follow the procedures documented in the 3rd Annual Post-Test materials. This measure may **not** be administered to a proxy.

f. Section G: MMSE

Essentially no changes have been made to the procedures for administration of the MMSE. No eligibility scoring is required for the Abbreviated Battery. Follow the procedures documented in the QxQs for the 3rd Annual Post Test Individual Assessment Part I session. This measure may **not** be administered to a proxy.

g. Section I: Timed IADL

No changes have been made to the procedures for administration of the Timed IADL. Follow the procedures documented elsewhere. This measure may **not** be administered to a proxy.

h. Section K: UFOV

No changes have been made to the procedures for administration of the UFOV. Follow the procedures documented elsewhere. As always, if the participant has a physical limitation that makes it difficult for him/her to touch the screen, the participant may

verbally respond and the Tester may touch the screen for him or her. This measure may **not** be administered to a proxy.

D. The Proxy Interview

Selected tests/interviews in the Abbreviated Battery may be completed with a proxy. Proxy interviews may be conducted on the telephone or in-person, either at the field site's testing site, at the participant's home, at the proxy's home, or an alternate location. All tests that may be completed with a proxy are included in Part 1 session. Part1, Form # 706 has been developed for proxy use in the 3rd Annual PT. Form # 706 clearly indicates which measures may be completed with a proxy. The text of the sentences will need to be altered a bit to accommodate the proxy interview.

1. <u>Selection of a Proxy</u>

In order to collect accurate data, the proxy informant should be someone who lives with, or has frequent (preferably daily) contact with the participant. Typically, a proxy informant is a family member and often will co-reside with the participant. However, if a participant does not have family members close by or is in a nursing home or other institution, the appropriate proxy can be a non-relative or a formal caregiver. Again, this person should have frequent contact with the participant to be able to provide the information requested. Only factual data are collected from proxy informants.

2. <u>Materials / Equipment Needed</u>

The **Abbreviated Battery**, **Part 1**, **Annual PT Form # 706** with ID label attached should be assembled in advance of the proxy interview.

3. Preparation

- a. Only certified ACTIVE Testers are qualified to complete this session.
- b. Testers should review and practice the interview as a proxy interview prior to actual administration. Measures that may be administered to a proxy are clearly marked in Form # 706 but Testers should flag the tests in advance of an actual proxy interview and make special notations in the margins to allow for a smooth delivery.
- c. An appointment should always be scheduled with the proxy in advance of the session. If completed in one session (preferable) the interview may take as long as 45 minutes.
- d. Ideally, this session will be completed as an in-person interview, but it may be completed as a telephone interview.
- e. In advance of the interview, the tester should assemble all the forms necessary to complete the interview.
- f. The area selected to complete the interview must allow for the conduct of a private, confidential interview. If completing the interview on the telephone, remind the proxy to be situated in a comfortable chair.

4. Order of Administration

The order of administration for the Proxy Interview should be as follows:

- MDS (15 minutes)
- Life Space/Falls (10 minutes)
- Health Conditions (5 minutes)
- Health Services Utilization (5 minutes)
- Medication Audit (10 minutes)

Ideally, a proxy interview will be completed in a single session.

ATTACHMENT A

Testers' Guide for ACTIVE Participants Who Cannot/Will Not Schedule An Appointment for An Annual Post-Test Session.

ACTIVE Testers should use this guide when calling participants to schedule 3rd – 6th Annual Post-Test sessions. At the time of telephone contact with the participant or household member, the tester may discover that the participant cannot or will not schedule an appointment for Post-Testing during the prescribed study visit window. The following are the most common reasons participants/relatives will cite for non-participation.

- The participant is suffering from a serious or debilitating illness and/or they are institutionalized
- The participant moved too far away or they are living in another location during the entire study visit window
- A close family member is suffering from a serious illness, or there has been a major change in an alternate obligation preventing full participation
- The participant simply refuses to participate stating reason such as, "I just am too busy to continue." "It just takes too long." "I can't go through that again." "Please don't ask me to do that again.", etc.
- A household member reports that the participant has died

When a participant cannot/will not schedule an appointment for an Annual Post-Test during the prescribed study visit window, the Tester should use the guides below to gather as much information as possible regarding the participant's situation. This information should be reported to the PI/Study Coordinator for determination of the appropriate follow-up action. It is important to gather as much information as possible to allow planning for the most appropriate follow-up.

The following script outlines are provided as rough guides and should be expanded as needed to address specific participant situations.

Debilitating Illness with or without Institutionalization

- 1. Offer condolences.
- 2. Inquire about the participant's well being. Inquire about the seriousness of the participant's illness/disability. Inquire about the prognosis/expected progress toward recuperation? Get specifics without acting like an interrogator, i.e. What happened?, Was there a main event, e.g. stroke, fracture,?, When did it happen? Is their vision affected, hearing, ability to read or write, upper/lower extremity mobility?
- 3. Determine if participant is living at home or in an institution such as a hospital, a rehabilitation center, a nursing home, an assisted living center, etc.
 - 3a. If the participant is living in an institution:
 - Get the name/general location of the institution or center (city and state).
 - Inquire about the expected length of stay.
- 4. Get a sense of the participant's cognitive status, physical and mental strength/stamina.
- 5. Determine if the participant could travel to the testing center to complete all or any of the measures. Does the participant require transportation be provided?
- 5a. If the participant cannot travel to the testing center, would they allow a tester to come to their home or institution to complete all or any of the measures?
- 6. If appropriate, tell the participant you will consult with your supervisor re: the best way to proceed and that you (or someone else) will call them back very soon (specify when). Determine convenient callback times.

Moved too far away

- 1. Obtain contact information for direct telephone and written contact.
- 2. Contact participant directly.
- 3. Determine when the participant moved.
- 4. Determine if the move is permanent or temporary.
- 5. If temporary, determine when participant will return. Is it prior to the close of their study visit window? If yes, schedule a time to complete the full battery per protocol. If the move is permanent or return is after the close of the study visit window, determine if the participant is located close to an alternate ACTIVE study site.
- 6a. If yes, make arrangements for alternate study site staff to complete follow-up testing.
- 6b. If no, ask participant if they can complete some ACTIVE measures on the telephone.
- 6. If appropriate, tell the participant you will consult with your supervisor re: the best way to proceed and that you (or someone else) will call them back very soon (specify when). Determine convenient callback times.

Deceased

- 1. Offer condolences.
- 2. Identify the informant by name and relationship to the participant.
- 3. Attempt to determine <u>when</u> the participant died, where they died, what was the cause of death.
- 4. Thank the informant and provide appropriate assurances if possible. Comment about the fact that the participant made a valuable contribution to the ACTIVE project.

General Refusal

- 1. Express regrets.
- 2. Ask the participant for reason why they are refusing.
- 2a. Is there a problem with transportation? Could they participate if transportation was provided for them?
- 2b. Do they have a very busy daytime schedule? Could they participate if the appointment time or place was changed to be more convenient to them?
- 2c. Were there aspects of the testing (or training) that they found upsetting or too burdensome? If yes, which aspects?
- 2d. Are they refusing because they have a partner/spouse/family member that is seriously ill or disabled that requires their undivided attention? If yes, offer condolences. Inquire about their partner's well being. Get specifics without acting like an interrogator, i.e. What happened?, Was there a main event, e.g. stroke, fracture,?, When did it happen?