

YEAR 16 MEMPHIS CLINIC VISIT OVERVIEW

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YEAR 16 MEMPHIS CLINIC VISIT**1. Overview of measurements**

At least 275 participants will have a Year 16 clinic or home visit. For home visit components, please see the home visit operations manual chapter. The clinic visit includes the following measurements:

- 20-meter walk
- Accelerometry (participant will be given the accelerometers to wear home with them)
- Blood pressure
- Balance walks
- Chair stands
- Grip strength
- Isokinetic strength (Kin-Com)
- Medication inventory
- Modified Mini-Mental State (3MS)
- Radial pulse
- Standing balance
- Standing height
- Weight
- DXA scan – whole body and hip

After the completion of each component of the Health ABC Year 16 clinic visit, the Procedure Checklist should be completed (see Appendix 1). Consent for release of results to physicians should also be indicated on the cover sheet of the Health ABC Year 16 Memphis Clinic Visit Workbook.

Scripts in protocols and worksheets

It is very important that examiners read the Health ABC operations manual. Scripts are included in the operations manual in order to standardize the administration of the many tests given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. A number of data forms also include script. Examiners are encouraged to learn the standardized script that appears in the protocols and/or forms, but they are free to modify the script in order for the presentation to sound natural, as long the same information is conveyed to the participants and is presented in the same order as the standardized script. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

2. Working with older participants

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people who volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

It is imperative that research participants are always treated with respect. This involves, but is not limited to, providing the necessary information to prepare them for their visit, greeting them warmly as they arrive in clinic, thanking them for their participation before the exams are started, answering any questions that they may have, explaining available test results at the end of the visit, thanking them again for their time and interest at the end of the visit, and not wasting their time by making them wait for long periods unnecessarily.

Dealing successfully with older research participants requires that we be sensitive to their potential needs and concerns. These needs may be related to ambulation difficulties, hearing and sight difficulties, discomforts associated with completing the clinic visit (e.g., fatigue due to their health status combined with a long visit, etc.), competing personal difficulties (e.g., depression, an ill spouse, etc.), and the experience of being a research participant.

The information we collect as research data may identify a new medical problem that may need to be brought to the attention of a participant's primary care physician for follow-up. We, as study staff, do not provide diagnosis or treatment. However, when participant consent has been obtained, we may need to notify appropriate parties (i.e., physicians, participants themselves, proxies, etc.) of a new abnormal finding. This should be accomplished by the clinic coordinator(s) after discussing the finding with the medical director/investigator.

Occasionally participants are wary of finding out that there is something "wrong" with them that they would rather not know. Tread lightly! Participants have a right to have this information remain unreported to them or to their physicians, family members, etc. Again, often their refusal is due to a lack of understanding and/or information. Take the time to discuss their fears. Contact the clinic coordinator to assist in the discussion as needed. However, participants do have the right to refuse to have information made known to themselves and/or others.

Keep in mind that, for the most part, participants who report feeling "fine" are "fine." Relax and enjoy your time with our Health ABC participants!

For Clinic Coordinators and Investigators

We have an obligation to communicate with our participants and/or their physicians when appropriate. Participants deserve to receive their test results in a timely fashion. These results should be reviewed by the clinic coordinator/investigators prior to being sent to the participant and/or their physician. There should be no surprises when a participant receives their results in the mail. When possible, the clinic coordinator should discuss any abnormal findings with participants BEFORE the results are sent in the mail. Coordinators need to be sure that test results are complete and accurate; and these results must be sent out as quickly as possible.

3. Equipment and supplies

Each operations manual chapter includes an equipment and supply section. For the complete list of equipment and supplies needed for this visit, please click on the Equipment List link on the Health ABC website header.

4. Training and certification

Every measurement should be administered by an examiner who has been trained and certified in that measurement. Operations manuals and certification forms are posted on the Health ABC website. Operations manuals can be found on the “Operations Manual” link and certification forms can be found on the “QC Examiner Certification” link. The completed certification forms should be PDF’ed and sent via e-mail to the Health ABC Help Desk at HABCHelp@psg.ucsf.edu.

5. Preparation for the Year 16 clinic visits**5.1 Participant preparation**

Each participant who comes to the Health ABC Year 16 clinic visits will have been told about the contents of the visits during the phone conversation to schedule the clinic visits. Reminder letters should be mailed approximately 7 to 10 days prior to the first visit to emphasize the following:

- date and time of the Year 16 clinic visit
- that participants take all of their regular medications, as usual
- that participants bring all of their prescription and non-prescription medications to clinic
- that participants should wear comfortable clothing (short sleeved) and footwear, and not wear jewelry or pantyhose or girdles
- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances

- that participants who wear hearing aids should bring or wear them to the clinic

5.2 Year 16 clinic visit preparation

At the time of the Year 16 clinic visit, the following should be available for each participant:

- A Data from Prior Visits Report should be generated with information that will be needed for the Year 16 clinic visit (see Appendix 3)
- The participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.)
- A Year 16 Memphis Clinic Visit Workbook preprinted with the acrostic and Health ABC enrollment ID number. It is important to double-check the accuracy of the pre-printed acrostic at the top of the first page of the Year 16 Memphis Clinic Visit Workbook as compared with the participant's name. After you print the participant's name on the first page of the Year 16 Memphis Clinic Visit Workbook, look at the first letter of the first name and the first three letters of the last name to make sure that these match the pre-printed acrostic at the top of the page.
- A Year 16 Participant Results Report to give the participant at the end of their clinic visit.
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

Table 1 [below on next page] lists all the forms that are completed for the Memphis Year 16 clinic visit.

Table 1
Health ABC Year 16 Memphis Clinic Visit Forms

Year 16 Memphis Clinic Visit Workbook:

Radial pulse
Blood pressure
Medication inventory
Modified Mini-Mental State (3MS)
Grip strength
Chair stands
Standing balance
Balance walks
20-meter walk
Height
Weight
DXA scan, hip and whole body
Isokinetic strength (Kin-Com)
Accelerometer screener and distribution

Participant take home:

Activity Monitor Logs

Visit follow up:

Accelerometer return and reading

6. Clinic flow and measurements

6.1 Overview of clinic flow

Every effort should be made to keep the visit as short as possible. One timesaving idea is to do tests consecutively that require that participants not be wearing shoes (height and weight). Also, if the Consent Form is sent out ahead of time, many participants will be ready to sign it right away when they arrive at the field center, instead of taking the time to read it during their clinic visit. The following guidelines for the order of specific measurements are divided into mandatory, which must be followed, and preferable, which are highly recommended but may be modified without jeopardizing the standardization of the measurements:

Mandatory:

Arm measured for cuff size before blood pressure
Blood pressure exams before Kin-Com and caffeine ingestion
Standing balance before tandem stand
Standing balance before balance walks
Height and weight before DXA

Preferable:

Group together standing height and weight

6.1.1 Blood pressure and radial pulse

Radial pulse and blood pressure will be measured and recorded at the Year 16 clinic visit. In addition, individuals with extremely high levels of blood pressure will be excluded from the isokinetic strength test and referred for medical care according to the protocol for referrals.

See Blood Pressure and Radial Pulse operations manual chapter for detailed procedures.

6.1.2 Medication assessment

Prescription medications will be recorded. A complete and accurate list of current prescription medication use is essential for several reasons: Some medications affect body composition and bone mass; medication use increases with increasing disability; and a number of ancillary studies require complete medication lists.

We are specifically interested in how individual medications have been actually taken (during the preceding 30 days) rather than how they were prescribed or intended to be taken.

See Medication Inventory operations manual for detailed procedures.

6.1.3 Modified Mini-Mental State (3MS)

The Modified Mini-Mental State Examination (3MS) is a widely used test of cognitive function among the elderly. It includes tests of orientation, registration, attention, calculation, recall, and visual-spatial skills. The 3MS is an expanded 100-point version of the original Folstein MMSE designed to increase the standardization, sensitivity, and specificity of the test as a screen for dementia. This form of the test was designed to sample a broader variety of cognitive functions, cover a wider range of difficulty levels, and enhance the reliability and validity of the scores.

See Modified Mini-Mental State (3MS) operations manual for detailed procedures.

6.1.4 Grip strength

Grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty. Grip strength in both hands will be measured using an adjustable, hydraulic grip strength dynamometer.

See Grip Strength operations manual for detailed procedures.

6.1.5 Performance-based measures (chair stands, standing balance, and balance walks)

Direct assessments of physical performance have become standard measurements in epidemiological studies in the elderly. These assessments generally tap multiple domains of physiological performance, including lower extremity strength, balance, coordination, and flexibility. The assessment techniques used in Health ABC have been derived from a number of previous studies, are reliable when performed in a standardized fashion, and are well tolerated by elderly participants. The following assessments are included in the Health ABC performance battery: single and multiple chair stands, standing balance, and balance walks.

See Performance-based measurement operations manual chapter for detailed procedures.

6.1.6 20-meter walk

This is a modification of the short walk test used in many epidemiological and clinical studies. The test is divided into two parts.

- the time to walk 20 meters at the participant's usual pace along with the number of steps, and
- the time to walk 20 meters as fast as the participant can, along with the number of steps

See 20-meter Walk operations manual for detailed procedures.

6.1.7 Anthropometry and physical measures

Two anthropometric and physical measurements will be made on all participants who attend the Year 16 clinic visit: standing height and weight. One of the most important measurements that are done for Health ABC is the weight measurement.

See Standing Height and Weight operations manual chapters.

6.1.8 DXA

Bone mineral density of the whole body will be performed using the Hologic QDR 4500 instrument. Body composition measurements are obtained during the whole body scan. Participants should have the BMD of their hip obtained during Year 16 on the same side that was scanned at baseline, unless the participant has had a fracture or hip replacement on that side.

See Bone Density Scan (DXA) operations manual for detailed procedures.

6.1.9 Isokinetic strength (Kin-Com)

A Kin-Com isokinetic dynamometer will be used to evaluate the concentric strength of the knee extensors.

See Isokinetic Strength operations manual for detailed procedures.

6.1.10 Accelerometry

An accelerometer (ActiGraph) measures the existence and intensity of motion in terms of “counts.” The devices are small, easy to use and can store data for multiple days. The data can be used to evaluate patterns of physical activity.

Participants will be given a wrist and hip accelerometer and monitor log during their Year 16 clinic visit and will be instructed about how to wear these accelerometers and how to complete the monitor log. They will return the accelerometers and their monitor logs 8 days later.

See Accelerometry operations manual for detailed procedures.

6.2 Procedure checklist and exit interview

At the end of the Year 16 clinic visit an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 16 Memphis Clinic Visit Workbook Procedure Checklist is completed; ie., the header information including the Health ABC Enrollment ID #; participant's first and last name; whether accelerometers and activity monitor logs were given to participant; and permission to send test results to the physician (see Appendix 1). Confirm that all exams and measurements were completed. Review the Year 16 Memphis Clinic Visit Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected results (Appendix 4). Participants will be given the following results:
 - ⇒ Height. Standing height in feet and inches should be provided.
 - ⇒ Weight. Weight in pounds should be provided.
 - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
 - ⇒ Body Composition. The participant will receive a body composition results report that includes their percent body fat.
 - ⇒ Bone mineral density (BMD). Their BMD will be plotted by the DXA technician on a sex and race-specific normative curve.

- Determine if the participant would like their test results sent to their physician. Note consent for release of reports to physician (yes or no) on the Year 16 Memphis Clinic Visit Procedure Checklist.
- Summarize future contact with the study both for scheduled telephone contacts and endpoints. Participants should be reminded to immediately contact the clinic for any of the following events:
 - ⇒ Hospitalization. Any overnight stay in an acute care facility.
 - ⇒ Surgery. Any surgery requiring regional (e.g., spinal) or generalized anesthesia. This includes same-day surgery for angioplasty.
 - ⇒ Fracture. Any broken bone, excluding minor fractures of the ribs, toes, fingers, etc.
 - ⇒ Cancer. Any newly diagnosed cancer, excluding non-melanoma skin cancer.

Suggested script: "It is very important to the study for us to know as soon as possible about changes in your health. Between study visits, we ask that you call the clinic at this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, are told that you have a new cancer, break any bones, or have outpatient surgery to open an artery (angioplasty)."

6.3 Incomplete visits

Occasionally, a participant may not complete their entire clinic visit. They may agree to come in at a later date to have the exams that they missed during their first visit. It is important to minimize the amount of time between the first and the second visit.

7. Alerts and notifications

At the clinic visit, participants will receive a report that includes height, weight, and blood pressure (see Appendix 4), whole body composition and bone density. Appendix 7 contains an example of an alert letter to a physician.

7.1.1 Blood pressure

Page 1 of the Year 16 Participant Results Report includes a place for the participant's name and for their systolic and diastolic blood pressure values that can found in the Year 16 Memphis Clinic Visit Workbook. Record these results on the Year 16 Participant Results Report. Review the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommendations based on the participant's blood pressure (see below).

Normal:	Less than 120/80 mm Hg
Prehypertension:	120-139/80-89 mm Hg
Hypertension:	140/90 mm Hg or higher

There are five categories to check on the blood pressure portion of the Year 16 Participant Results Report:

- If the participant's systolic blood pressure is normal, i.e., <120 systolic, and < 80 diastolic or prehypertension, 120-139 systolic, or 80-89 diastolic, check "Recheck blood pressure within 1 year" on the Year 16 Participant Results Report.
- If the participant's systolic blood pressure is 140 to 159, or their diastolic blood pressure is 90-99, check the box on the Year 16 Participant Results Report that says "Recheck blood pressure within 2 months." Suggest to the participant that they have their blood pressure rechecked within 2 months.
- If the participant's systolic blood pressure is 160 to 179, or their diastolic blood pressure is 100-109, check the box on the Year 16 Participant Results Report that says "See your doctor in 1 month." Suggest to the participant that they see their doctor within one month.
- If the participant's systolic blood pressure is 180 to 209, or their diastolic blood pressure is 110-119, check the box on the Year 16 Participant Results Report that says "See your doctor in 1 week." If the participant gives their permission, you can contact their primary care provider within one week, or instruct the participant to contact their primary care provider within one week.
- If the participant's systolic blood pressure is ≥ 210 , or their diastolic blood pressure is ≥ 120 , check the box on the Year 16 Participant Results Report that says "See your doctor immediately." If the participant gives their permission, you can contact their primary care provider immediately, or instruct the participant to contact their primary care provider immediately.

Instruct the participant to talk with their doctor about any specific questions that they may have about their blood pressure.

7.1.2 Bone density (DXA)

The alert for DXA is loss of bone at a greater rate than 16% since baseline. (See Appendix 6 for alert letter to participant and Appendix 7 for the alert letter to physician to be sent after confirmation of excess bone loss from the DXA Reading Center [see Appendix 5 - Excessive Bone Loss Form].)

8. Clinic safety

8.1 Background and rationale

All life threatening emergencies that occur at the Health ABC clinic, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken in the clinic before departure. Minor emergencies, such as hypotension or fainting, receive treatment in the clinic. Although most emergencies are of even less severe nature, Health ABC Field Center Clinics are prepared for both types.

8.2 Major emergencies

When a serious life-threatening event occurs in the clinic setting, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. It is imperative that local emergency measures be activated; in most cases, this requires calling 911. Do not take the participant to the emergency room. Let the paramedics do that. At every clinic session a physician, physician assistant, or registered nurse with certification in basic life support is on duty and physically present. Needed life support procedures should be continued until emergency care arrives or the participant is transported to a hospital.

Each Health ABC clinic has specific emergency procedures which define:

1. Who is in charge during the emergency
2. Who administers treatments
3. Who is notified
4. What action clinic staff takes
5. Which reports are filed

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place, such as the reception area, the following:

- phone number of police station
- phone number of fire stations
- phone number of ambulance services

} **CALL 911 !**

In each participant's folder, the name and phone number of their physician or usual source of health care is available on a standard Health ABC form. The home and work telephone number of the next-of-kin are also listed.

All medical emergency situations should be coordinated by a physician when present in the clinic. In the physical absence of the latter, this role should be assumed by the charge nurse or senior physician assistant. When not physically present in clinic, they are within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the head nurse and/or senior physician assistant so that the name of the responsible physician is readily accessible. However, in no case should emergency referral and/or care be deferred while staff is attempting to locate a clinic doctor. All personnel should be trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly, inclusive of any emergency drill.

All major emergencies should be documented, identifying the type of emergency and action taken. This report should be completed by the clinic coordinator and co-signed by a clinic physician and the Principal Investigator. These reports should be maintained in a central file at each field center and a copy of the report should be kept in the participant's chart.

8.3 Minor emergencies

The most common minor emergency is simple syncope (fainting) and near syncope.

In any situation in which syncope is likely, staff should verify that the participant does not look or feel faint. When the participant looks faint or feels faint the following steps should be implemented:

1. Have the person remain in the chair and sit with their head between their knees or lie down.
2. Crush an ampule of smelling salts and wave under the participant's nose for a few seconds. DO NOT place ampule directly under the nose.
3. Provide the participant with a basin and a towel when they feel nauseous.
4. Check blood pressure and pulse.
5. Have the participant stay in the chair until they feel better and their color returns. Re-check blood pressure and pulse.

If the participant continues to feel sick, recline the chair, place a cold, wet towel on the back of the person's neck, and notify the clinic nurse coordinator. When a participant faints, they should be cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house physician or nurse to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. When life support measures are needed, the measures outlined in the above sections are followed.

8.4 Emergency equipment

A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every 6 months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

8.5 Emergency plans in case of fire

1. Notify the emergency management system (911) to report the fire.
2. Close all windows and doors.
3. Escort all participants to the nearest fire exit and assemble a safe distance from the building.
4. Alert the clinic coordinator and the building supervisor of the emergency situation.

Appendix 2 Year 16 Memphis Clinic Visit Instructions



Instructions for Year 16 Clinic Visit

We're looking forward to seeing you for your Health ABC Year 16 Clinic Visit scheduled for: _____ at _____ a.m. at XXXXXXXXXXXX, XXXXXXXXXXXX. Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

Please be sure to review these instructions for your upcoming clinic visit, since they are very important for the success of your tests:

- Read all enclosed materials.
- Take all of your regular medications, as usual.
- Bring all of your prescription and non-prescription medications to clinic.
- Wear comfortable shoes for walking. It would be helpful if you wear a short-sleeved shirt, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles.
- Do not wear jewelry to the clinic, if possible, since this may make it more difficult to do your bone scan.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.

Thank you again for your very valuable help in this important research study! We look forward to seeing you again.

Please call XXX-XXXX if you have any questions about your visit.

6/28/13

Appendix 3 Data from Prior Visits Report**Year 16 Memphis Clinic Visit
Data from Prior Visits Report**

Participant Name:
Health ABC Enrollment ID#:
Acrostic:

YEAR 16Q3 INTERVIEW

1) Status of Year 16Q3 participant interview (participant completed; proxy completed; missed interview):

1a) If missed Year 16Q3 interview, reason for missed interview:

BLOOD PRESSURE

2) Which arm was used for the baseline (Year 1) blood pressure?

HEIGHT

3) Was the participant standing sideways at the baseline (Year 1) visit when their height was measured?

4) Was the participant standing sideways at the Year 11 clinic visit when their height was measured? If sideways at Year 11 visit, measure height sideways.

BONE DENSITY (DXA)

5) Which hip was scanned at the baseline (Year 1) clinic visit?

ISOKINETIC QUADRICEPS STRENGTH (KIN COM)

If possible, use settings from the Baseline or First Measurement of Isokinetic Quadriceps Strength (noted below), unless contraindicated. If contraindicated, use settings from Last (Most Recent) Measurement of Isokinetic Quadriceps Strength (also noted below) or modify settings as needed in order to safely test participant.

Baseline or First Measurement of Isokinetic Quadriceps Strength

6) Which leg was tested at the baseline clinic visit (or if test not done at baseline, for the first measurement of isokinetic quadriceps strength)?

7) Which hip was scanned at the baseline (Year 1) clinic visit?

8) Manual position for baseline (or first) measurement of isokinetic quadriceps strength:

- | | |
|---------------------------|----------------------|
| a. Dynamometer tilt | e. Seat rotation |
| b. Dynamometer rotation | f. Seat back angle |
| c. Lever arm green C stop | g. Seat bottom depth |
| d. Lever arm red D stop | h. Seat bottom angle |
| | i. Lever arm length |

Last (Most Recent) Measurement of Isokinetic Quadriceps Strength below.

9) Which leg was tested for participant's last (most recent) measurement of isokinetic quadriceps strength?

10) Manual position for last (most recent) measurement of isokinetic quadriceps strength:

- | | |
|---------------------------|----------------------|
| a. Dynamometer tilt | e. Seat rotation |
| b. Dynamometer rotation | f. Seat back angle |
| c. Lever arm green C stop | g. Seat bottom depth |
| d. Lever arm red D stop | h. Seat bottom angle |
| | i. Lever arm length |

ACCELEROMETRY

11) Does participant have a TICS score less than 20?

12) (HOME VISIT ONLY) What was the participant's height at their last visit?

13) Which hand does participant use to write with?

MEDICATION INVENTORY

14) The following is a listing of prescription medications used by the participant in Year 11. Please use this list to confirm with the participant that they brought all of the medication they used in the past 30 days.

Medication Name	Formulation Code	Frequency	Still Using
-----------------	------------------	-----------	-------------

EVENTS

Appendix 4 Health ABC Participant Results – Clinic Visit



 Year 16 Clinic Visit
Participant Results Report

Participant Name: _____

Date of Year 16 Visit: ___ / ___ / ___
 Month Day Year

Height: ___ feet ___ inches

Weight: ___ ___ ___ pounds

Blood Pressure: ___ ___ ___ / ___ ___ ___ mm Hg

Normal:	Less than 120 / 80 mm Hg
Prehypertention:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- Have your blood pressure rechecked within 1 year
- Have your blood pressure rechecked within 2 months
- See your doctor about your blood pressure within 1 month
- See your doctor about your blood pressure within 1 week
- See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

BODY COMPOSITION

One of the goals of Health ABC is to determine how weight and body composition (fat and lean muscle mass) affect health as we get older. With age, our weight changes and this is often the result of an increase in body fat along with a decrease in lean mass. These changes in body fat and lean mass may lead to an increased risk for health problems and disability. For example, obesity (high percent body fat) may reduce life expectancy by increasing the risk of developing coronary artery disease, high blood pressure, Type II diabetes, certain types of cancer, and several other diseases including arthritis. Although less common, a person may have too little body fat. Since we need a certain amount of body fat (called essential fat) to maintain normal body functions, older men and women with too little fat may also be at risk for health problems.

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your body fat percentage is marked below. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older adults. As a participant in Health ABC, you are helping us to determine what percentage of body fat either maintains or improves health as we age or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %

BONE MINERAL DENSITY

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 16 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young men / women and is at the level checked below:

_____ Normal
_____ Low
_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a local doctor who specializes in treating osteoporosis.

If you have questions regarding these results, please contact _____
_____ at _____.

Memory tests

There are no “normal” values for many of these tests. By repeating these tests in previous and future visits you will help us learn more about how memory and reaction time changes with age and in relation to lifestyle and changes in health.

Muscle strength, flexibility, balance, and walking speed tests

We do not know yet what results are considered “normal” for these tests. You are helping us understand how body changes may cause new health problems and how to prevent disability as we get older. In future years, with your continued participation, we may be able to tell you how your test results compare with others.

We would like to thank you for your continued participation in the Health ABC study. These tests were done for research purposes only and were not intended to diagnose any health problems. However, we encourage you to share these results with your doctor. If you have any questions, please call the Health ABC clinic at:

() _____.

Appendix 6 Sample Letter to Participant Regarding Alert Values

August 13, 2013

Jane Doe
1234 Market Street
Memphis, TN 38105

Dear Ms. Doe:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than or equal to 16% since your baseline measurement was made.

This loss is greater than average for a person your age and may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications.

We have enclosed both copies of your hip scan, your baseline measurement and your last measurement. We suggest that you consult with your personal doctor to find out why this is occurring, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in Memphis.

Thank you for your time and interest in the Health ABC study. Please do not hesitate to call us if you have questions at (____)_____ and ask for _____.

Sincerely,

Suzanne Satterfield M.D., D.P.H.
Health ABC Principal Investigator

/sa

Appendix 7 Sample Letter to Physician Regarding Alert Values

August 13, 2013

Abe Friedman, M.D.
5845 Centre Avenue
Memphis, TN 38105

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Health ABC study for the past 16 years, was here on ____/____/____ for his/her annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline, Year 3, Year 5, Year 8, Year 10, and now at Year 16. The BMD scans of his/her total hip showed 16% bone loss since the start of the study. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as “excessive bone loss” by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma, but we cannot rule out the possibility of positioning or other measurement errors.

We are enclosing a copy of the participant’s hip scan and reference plots that show the bone loss to be ____%.

If you have any questions, please feel free to contact us at (____)_____.

Sincerely,

Suzanne Satterfield M.D., D.P.H.
Health ABC Principal Investigator

/sa