

YEAR 3 CLINIC VISIT**TABLE OF CONTENTS**

| | | |
|---------------|---|-----------|
| 1. | Overview of measurements..... | 1 |
| 2. | Working with older participants..... | 2 |
| 3. | Preparation for the Year 3 clinic visit..... | 3 |
| 3.1 | Participant preparation | 4 |
| 3.2 | Clinic preparation..... | 4 |
| 3.2.1 | Pre-visit screening | 4 |
| 3.2.2 | Year 3 clinic visit preparation | 4 |
| 4. | Clinic flow and measurements | 6 |
| 4.1 | Overview of clinic flow | 6 |
| 4.1.1 | Year 3 in-clinic follow-up interview..... | 7 |
| 4.1.2 | Blood collection..... | 7 |
| 4.1.3 | Medication use..... | 7 |
| 4.1.4 | Weight..... | 8 |
| 4.1.5 | Radial pulse and blood pressure | 8 |
| 4.1.6 | Bone density (DXA)..... | 8 |
| 4.1.7 | Muscle fatigue and work capacity (Kin-Com)..... | 9 |
| 4.1.8 | 20-meter walk..... | 9 |
| 4.1.9 | Rapid Assessment of Adult Literacy in Medicine (REALM) | 9 |
| 4.1.10 | Teng Mini-Mental..... | 9 |
| 4.1.11 | Executive control function (CLOX1 and EXIT15)..... | 10 |
| 4.1.12 | Functional vision..... | 10 |
| 4.1.13 | Olfaction..... | 10 |

YEAR 3 CLINIC VISIT

1. Overview of measurements

All Health ABC participants who attend the Year 3 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Review of medications used in the past two weeks (Medication Inventory Form)
- Assessment of cognitive function (Teng Mini-Mental State, Literacy assessment [REALM], and Executive function [CLOX1 and EXIT15])
- Weight
- 20-meter Walk
- Muscle fatigue and work capacity (Kin-Com)
- Isometric strength (Isometric Chair)
- Bone mineral density and body composition by DXA
- Serum for laboratory testing, and arterialized blood for blood gas assessment.

Subgroups of participants may have the following tests:

- A cognitive vitality sub-study (Buschke SRT, Boxes, Digit Copy, Pattern Comparison, Letter Comparison, Reaction Time, Personality Assessment, and Activity Assessment) will be done on a sub-sample of participants.
- Energy expenditure, knee x-ray and MRI, periodontal assessment, and cell collection on participants who are eligible but did not have these assessments during their Year 2 clinic visit

After the completion of each component of the Health ABC Year 3 Clinic Visit, the Procedure Checklist should be checked (see Appendix 1). Consent for release of reports to physicians should also be indicated on the cover sheet of the Health ABC Year 3 Clinic Visit Workbook (Memphis only).

Scripts in protocols and worksheets

It is very important that examiners read the Health ABC operations manual protocols. 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 worksheets also include script. Examiners are encouraged to memorize the standardized script that appears in the protocols and/or worksheets, but they are free to adapt the script to their own words, when appropriate, as long as the same information is conveyed to the participants and is presented in the same order as the standardized script. However, please note that the administration of the Teng Mini-Mental State Exam, the Rapid Assessment of Adult Literacy in Medicine (REALM), the Executive function tests, and the Cognitive Vitality Substudy tests require the use of the exact script that is included in the protocols and worksheets.

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. Remember, in order for Health ABC to be successful, we need participants to agree to return for the next 6 years after their baseline visit. If they do not feel that they were treated with respect, we may lose them for follow-up. Time spent in making their visit as pleasant as possible is time well spent.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people that 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 we always treat each research participant 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., long periods of fasting without even a cup of coffee, difficult blood draws, 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.

We must also be aware that 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 a 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 here! 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 nurse 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. The participant report serves as an important thank-you for time spent participating in each Health ABC examination.

3. Preparation for the Year 3 clinic visit

3.1 Participant preparation

Each participant who comes to the Health ABC Clinic Visit will have been told about the contents of the visit during the phone conversation to set up the clinic visit. We recommend reminder phone calls or postcards prior to the visit to re-emphasize the following:

- The participant should bring in all prescription and non prescription medications used in the preceding two weeks.
- Dietary guidelines prior to the visit should be followed. The participant should finish eating one hour before they leave for their clinic visit.
- Guidelines should be followed for footwear and undergarments for women

Please see an example of a reminder letter in Appendix 3.

3.2 Clinic preparation

3.2.1 Pre-visit screening

The Cognitive Vitality Substudy is being done on a sample of the Health ABC cohort during the Year 3 visit. To determine whether or not a participant is eligible for the Cognitive Vitality Substudy, the questions on the Pre-Visit Screener for Cognitive Vitality will be answered by the participants over the phone before their scheduled appointment.

The Energy Expenditure test, begun during Year 2 of the Health ABC study, will continue to be done on a random sample of Health ABC participants. During the pre-visit screening call, the eligibility of those participants who are randomly chosen for the energy expenditure examination will be determined by the participants' answers to the questions on the Pre-visit Screener for Energy Expenditure form.

3.2.2 Year 3 clinic visit preparation

At the time of the Year 3 clinic visit, the following should be available for each participant:

- A completed Pre-visit Screener for Knee X-ray form[????]

See Table 1 [below] for complete list of the forms that are completed during the Year 3 Clinic Visit. Note that the Energy Expenditure and Cognitive Vitality Substudy forms are completed only for a sub-sample of participants; the Knee X-ray Tracking form is completed only for participants who are eligible for a knee x-ray; and the Knee MRI Eligibility and Tracking form is completed for those participants who are being given the MRI exam. The Dental and Periodontal Exam forms are only filled out for participants who missed these exams during their Year 2 clinic visit.

| Table 1 | |
|--|---|
| <u>Health ABC Year 3 Clinic Visit Forms</u> | |
| Pre-visit Screener for Knee X-ray | Year 3 Clinic Visit Workbook (cont.) |
| Pre-visit Screener for Energy Expenditure | Olfaction |
| Pre-visit Screener for Cognitive Vitality | Phlebotomy |
| Year 3 Questionnaire | Laboratory Processing (including |
| Year 3 Clinic Visit Workbook: | Arterial Venous Blood Gas) |
| Year 3 Clinic Visit Procedure Checklist | Cognitive Vitality Substudy |
| Medication Inventory | Buschke, Boxes, Digit Copy, Pattern |
| Weight | Comparison, Letter Comparison, Reaction time, |
| Blood Pressure | Personality Assessment, Activity Assessment |
| 20-meter Walk | Knee X-ray Tracking |
| Bone Density (DXA) Scan | Knee MRI Eligibility and Tracking |
| Muscle Fatigue and Work Capacity (Kin-Com) | Energy Expenditure (Visit 1) |
| Isometric Strength (Isometric Chair) | Dental Examination |
| Rapid Assessment of Literacy in Medicine | Periodontal Exam Eligibility Assessment |
| (REALM) | Periodontal Examination: |
| Teng Mini-Mental State | Backup for Voice Recognition |
| Executive Function (CLOX1 & EXIT15) | Energy Expenditure (Visit 2) |

4. Clinic flow and measurements

4.1 Overview of clinic flow

Since participants are arriving to the clinic in a moderately fasting state it is preferable for the participants' comfort that their laboratory work be done as soon as possible so that they can have a snack. Also, every effort should be made to keep the visit as short as possible. One way to save time is to have the participant put on their robe after their blood pressure exam so that they don't have to put on the robe and then take it off. Another time-saving idea is to do tests consecutively that require that participants not be wearing shoes (DXA, 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 measurements:

Mandatory

Blood pressure before Muscle Fatigue and Work Capacity (Kin-Com)

Radial pulse before Muscle Fatigue and Work Capacity (Kin-Com)

DXA before Muscle Fatigue and Work Capacity (Kin-Com)

Rapid Estimate of Adult Literacy in Medicine (REALM) before Functional Vision

Preferable:

Blood collection before other tests

4.1.1 Year 3 in-clinic follow-up interview

The Year 3 Questionnaire will be administered during the year 3 clinic visit. The questionnaire does not have to be completed all at once, and can be administered in sections during the course of the clinic visit, with special care that each section be completed.

4.1.2 Blood collection

The Health ABC study Year 3 clinic visit involves the collection of approximately 20 mL of blood (including blood for the arterialized blood gas protocol, a pediatric tube for a complete blood count, and 10 cc serum tube for archival purposes), unless the cell protocol was skipped in Year 2. With the collection of blood for the cell protocol, the total volume is 36 mL

See Chapter 2C, 2D, and 2E for detailed procedures.

4.1.3 Medication use

Prescription and non-prescription medications used by participants in the two weeks prior to their Year 3 clinic visit will be recorded on the Medication Inventory Form (MIF) in the Year 3 Clinic Visit Workbook. Review the Data from Prior Visits printout for start dates and dosages of medications that the participant was taking at their Year 2 clinic visit. Determine if the medications have been taken continuously or intermittently. If these medications were taken in the past two weeks, they have to be re-written on the Year 3 Medication Inventory form, but time will be saved if you review the medications that are listed on this form. Also, add any new medications that the participant has used in the past two weeks.

See Chapter 2B for detailed procedures.

4.1.4 Weight

One of the most important measurements that is done for Health ABC is the weight measurement. The measurement of weight comes early in the exam and offers a good opportunity to answer questions and promote goodwill towards the study.

See Chapter 2P for detailed procedures.

4.1.5 Radial pulse and blood pressure

Blood pressure measurements will be recorded to document blood pressure, and radial pulse will be counted to document heart rate. Also, the blood pressure and radial pulse measurements will be used for the Muscle Fatigue and Work Capacity (Kin-Com) exam; individuals with extremely high levels of blood pressure will be excluded from muscle fatigue testing and referred for medical care according to the protocol for referrals. Also, participants with very low or very high heart rates will be excluded from the muscle fatigue testing.

See Chapter 2L for detailed procedures

4.1.6 Bone density (DXA)

Bone mineral density of the hip and whole body will be performed using the Hologic QDR 4500 instrument. Body composition measurements are obtained during the whole body scan. BMD of the hip should be performed on the same side that was scanned at baseline, unless the participant has had a hip replacement on that side. Also, the side chosen for the Muscle Fatigue and Work Capacity Test (Kin-Com) will depend, at least in part, on which hip was scanned during the DXA exam.

See Chapter 2F for detailed procedures.

4.1.7 Muscle fatigue and work capacity (Kin-Com)

Using the KinCom isokinetic dynamometer we will measure muscle fatigue of the knee extensors and flexors (concentric) as an independent measure of muscle function and potential predictor of functional capacity, disability and morbidity at the year 3 examination. Kin-Com testing should be performed on the same side as hip BMD.

See Chapter 2N for detailed procedures.

4.1.8 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 Chapter 2M for detailed procedures.

4.1.9 Rapid Assessment of Adult Literacy in Medicine (REALM)

The REALM is a brief, highly reliable, and well-validated word recognition based measure of reading level, targeted to identify low literacy. It consists of 66 common lay-medical terms of variable difficulty and takes 1 to 3 minutes to administer.

See Chapter 2G for detailed procedures.

4.1.10 Teng Mini-Mental

The MMSE (Mini-Mental State Examination) 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 Teng Mini-Mental 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 Chapter 2H for detailed procedures.

4.1.11 Executive control function (CLOX1 and EXIT15)

Executive control function will be measured using the CLOX 1, a clock-drawing test, and the EXIT15, a modification of the EXIT25. Impairment in ECF is thought to contribute to loss of independence through interference with the ability to initiate, direct, plan, and execute complex goal-directed activities, such as preparing meals, following a medication regimen, etc.

See Chapter 2I for detailed procedures.

4.1.12 Functional vision

Three aspects of functional vision will be tested during Year 3 of Health ABC: stereopsis (depth perception) and contrast sensitivity, both good predictors of falls, and high-contrast acuity (a predictor of poor survival, physical disability, decline in physical functioning, and impairment of mobility and activities of daily living).

See Chapter 2K for detailed procedures.

4.1.13 Olfaction

Year 3 of Health ABC will include a short, 12-item smell test. It has been suggested that sense of smell deteriorates with age and that this is associated with decreased appetite. In addition, there has been some work suggesting that loss of the sense of smell may be an early predictor for onset of cognitive impairment and Alzheimer's Disease.

See Chapter 2O for detailed procedures.

4.2 Procedure checklist and exit interview

At the end the Year 3 Clinic Visit, an exit interview should be performed to:

- Thank the participant. The Year 3 clinic visit is long and can be tedious. Be sure the participant knows how much we appreciate their participation and patience.
- Answer questions. Some participants may have questions about various examinations.
- Confirm that all exams and measurements were completed. Review the Year 3 Clinic Visit Workbook and complete the Procedure Checklist appropriately.
- Make sure the Year 3 Clinic Visit Workbook cover sheet is completed; ie., the header information including the Health ABC Enrollment ID #; time of arrival; time of departure; whether the visit included scheduling a knee x-ray and/or MRI; whether the visit included a periodontal eligibility assessment, periodontal exam, or dental exam; whether the energy expenditure visit 1 exam was administered; and permission to send test results to the physician (see Appendix 2).
- Provide selected results (Appendix 3). Participants will be given the following results:
 - ^ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
 - ^ Weight. Weight in pounds should be provided.
 - ^ Functional vision. Participants will get the results (with explanations) of their vision tests.
 - ^ BMD and body composition. DXA results from the total hip should be provided as this site is the most reproducible and is used clinically. The participants BMD will be plotted by the DXA technician on a sex and race-specific normative curve. A brief explanation of these results will be included on this printout. Percent body fat will be given but no reference range will be provided.

- Tell participant that additional results and a summary will be sent to them within 8 weeks of their Year 3 Clinic Visit. 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 Clinic Visit Procedure Checklist.
- Summarize future contact with the study both for scheduled visits 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 that does not result in an overnight hospitalization.
 - ^ Fracture. Any broken bone, including minor fractures of the toes, fingers, etc.

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 and this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, or break any bones.”

4.3 Incomplete Visits

Occasionally, participants who have not fasted before their baseline clinic visit will return for their oral glucose tolerance test at a later date (see section **4.1.2** in this chapter). Some participants may return to give a urine sample (see section **4.1**); or may return for their CT, PFT, or DXA exam. Examiners are instructed to fill out the first page of the Baseline Clinic Visit Workbook to indicate that the clinic visit was incomplete or complete except for CT.

It is important to minimize the amount of time between the first and the second visit. It is not necessary to reweigh the participants who come in for a second clinic visit. Use the weight that is recorded on page 12 of the Baseline Clinic Visit Workbook for both the DXA and the PFT exams.

Very rarely, a measurement is not taken. For example, if the participant has a colostomy bag, the sagittal diameter cannot be measured. Whenever a measurement is not taken, write the reason next to the blank results field on the Baseline Clinic Visit Workbook and include a note in the progress notes in the participant's chart explaining why the measurement was not taken.

5. Alerts and Notifications

At the clinic visit, participants will receive a report that includes height, weight, blood pressure, PFT and DXA results (see Appendix 3). Other test results will follow as a final report except for alerts or abnormalities requiring earlier notification. The final report will be mailed to participants within eight weeks of the clinic visit. Alerts will be sent from the laboratory/reading centers within 1 to 2 days, and in most instances the participant and their medical provider should be contacted by the coordinator after consultation with the medical director. (Table 2 lists measures that have alert values.)

| Table 2 | |
|--|---|
| <u>Health ABC Tests: Alert Values</u> | |
| <u>Defined Values</u> | <u>Examiner Discretion</u> |
| Blood Pressure | CES-D |
| DXA /low BMD and excessive bone loss | Teng Mini-Mental State Exam Long Distance Corridor Walk (symptoms related to) |
| Lab tests | |

5.2 Biochemical Tests

| | | | |
|-------------------------|--------|-----------------|--|
| Creatinine | normal | 0.7 - 1.5 mg/dl | ALERT > 3.0 mg/dl |
| Albumin | normal | 3.0-5.5 mg/dl | No alert value |
| Alkaline phosphatase | normal | 40-140 u/L | ALERT >350 u/L |
| Hg A ₁ C | normal | 4-6% | No alert value >7 may indicate elevated glucose levels |

5.4 Blood Pressure

Immediate alert: ≥ 210 SBP or ≥ 120 DBP, refer to source of care immediately after discussion with the clinic physician.

Below are ranges of blood pressure measurements that require various schedules for referral to sources of care and ranges that are considered to be normal.

180-209 SBP or 110-119 DBP, refer to source of care within 1 week
160-179 SBP or 100-109 DBP, refer to source of care within 1 month
140-159 SBP or 90-99 DBP, confirm within two months
130-139 SBP or 85-89 DBP, high normal, no referral required
<130 SBP or < 85 DBP, normal, no referral required

Blood pressure measurements will be given to the participant at the time of the clinic visit. A printed form with the above referral information and levels, with blanks for recording the participant's values will be provided. The same information will be included in the final report to the participant and to the participant's physician (see Appendices 10 and 11).

5.6 DXA

Total Hip BMD will be reported to the participant at the time of the clinic visit. The value will be plotted on an appropriate sex and race-specific reference based upon normative data from NHANES III. Percent body fat from the DXA will also be reported without reference to a normal range, but with reference to the other Health ABC participants. A report similar to the one attached will be included in the report given to the participant at the clinic visit. The same report would be included in the final report for both the participant and the physician (see Appendix 3). Participants will be given an alert letter at their Year 3 clinic visit if their BMD t-value is at or below -2.5 . The participant and their physician will receive an excessive bone loss letter if their bone loss exceeds 4% per year. The excessive bone loss letters will not go out until after the scans are re-analyzed at the Coordinating Center.

5.9 Teng Mini-Mental State Exam

Scores from the Teng Mini-Mental State Exam will not be routinely reported to the participant or physician. However, the clinic nurse coordinator or physician/investigator may decide on an individual basis that the first year score should be discussed with the participant and reported to the participant's physician. (Some experts suggest that a score of 75 or below might prompt consideration of notification.)

If there is a significant decline in the score or a persistent low score at the second administration of the exam, the participant's physician may be notified. (Details of this notification and definitions of significant decline to be determined.)

5.10 CES-D

Scores from the CES-D will not be routinely reported to the participant or physician.

Interviewers will review responses to the CES-D portion of the questionnaire. Interviewers will discuss reported symptoms of depression with the participant to ensure that the participant is either receiving treatment or has information on sources of care. Alternatively, the clinic nurse coordinator may discuss the symptoms of depression with the participant at the clinic visit. Notification of a high CES-D score will be sent to the participant's physician only if the participant requests it.

5.12 Height and Weight

Weight will be recorded on the form given to the participant at the time of the visit (see Appendix 3). This measurement will also be included in the final report to the participant and their physician.

6. Clinic Safety

6.1 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.

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.

6.3 Minor Emergencies

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during venipuncture or the pulmonary function test. Management of simple syncope or near syncope is the same whether associated with drawing blood or performing the pulmonary function test.

In any situation in which syncope is likely, such as during venipuncture, 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.

6.4 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 six months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

6.5 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 1



Staff ID #

| | | |
|--|--|--|
| | | |
|--|--|--|

BASELINE CLINIC VISIT PROCEDURE CHECKLIST

| | Page Numbers | Please check if done | | Comments |
|-----------------------------------|--------------|------------------------------|-----------------------------|--|
| 1. ECG Tracking | 3 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 2. Phlebotomy | 4 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 3. Oral Glucose Tolerance | 5 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 4. Laboratory Processing | 6 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 5. Medication Inventory | 7-11 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 6. Standing Height | 12 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 7. Sitting Height | 12 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 8. Sagittal Diameter | 12 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 9. Weight | 12 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 10. Blood Pressure | 13 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 11. Ankle-Arm Blood Pressure | 14 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 12. Pulse Wave Velocity | 15 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 13. Side to Measure Assessment | 16 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 14. Isokinetic Strength (Kin-Com) | 17-18 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Right leg <input type="checkbox"/> Left leg |
| 15. Bone Density Scan (DXA) | 19-20 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Right leg <input type="checkbox"/> Left leg |
| 16. Thigh Circumference | 21 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Right leg <input type="checkbox"/> Left leg |
| 17. Abdominal Circumference | 21 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 18. Chair Stands | 22-23 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 19. Standing Balance | 24-25 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 20. Balance Walks | 26 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 21. Long Distance Corridor Walk | 27-31 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 22. Teng Mini-Mental State | 32-39 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 23. Digit Symbol Substitution | 40-42 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 24. Grip Strength | 43 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 25. Finger Tapping | 44 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 26. Pulmonary Function | 45 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| 27. CT | 46 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Right Thigh <input type="checkbox"/> Left Thigh |

Page Link #

◆Page 2◆

Version 1.2a, 9/16/97



25751

APPENDIX 2



BASELINE CLINIC VISIT WORKBOOK

| HCFA Screening ID # | HABC Enrollment ID # | Acrostic | Date Form Completed | Staff ID # |
|----------------------|-----------------------|-----------------------|--|-----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> / <input type="text"/> / <input type="text"/> | <input type="text"/> |
| 0 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 1 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Examiner Note: Write the HCFA Screening ID # in the boxes and fill in the circles below that correspond to these numbers. The circles are the scannable portions of this field, so it is essential that they are filled in.

Time of arrival: :

Time of departure: :

What is the status of the clinic visit?

- Clinic visit completed
- Clinic visit completed **except** for CT
- Incomplete visit

Memphis Only:

Would you like us to send a copy of your test results to your doctor? Yes No

Page Link #

♦Page 1♦

Version 1.2a, 9/16/97



APPENDIX 3
page 1 of 6**Health ABC Examination Results Form**

Participant Name: _____
(Please Print)

Date of Clinic Visit: ____/____/____
Month Day Year

Blood Pressure:

Measurement 1 ____/____ mm Hg

Measurement 2 ____/____ mm Hg

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends for you:
(Check appropriate box.)

- Recheck blood pressure within 1 year
- Recheck blood pressure within 2 months
- See your doctor in 1 month
- See your doctor in 1 week
- See your doctor immediately

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

Standing Height: _____
(feet and inches)

Weight: _____
(pounds)

Health ABC Examiner Name: _____

(Please Print)

Health ABC Staff ID #: _____

APPENDIX 3
page 2 of 6**Pulmonary Function Report**

Name: _____

Date: _____

A preliminary report of your lung function is shown below. A final report will be sent to you after these results have been analyzed. The report below is not a final report.

_____ Test was not performed or lung function could not be determined accurately.

Results:

| Lung Function Test | Your Value | Usual Normal Range |
|------------------------|--------------------|--------------------|
| FVC | _____ of Predicted | 80% and greater |
| FEV ₁ | _____ of Predicted | 80% and greater |
| FEV ₁ / FVC | _____ | 65% and greater |

FVC is the total amount of air you blew out of your lungs. FEV₁ is the amount of air you were able to blow out in the first second. FEV₁ / FVC is the ratio of the other two volumes.

_____ If the values are within the normal range or above, your lung function is normal.

_____ If these values are below the usual range, your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.

_____ If either FVC or FEV₁ are less than 50% of your predicted normal value, or if your FEV₁ / FVC ratio is less than 50%, your function is substantially reduced. If you and your physician were unaware of this, you should see them soon for evaluation.

Health ABC Bone Density Results

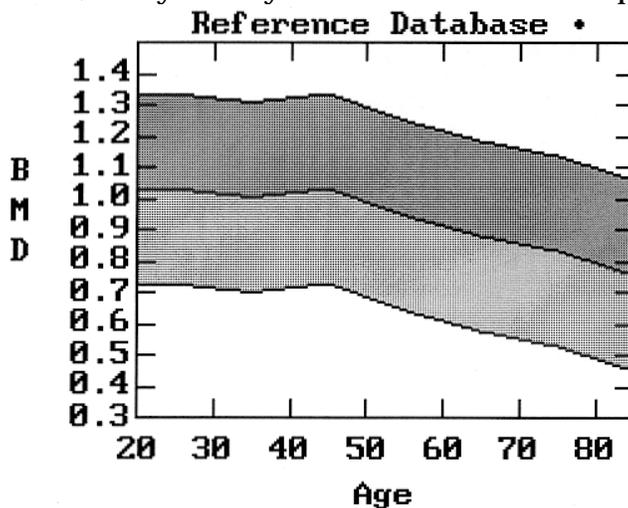
Name: _____ Date of Scan: _____

As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.



Total hip BMD: _____g/cm²

% body fat _____.

(Black Female)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

Health ABC Bone Density Results

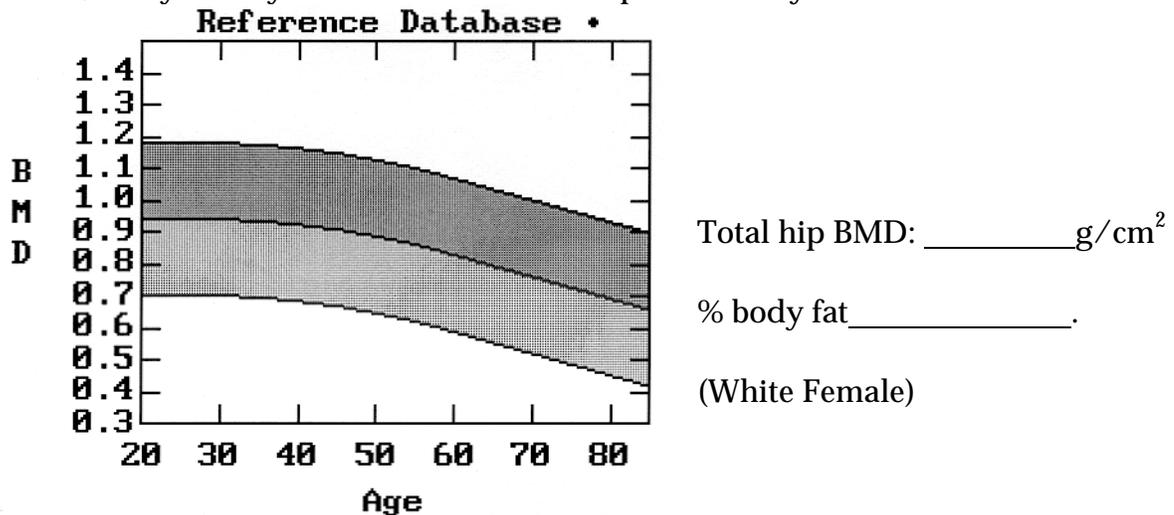
Name: _____ Date of Scan: _____

As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.



Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

Health ABC Bone Density Results

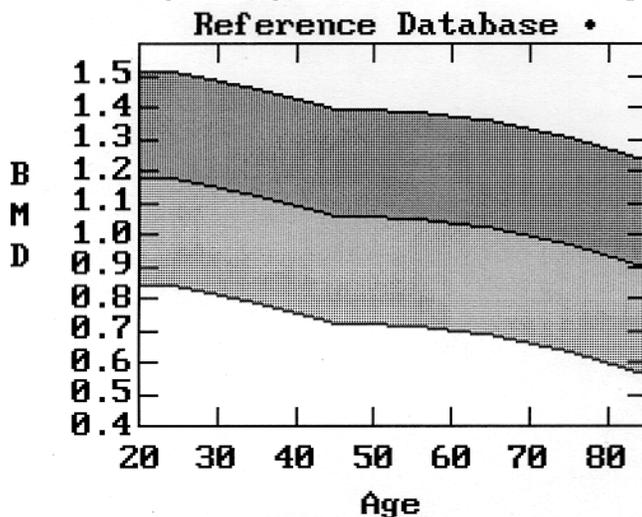
Name: _____ Date of Scan: _____

As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.



Total hip BMD: _____ g/cm²

% body fat _____.

(Black Male)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

Health ABC Bone Density Results

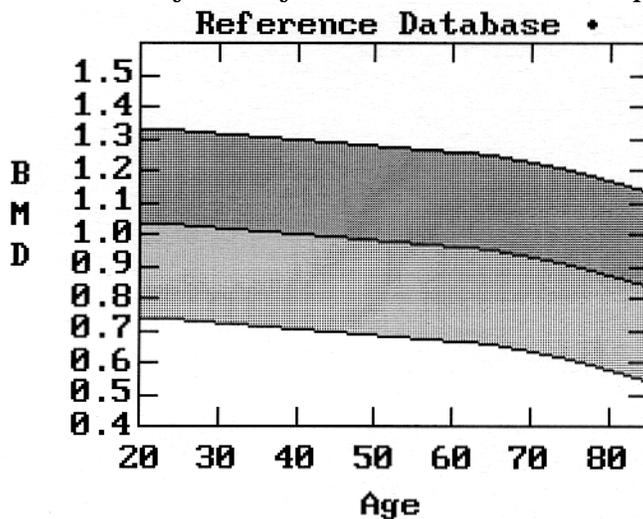
Name: _____ Date of Scan: _____

As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.



Total hip BMD: _____ g/cm²

% body fat _____.

(White Male)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

**APPENDIX 4:
HEALTH ABC APPOINTMENT REMINDER****JUST A REMINDER . . .**

Your Health ABC appointment is scheduled for:

(Date/Time)

Please remember to:

- Fast for 12 hours prior to your visit (no eating or drinking, except water and prescription medications.)
- Drink plenty of water.
- Please DO take any prescription medication you normally take the morning of your visit, except:

For those participants with diabetes: DO NOT take your insulin or hypoglycemic medications the morning of your clinic visit. You will take these medications in the clinic after the blood draw. Please be sure to bring these with you.

- Bring ALL medications (in their containers) with you (including prescription, non-prescription medications, insulin, vitamins) that you have used in the two weeks prior to your clinic visit.
- Refrain from smoking or vigorous physical activity for 12 hours prior to your visit.
- Please: No jewelry, no hair pieces, no girdles or pantyhose.
- Bring reading glasses and/or hearing aids with you.
- Wear comfortable shoes for walking.
- A urine specimen will be collected shortly after you arrive in the clinic.

If you need to reschedule, please call _____. Tell the operator you wish to reschedule your Health ABC appointment.

**APPENDIX 5:
OGTT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A fasting and 2-hour OGTT glucose were obtained and the results of the fasting glucose are 76 mg/dl, and the 2-hour glucose was 40 mg/dl. (Alert values are <50 mg/dl or >500 mg/dl.)] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa

**APPENDIX 6:
LAB ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A serum creatinine of 5.2 mg/dl and a phosphatase of 360 u/L were obtained. (Alert values are serum creatinine > 3.0 mg/dl and alkaline phosphatase > 35 u/L.)] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa

**APPENDIX 7:
ECG ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Charles Cutler, M.D.
512 Hamilton Road
Marion, PA 19066

Dear Dr. Cutler:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [An ECG was obtained and indicates the participant now has evidence of an abnormality. A copy of the tracing is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa

**APPENDIX 8:
CT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A CT was obtained and indicates the participant now has evidence of an abnormality. A copy of the image is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa

**APPENDIX 9:
PFT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A pulmonary function test was performed and indicates the participant now has evidence of an abnormality. (Alert values are: FEV1 <1.0 liter and 40% of predicted.) A copy of the pulmonary function report is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd
Coordinator of Clinical Studies

/sa