

## YEAR 4 CLINIC VISIT

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## YEAR 4 CLINIC VISIT

### 1. Overview of measurements

All Health ABC participants who attend the Year 4 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Blood pressure
- Ankle-arm blood pressure
- Resting ECG
- Standing height
- Weight
- Grip Strength
- Performance measures (chair stands, standing balance, balance walks)
- 20-meter walk
- Long distance corridor walk
- Isokinetic strength (Kin-Com)
- Peripheral neuropathy (vibration perception threshold, peroneal motor nerve conduction, and monofilament testing)
- Whole body composition by DXA
- Blood draw
- Weight change substudy eligibility assessment

Subgroups of participants may have the following measurements:

- Isometric strength (chair)
- In-clinic interview related to weight changes
- In-clinic interview related to flu

After the completion of each component of the Health ABC Year 4 clinic visit, the Procedure Checklist should be completed (see Appendix 2). Consent for release of results to physicians should also be indicated on the cover sheet of the Health ABC Year 4 Clinic Visit Workbook (Memphis only).

### **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 worksheets also include script. Examiners are encouraged to learn the standardized script that appears in the protocols and/or worksheets, 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.

## **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. In order for Health ABC to be successful, we need participants to agree to return for the next 3 years after their Year 4 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 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., 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.

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 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 4 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 schedule the clinic visit. We recommend reminder letters to be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- Dietary guidelines prior to the visit should be followed. The participant should not eat for 12 hours before their clinic visit.
- Guidelines should be followed for footwear and undergarments for women.
- Glasses and hearing aids should be worn.

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 3.

#### **3.2 Year 4 clinic visit preparation**

At the time of the Year 4 clinic visit, the following should be available for each participant:

- A Data from Prior Visits Report with information that will be needed for the Year 4 clinic visit (see Appendix 1)
- A Year 4 Questionnaire labeled with the participant's name, acrostic, and Health ABC Enrollment ID Number
- A Year 4 Clinic Visit Workbook labeled with the participant's name, acrostic, and Health ABC Enrollment ID Number
- A Weight Change Substudy Eligibility Assessment data collection form for the weight change substudy

- A Year 4 Participant Results form 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 initialed by the examiner recording the note.

The following should be available for sub-sets of Health ABC participants:

- A Weight Change Substudy Workbook
- A Flu Substudy Eligibility Assessment form
- A Flu Substudy Workbook
- A Knee X-ray Tracking form for participants who are eligible for knee x-rays for those participants who were eligible but did not receive x-rays during Year 2 or 3 of Health ABC

See Table 1 [below] for complete list of the forms that are completed during the Year 4 Clinic Visit. Note that the Weight Change and Flu Substudy Workbooks 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.

<b>Table 1</b>	
<b><u>Health ABC Year 4 Clinic Visit Forms</u></b>	
Year 4 Questionnaire	Year 4 Clinic Visit Workbook (cont.)
Year 4 Clinic Visit Workbook:	Performance Measures:
Year 4 Clinic Visit Procedure Checklist	Chair Stands
Standing Height	Standing Balance
Weight	Balance Walks
Blood Pressure	20-meter Walk
Ankle-arm Blood Pressure	Long Distance Corridor Walk
Resting ECG	Knee X-ray Eligibility
Leg symptoms	Phlebotomy
Vibration Perception Threshold	Laboratory Processing
Peroneal Motor Nerve Conduction	
Monofilament Testing	Knee X-ray Tracking Form
Bone Density (DXA) Scan	Weight Change Substudy Eligibility Assessment
Isokinetic Strength (Kin-Com)	Weight Change Substudy Workbook
Grip Strength	Flu Substudy Eligibility Assessment
	Flu Substudy Workbook

#### **4. Clinic flow and measurements**

##### **4.1 Overview of clinic flow**

Since participants will arrive at the clinic in a 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 exams 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, Standing Height). 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

Year 4 Questionnaire (Questions #54, 55, and 56, pages 26, 27, and 28)

before Knee X-ray Eligibility (page 37 in Year 4 Clinic Visit Workbook)

Year 4 Questionnaire (Question #6, page 2) before Flu Substudy Workbook

Year 4 Questionnaire (Questions #28 and #29, page 17) before Weight Change Substudy Eligibility Assessment

Weight Change Substudy Eligibility Assessment before Weight Change Substudy Workbook

Flu Substudy Eligibility Assessment before Flu Substudy Workbook

Blood collection before snack

ECG before snack and before Long Distance Corridor Walk

Blood pressure before Isokinetic Strength (Kin-Com)  
and Long Distance Corridor Walk

#### Preferable:

Blood collection before other tests

Group together ECG, blood pressure, and ankle-arm blood pressure

### **4.1.1 Year 4 in-clinic follow-up interview**

The Year 4 Questionnaire will be administered during the Year 4 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. Also, there are sections of the questionnaire that must be administered before the knee x-ray eligibility assessment, the weight change substudy eligibility assessment, and before the flu substudy workbook can be administered.

### **4.1.2 Blood collection and processing**

The Health ABC Year 4 clinic visit involves the collection of approximately 17 mL of blood: one tube w/anticoagulant for analysis of HbA<sub>1</sub>C and for archiving plasma; and one tube without anticoagulant so that the blood clots to form serum for analysis of fasting glucose, cholesterol and for archiving.

See Chapters 2B and 2C for detailed procedures.

### **4.1.3 Standing Height**

The measurement of stature (standing height) will be used to address three main questions. First, is height loss associated with a decline in physical function? Second, is height loss related to the risk of weight-related disease, disability or mortality? Third, how well does body mass index (weight/stature<sup>2</sup>) approximate total body fatness in the elderly? Standing height is measured in millimeters with a wall-mounted Harpenden stadiometer.

See Chapter 2D 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 2E for detailed procedures.

### **4.1.5 Blood pressure**

Blood pressure measurements will be recorded to document blood pressure. Also, the blood pressure will be used for the Isokinetic Strength (Kin-Com) and Long Distance Corridor Walk exam; individuals with extremely high blood pressure will be excluded from isokinetic strength and long distance corridor walk testing and referred for medical care according to the protocol for referrals.

See Chapter 2F for detailed procedures.

#### **4.1.6 Ankle-arm blood pressure**

The ankle-arm index (AAI) is the ratio of the ankle to arm systolic blood pressure. It is reduced to less than 1.0 when there is obstruction to blood flow in legs. The AAI is a non-invasive measure of atherosclerotic obstruction in the legs and is a general marker of atherosclerotic burden.

See Chapter 2G for detailed procedures.

#### **4.1.7 Resting ECG**

The purpose of the ECG is to characterize coronary disease prevalence and to determine the contribution of cardiovascular disease as assessed clinically and electrocardiographically to risk of accelerated sarcopenia.

Resting ECG must be done before the long distance corridor walk. The ECG form in the Year 4 Clinic Visit Workbook must be completed to record whether or not a successful test was obtained (and if not, what was the reason); whether or not hard copies were printed out with and without interpretation; and if there were any protocol deviations.

See Chapter 2H for detailed procedures.

#### **4.1.8 Bone density (DXA)**

Body composition measurements are obtained during the whole body scan using the Hologic QDR 4500 instrument.

See Chapter 2I for detailed procedures.

#### **4.1.9 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 Chapter 2J for detailed procedures.

#### 4.1.10 Performance Tests

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 several 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 short walk tests with narrowed base of support.

See Chapter 2K for detailed procedures.

#### 4.1.11 Isokinetic Strength (Kin-Com)

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

See Chapter 2L for detailed procedures.

#### 4.1.12 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.

#### 4.1.13 Long Distance Corridor Walk

The Health ABC long distance corridor walk (LDCW) is a two-stage walking-based test of exercise tolerance and fitness level. The first stage consists of a 2-minute walk where participants are instructed to cover as much ground as they can at a pace they can maintain. The second stage consists of the 400-meter walk, which follows after a 30 second pause to get the pulse rate.

See Chapter 2N for detailed procedures.

#### **4.1.14 Peripheral Neuropathy**

Measures of peripheral neuropathy in Health ABC include standard tests that have been used in other epidemiologic studies, and involve measurement of both sensory and motor nerve function. Peripheral neuropathy measurements are divided into three parts:

1. Quantitative sensory testing (QST) of the great toe using the Medoc vibration device

See Chapter 2O for detailed procedures.

2. Nerve conduction (NC) studies using the NeuroMax 8 to measure several parameters associated with the peroneal nerve

See Chapter 2P for detailed procedures.

3. Testing of loss of protective sensation using the monofilament

See Chapter 2Q for detailed procedures.

## **4.2 Substudies**

### **4.2.1 Knee Osteoarthritis (OA) Assessment**

Radiological assessment of structural abnormality of joints is the current standard for classifying OA for epidemiological research and a key component of clinical diagnosis. Numerous studies have demonstrated a strong relationship between radiographic findings, symptoms, and outcome for knee OA.

In order to determine whether or not a participant is eligible for a knee x-ray during Year 4, Questions #54, 55, and 56 on pages 26 through 28 in the Year 4 Questionnaire must be asked. These questions are about knee symptoms. After these questions are asked the Knee X-ray Eligibility Assessment form (page 37 in the Year 4 Clinic Visit Workbook) is filled out. A participant is scheduled for a knee x-ray during Year 4 if the Year 4 Questionnaire questions related to knee symptoms included asterisked answers, and they did not already receive a knee x-ray during Year 2 or Year 3 of the Health ABC study. To determine whether or not the participant has already received a knee x-ray during Year 2 or Year 3 of Health ABC, refer to the Data from Prior Visits Report.

### **4.2.2 Flu Substudy**

In order to determine whether or not a participant will be eligible as a case or as a control for the flu substudy, Question #6 on page 2 of the Year 4 Questionnaire must be asked: “Since we last spoke to you about 6 months ago, have you had a cold or flu that was bad enough to keep you in bed for all or most of the day?” If the participant answers “Yes” and had a temperature of 100 degrees or higher, they may be eligible to be part of the flu substudy as a case, and the Flu Substudy Eligibility Assessment form should be completed. If they say, “No” they may be eligible as a control, and, if randomly selected to be a control, the Flu Substudy Workbook should be completed for them as well.

### **4.2.3 Weight Change Substudy**

Complete a Weight Change Substudy Eligibility Assessment form for every participant during the Year 4 clinic visit. If their weight (entered on page 2 of the Year 4 Clinic Visit Workbook) has increased or decreased 5% or more since Year 3 (see Data from Prior Visits Report), they are eligible to be in the weight change substudy as a case, and a Weight Change Substudy Workbook should be completed. If their weight has not increased or decreased 5% or more, and is stable (the “No” response option is recorded for Questions #3 and #4 on the Weight Change Substudy Eligibility Assessment form) they are eligible as a control, and, if randomly selected to be a control, the Weight Change Substudy Workbook should be completed for them as well.

## **4.3 Procedure checklist and exit interview**

At the end the Year 4 Clinic Visit, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation and patience.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 4 Clinic Visit Workbook Procedure Checklist 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 permission to send test results to the physician (see Appendix 2). Confirm that all exams and measurements were completed. Review the Year 4 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:
    - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
    - ⇒ Standing height. Height should be converted from mm to feet and inches for the participant.
    - ⇒ Weight. Weight in pounds should be provided.
    - ⇒ Indication about whether or not their peroneal motor nerve conduction and monofilament tests were within the normal range.
    - ⇒ Body composition. The participant will receive a body composition results letter that includes their percent body fat and where they fit in the Health ABC range.
  - Tell participant that additional results and a summary will be sent to them within 8 weeks of their Year 4 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 at this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, or break any bones.”

#### **4.4 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. It is not necessary to reweigh the participants who come in for a second clinic visit. Use the weight that is recorded on page 2 of the Year 4 Clinic Visit Workbook for the DXA exam.

Very rarely, a measurement is not taken. Whenever a measurement is not taken, write the reason in the Comments section of the Year 4 Clinic Visit Procedure Checklist, 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 standing height, weight, blood pressure, and DXA results, and whether or not their nerve tests were within the normal range (see Appendix 4). 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 8 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; Appendices 5, 6, and 7 contain examples of alert letters to physicians.)

**Table 2**

**Health ABC Tests: Alert Values**

**Defined Values**

Fasting Glucose  
Resting ECG  
Blood Pressure

**Examiner Discretion**

Long Distance Corridor Walk  
(symptoms related to)  
Weight loss or gain  $\geq 10\%$

**5.1.1 Biochemical Tests**

Analyte	Reference Range for Reports	Immediate Alerts*
Glucose Metabolism:		
Fasting Glucose	<110 and ≥50 mg/dL    Normal 110-125 mg/dL        Borderline ≥126 mg/dL            Elevated**	<b>&gt;350 mg/dL OR &lt;50 mg/dL</b>
General Chemistries:		
Hg A <sub>1</sub> C	4-6%    Greater than 7% may indicate prior or current elevated glucose levels.	None
Lipids:		
Total Cholesterol	<200 mg/dL            Normal 200-239 mg/dL        Borderline >239 mg/dL            Elevated**	None

Lab calls Field Centers. Field center notifies participant and participant’s physician by telephone/fax if participant has granted permission to notify physician. Use modified letter from CHS (see Appendix 5) with abnormal value filled in.

\*\*Notify participant and participant’s physician by fax/letter if participant has granted permission to notify physician. Use modified letter from CHS with abnormal value filled in.

**5.1.2 Height and Weight**

Weight will be recorded on the form given to the participant at the time of the visit (see Appendix 4). This measurement will also be included in the final report to the participant and their physician.

**5.1.3 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 (see Appendix 4).

#### 5.1.4 Ankle-arm blood pressure

This is a screening test for atherosclerotic obstruction in the lower legs. Participants will receive a report of the ankle-arm index in each leg after these results have been hand-entered on the Ankle-arm Blood Pressure Results form which includes the information described below:

The ankle-arm blood pressure index is the ratio of the ankle to the arm blood pressure. It is a screening test for peripheral arterial disease. A low ratio may mean that there is an obstruction or blockage.

<b>Left leg</b>	<b>Right leg</b>
<input type="checkbox"/> Normal	<input type="checkbox"/> Normal
<input type="checkbox"/> Low	<input type="checkbox"/> Low

#### 5.1.5 Resting ECG

ECG procedure would include printing one tracing with the Marquette machine reading and two tracings without the reading. Any abnormal result as listed below would be overread by a physician in the clinic before the participant leaves unless the abnormal result is exactly the same as the abnormal result listed during the Baseline (Year 1) clinic visit. Examiners should check the Year 4 Data from Prior Visits Report to see if there were any abnormal Marquette readings at Baseline, and to see what statements were included on the Baseline Marquette report. The following statements would require clinic physician review if not previously reported:

- Heart rate <40 (bradycardia) or >120 (tachycardia)
- Atrial fibrillation or atrial flutter (new onset)
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- Idioventricular rhythm
- Ventricular tachycardia
- Third degree or complete A-V block
- Any statement including reference to acute injury or ischemia, or marked T-wave abnormality

For any of the above alerts, the clinic physician will determine if immediate notification of participant's physician is required before the participant leaves the clinic. If necessary, ECG will be faxed to physician or sent with participant to his physician.

The clinic physician will overread all other abnormal ECGs (i.e., abnormalities not previously reported) within one week of participant's visit. The clinic physician will decide if participant and participant's physician should receive a report of the abnormal ECG before the final report is ready for distribution. A cover letter similar to that used in CHS will be sent to the participant and the participant's physician.

Final report to participant will include a statement that a copy of the ECG has been sent to their physician, with no classification as normal/abnormal. The final report to the participant's physician will include a copy of the ECG without interpretation. If the participant does not have a physician, a copy of the ECG will be included in the participant report.

### **5.1.6 Long distance corridor walk**

If the participant develops chest pain or other symptoms, the clinic supervisor should be notified immediately. (See clinic emergency procedure protocol.)

## **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.

### **6.2 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.

### **6.3 Minor Emergencies**

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during venipuncture.

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 6 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 Data from Prior Visits Report**

Participant Name: \_\_\_\_\_

Health ABC Enrollment ID# : \_\_\_\_\_

Acrostic: \_\_\_\_\_

**Health ABC Year 4 Data from Prior Visits Report**1. Date of last regularly scheduled contact.: [ ][ ]/[ ][ ]/[ ][ ]  
Month Day Year

2. Missed Year 3 clinic visit?

2a. Reason for Missed Year 3 clinic visit:

3. Participant's current address:

Street Address

Apt/Room

City

State

Zip Code

4. Participant's current phone number:

Home Telephone #: (Area Code) Telephone Number

Work Telephone #: (Area Code) Telephone Number

5. Contact who lives with the participant (a relative):

First Name

Last Name

Street Address

Apt/Room

City

State

Zip Code

Telephone

How is this person related to the participant?

Next of kin?

Power of attorney?

6. Names of two contacts who do not live with the participant:

Contact #1

First Name

Last Name

Street Address

Apt/Room

City

State  
Zip Code  
Telephone:  
How is this person related to the participant?  
Next of kin?  
Power of attorney?

Contact #2

First Name  
Last Name  
Street Address  
Apt/Room  
City  
State  
Zip Code  
Telephone  
How is this person related to the participant?  
Next of kin?  
Power of attorney?

7. Participant's next of kin:

First Name  
Last Name  
Street Address  
Apt/Room  
City  
State  
Zip Code  
Telephone  
How is this person related to the participant?

8. Participant's power of attorney:

First Name  
Last Name  
Street Address  
Apt/Room  
City  
State  
Zip Code  
Telephone  
How is this person related to the participant?

**STANDING HEIGHT**

Was the participant standing sideways at Baseline (Year 1) when their height was measured?  
\_\_Yes \_\_No

**BLOOD PRESSURE**

Which arm was used for Baseline (Year 1) blood pressure?  
Right Left

**ANKLE-ARM BLOOD PRESSURE**

Which arm was used for Baseline (Year 1) ankle-arm blood pressure?  
Right Left

**ISOKINETIC STRENGTH (KIN-COM)**

1. Which leg was tested at the Year 2 clinic visit?  
 Right leg  Left leg  Neither
  
2. Which leg was tested at the Baseline (Year 1) clinic visit?  
 Right leg  Left leg  Neither
  
3. Which hip was scanned at the Baseline (Year 1) Clinic Visit?  
 Right leg  Left leg  Neither
  
4. Manual position settings at Year 2 (or at Year 1 if not done at Year 2):
  - a. Dynamometer tilt
  - b. Dynamometer rotation
  - c. Lever arm green C stop
  - d. Lever arm red D stop
  - e. Seat rotation
  - f. Seat back angle
  - g. Seat bottom depth
  - h. Seat bottom angle
  - i. Lever arm length

**KNEE X-RAY ELIGIBILITY**

1. Did participant have knee symptoms in Year 2?  
 Yes  No
  
2. Did participant have knee symptoms in Year 3?  
 Yes  No
  
3. Did the participant have a knee x-ray in Year 2 or 3?  
 Yes  No

**ECG ALERT VALUES**

Were there abnormal Marquette Readings at the Baseline (Year 1) clinic visit?

Yes  No



What abnormalities?

- Heart rate <40 (bradycardia) or >135 (tachycardia)
- Atrial fibrillation or atrial flutter (new onset)
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- Idioventricular rhythm
- Ventricular tachycardia
- Third degree or complete A-V block
- Any statement including reference to acute injury or ischemia

**Examiner Note: If there is an abnormal Marquette Reading from Baseline and an abnormal Marquette Reading during the Year 4 clinic visit, determine whether or not the reading is the same as**

*the previously reported abnormality or if there is a new abnormality that would require reporting to the participant and their physician.*

**WEIGHT CHANGE SUBSTUDY ELIGIBILITY ASSESSMENT**

1. Participant's weight at their Year 3 clinic visit:  
[ ][ ] kg
2. Participant's weight at their Year 3 clinic visit (+) 5%:
3. Participant's weight at their Year 3 clinic visit (-) 5%:

**CORE HOME VISIT**

1. Has participant ever had an isometric chair measurement?
2. Which leg was tested during the most recent isometric chair measurement/

**EVENT FORM DATA**

The following Event Forms have been entered to date for this participant:

Event Form Reference #	Type of Event	Date of Event
------------------------	---------------	---------------

**APPENDIX 2 Year 4 Clinic Visit Workbook Procedure Checklist**

**Health ABC** HABC Enrollment ID #       Acrostic       Date Form Completed  /  /     Staff ID #

Month Day Year

**YEAR 4 CLINIC VISIT WORKBOOK**

Arrival Time:  :  :  Hours Minutes  
Departure Time:  :  :  Hours Minutes

**YEAR 4 CLINIC VISIT PROCEDURE CHECKLIST**

Measurement	Page #	Yes: Measurement fully completed	Yes: Measurement partially completed	No: Participant refused	No: Other reason	Comments
1. Was the Year 4 questionnaire administered?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. Standing height	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. Weight	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. Blood pressure	3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. Ankle-arm blood pressure	4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. ECG	5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. Leg symptoms	6	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. Vibration perception threshold	9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. Peroneal motor nerve conduction	12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
10. Monofilament testing	15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11. Bone density (DXA) scan	16	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
12. Isokinetic strength (Kin-Com)	18	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
13. Grip strength	22	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
14. Chair stands	24	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
15. Standing balance	25	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
16. Balance walks	27	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
17. 20-meter walk	28	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
18. Long distance corridor walk	29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
19. Knee X-ray eligibility assessment	37	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
20. Phlebotomy	38	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
21. Laboratory processing	41	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
22. Was the Weight Change Substudy Eligibility Assessment form completed?		<input type="radio"/> Yes	<input type="radio"/> No			
23. Was the Weight Change Substudy Workbook completed?		<input type="radio"/> Yes: Fully completed	<input type="radio"/> Yes: Partially completed	<input type="radio"/> No: Participant refused	<input type="radio"/> No: Not applicable	
24. Was the Flu Substudy Workbook completed?		<input type="radio"/> Yes: Fully completed	<input type="radio"/> Yes: Partially completed	<input type="radio"/> No: Participant refused	<input type="radio"/> No: Not applicable	
25. Did participant agree to schedule a knee x-ray?		<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not applicable	<input type="radio"/> Not eligible	

*Memphis Only:*

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

21824

Page Link #

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**APPENDIX 3: Health ABC Year 4 Pre-Visit Instructions**

Dear \_\_\_\_\_:

Your appointment for your Health ABC Year 4 Clinic Visit has been scheduled for: \_\_\_\_\_, \_\_\_\_\_ at \_\_\_\_\_ a.m. at XXXXXXXXXX, XXXXXXXXXX (A map is enclosed. Please park in the garage attached to our building so that we can validate your parking.)

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 and fill out the necessary forms.
- Please fast for 12 hours prior to your clinic visit (no eating or drinking, except for water and prescription medications).
- Take all your regular medications, as usual, with the following exception:

If you have diabetes, do NOT take your insulin or hypoglycemic medications the morning of your clinic visit. You will take these medications at the clinic after the blood draw. Please be sure to bring these with you.

- Drink plenty of water before you come into the clinic.
- Please wear comfortable shoes for walking and clothing without zippers, if possible. Do not wear pantyhose, girdles, or hair pieces. You will be asked to change clothes for some tests.
- If you have glasses, please bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, please 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.

APPENDIX 4 Health ABC Examination Results  
page 1 of 4



YEAR 4 PARTICIPANT RESULTS

Participant Name: \_\_\_\_\_  
(Please Print)

Date of Year 4 Clinic Visit:  /  /   
Month Day Year

Standing Height:  feet  inches

Weight:  pounds

Blood Pressure:  /  mm Hg

Normal:	Less than 130/85 mm Hg
High normal:	130-139 / 85-89 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:

- 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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

ECG:

A print-out of your ECG will be available for your doctor.

Version 1.0, 6/5/2000



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**YEAR 4 PARTICIPANT RESULTS**

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**Nerve Tests****Nerve Conduction Velocity Test:**

The nerve conduction velocity test, the test where we placed small patches on your foot, measured how quickly a feeling traveled down a nerve in your leg. This test looked at how well your nerves work, which may be related to your ability to walk.

- Nerve conduction velocity was normal.
- Nerve conduction velocity was slow.

---

**Monofilament Testing:**

The monofilament test, the test where we placed a nylon thread on the top of your toe, looked at whether you could feel a very light sensation on your foot. Being able to sense pressure on your feet helps you to keep from hurting them.

- The monofilament test was normal.
- The monofilament was not felt.

---

**Muscle strength, walking speed, and balance 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: (    ) \_\_\_\_\_

**Health ABC Body Composition Results Letter**

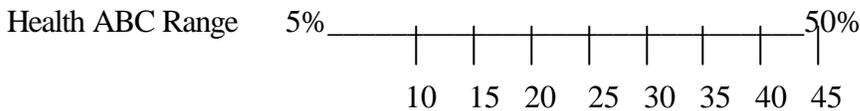
Date \_\_\_\_\_

Dear Mr. \_\_\_\_\_

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 presented below along with the range of body fat percentage in the Health ABC population. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older individuals. As a participant in Health ABC, you are helping us 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: \_\_\_\_\_ %



HABC.FT.MEN.LET

**Health ABC** YEAR 4 ANKLE-ARM BLOOD PRESSURE RESULTS

Participant Name: \_\_\_\_\_  
(Please Print)

Date of Year 4 Clinic Visit:   /   /    
Month Day Year

The ankle-arm blood pressure index is the ratio of the ankle to the arm blood pressure. It is a screening test for peripheral arterial disease. A low ratio may mean that there is an obstruction or blockage.

- | Left Leg                        | Right Leg                       |
|---------------------------------|---------------------------------|
| <input type="checkbox"/> Normal | <input type="checkbox"/> Normal |
| <input type="checkbox"/> Low    | <input type="checkbox"/> Low    |

We would like to thank you for your continued participation in the Health ABC study. This test was done for research purposes only and was 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: ( ) \_\_\_\_\_

Version 1.0, 8/16/2000 pjm

**APPENDIX 5: Lab Alert Letter for Physician**

September 1, 2000

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

Dear Dr. Friedman:

On August 15, 2000, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. A fasting glucose of 400 mg/dL was obtained. The alert value for fasting glucose is > 350 mg/dL or < 50 mg/dL.

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

Piera Kost  
Clinic Coordinator

**APPENDIX 6:  
ECG Alert Letter for Physician**

September 13, 2000

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

Dear Dr. Cutler:

On September 1, 2000, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. An ECG was obtained and indicates the participant 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

Piera Kost  
Clinic Coordinator

/sa

## APPENDIX 7

**Weight Change Alert Letter for Physician**

September 13, 2000

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

Dear Dr. Cutler:

On September 1, 2000, \_\_\_\_\_ was seen at the Health ABC Research Clinic.

At the last clinic visit one year ago, his/her weight was \_\_\_\_\_ lbs (kgs)  
The weight today was \_\_\_\_\_ lbs (kgs)

This weight is  $\geq 10\%$  (more) (less) than one year ago.

All tests done for Health ABC were performed for research purposes only and will be used to describe the health status of men and women in their seventies and eighties 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 \_\_\_\_\_.  
Thanks you for your support.

Sincerely,

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

Piera Kost