

## YEAR 11 CLINIC VISIT OVERVIEW

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## YEAR 11 CLINIC VISIT

### 1. Overview of measurements

All Health ABC participants who attend the Year 11 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Medication assessment
- Standing height
- Weight
- Radial pulse
- Blood pressure
- Ankle-arm blood pressure
- Vibration perception threshold
- Peroneal motor nerve conduction
- Monofilament testing
- Chair stands
- Standing balance
- Balance walks
- Teng mini-mental state
- Digit symbol substitution test
- Phlebotomy

Subgroups of participants may have the following measurements:

- Thigh, abdominal, spine CT
- Brain MRI

After the completion of each component of the Health ABC Year 11 clinic visit, the Procedure Checklist should be completed (see Appendix 1). Consent for release of results to physicians should also be indicated on the cover sheet of the Health ABC Year 11 Clinic Visit Workbook.

### **Scripts in protocols and worksheets**

It is very important that examiners read the Health ABC operations manual. Scripts are included in the operations manual in order to standardize the administration of the many tests given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. A number of 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. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

## **2. Working with older participants**

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

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

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

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

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

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

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

### **For Clinic Coordinators and Investigators:**

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

## **3. Preparation for the Year 11 clinic visit**

### **3.1 Participant preparation**

Each participant who comes to the Health ABC Year 11 clinic visit will have been told about the contents of the visit during the phone conversation to schedule the clinic visit. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the Year 11 clinic visit
- that participants fast for 12 hours prior to their clinic visit (no eating or drinking, except for water and prescription medications)
- that participants take all of their regular medications, as usual
- that participants drink plenty of water before coming into the clinic
- that participants should wear comfortable clothing (short sleeved) and footwear, and not wear jewelry or pantyhose or girdles
- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances
- that participants who wear hearing aids should bring or wear them to the clinic

- that participants bring in prescription medications and vitamins and minerals that were taken in the last 30 days only

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 2.

### 3.2 Year 11 clinic visit preparation

At the time of the Year 11 clinic visit, the following should be available for each participant:

- A Data from Prior Visits Report should be generated with information that will be needed for the Year 11 clinic visit (see Appendix 3)
- The participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.)
- A Year 11 Clinic Visit Workbook preprinted with the acrostic and Health ABC enrollment ID number (this workbook includes the Year 11 Questionnaire). It is important to double-check the accuracy of the pre-printed acrostic at the top of the first page of the Year 11 Clinic Visit Workbook as compared with the participant's name. After you print the participant's name on the first page of the Year 11 Clinic Visit Workbook, look at the first letter of the first name and the first three letters of the last name to make sure that these match the pre-printed acrostic at the top of the page.
- A Year 11 Participant Results Report to give the participant at the end of their clinic visit (Appendix 4)
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

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

- CT Tracking Form
- Brain MRI Workbook (including eligibility assessment and MRI tracking form)

Table 1 [below] lists all the forms that are completed during the Year 11 clinic visit; note that the Brain MRI Workbook is completed only for participants who are eligible for the brain MRI eligibility assessment, and the Year 11 CT Tracking form is completed only for participants who are eligible for a CT.

**Table 1**  
**Health ABC Year 11 Clinic Visit Forms**

Year 11 Clinic Visit Workbook:	Year 11 Clinic Visit Workbook (cont.)
Year 11 Clinic Visit Procedure Checklist	Chair stands
Year 11 Questionnaire	Standing balance
Medication assessment	Balance walks
Height (standing)	Teng mini-mental state
Weight	Digit symbol substitution test
Radial pulse	Phlebotomy
Blood pressure	Laboratory processing
Ankle-arm blood pressure	
Vibration perception threshold	Brain MRI Eligibility Assessment
Peroneal motor nerve conduction	Brain MRI Tracking Form
Monofilament testing	Year 11 CT Tracking Form

#### 4. Clinic flow and measurements

##### 4.1 Overview of clinic flow

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 gown after their blood pressure exams so that they don't have to put on the gown and then take it off. Another timesaving idea is to do tests consecutively that require that participants not be wearing shoes (height, weight, ankle-arm blood pressure, vibration perception threshold, peroneal motor nerve conduction, and monofilament testing). Also, if the Consent Form is sent out ahead of time, many participants will be ready to sign it right away when they arrive at the field center, instead of taking the time to read it during their clinic visit. The following guidelines for the order of specific measurements are divided into mandatory, which must be followed, and preferable, which are highly recommended but may be modified without jeopardizing the standardization of the measurements:

##### Mandatory

Arm measured for cuff size before blood pressure and ankle-arm blood pressure

Blood pressure exams before performance measures and caffeine ingestion

Blood pressure exams either before phlebotomy or at least 30 minutes after phlebotomy

##### Preferable:

Blood draw before exams

Group together standing height, weight, vibration threshold, peroneal motor nerve conduction, and monofilament testing.

#### **4.1.1 Year 11 in-clinic follow-up interview**

The Year 11 Questionnaire will be administered during the Year 11 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.

See Interviewing Guidelines chapter for interview guidelines.

#### **4.1.2 Anthropometry and physical measures**

Two anthropometric and physical measurements will be made on all participants who attend the Year 11 clinic visit: standing height and weight. One of the most important measurements that is done for Health ABC is the weight measurement. The measurements of height and weight come early in the exam and offer a good opportunity to answer questions and promote goodwill towards the study.

See Standing Height and Weight operations manual chapters.

#### **4.1.3 Blood pressure and radial pulse**

Blood pressure and radial pulse measurements will be recorded to document blood pressure and radial pulse. In addition, individuals with extremely high levels of blood pressure will be referred for medical care according to the protocol for referrals.

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

#### **4.1.4 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 Ankle-arm Blood Pressure operations manual chapter for detailed procedures.

#### **4.1.5 Performance-based measures (chair stands, standing balance, and balance walks)**

Direct assessments of physical performance have become standard measurements in epidemiological studies in the elderly. These assessments generally tap multiple domains of physiological performance, including lower extremity strength, balance, coordination, and flexibility. The assessment techniques used in Health ABC have been derived from 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 balance walks.

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

#### **4.1.6 Teng mini-mental state exam**

The Teng Mini-Mental State Examination (MMSE) 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 MMSE 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 Teng Mini-Mental State operations manual for detailed procedures.

#### **4.1.7 Digit symbol substitution**

The Digit Symbol Substitution Test (DSST) may be a more sensitive measure of dementia than the MMSE. The DSST requires response speed, sustained attention, visual spatial skills and set shifting. It is part of the Wechsler Adult Intelligence Scale, one of the most widely used measures of intelligence.

The DSST requires that the participant fill in a series of symbols correctly coded within 90 seconds. In this test the higher the score the better the person's performance.

See Digit Symbol Substitution Test operations manual for detailed procedures.

#### **4.1.8 Blood collection and processing**

This year, a maximum of 23 mL of whole blood will be collected.

See Biospecimen Collection and Processing operations manual chapters for detailed procedures.

#### **4.1.9 CT**

Pittsburgh participants who did not have a CT scan at the Year 10 visit will have CT scans at the Year 11 visit. The purpose of the CT scan is to provide a means of quantifying the muscle and fat volumes in participants in the Health ABC protocol. Participants in Pittsburgh will also have a CT scan to determine bone mineral density of the lumbar spine. The CT body composition image will be used to calculate:

- Subcutaneous fat volume and density at L4-L5
- Visceral fat volume and density at L4-L5
- Abdominal muscle volume and density at L4-L5
- Thigh muscle volume and density at mid-femur

- Subcutaneous fat volume and density at mid-femur
- Intramuscular fat volume and density at mid-femur

See Computed Tomography operations manual for detailed procedures.

#### 4.1.10 Brain MRI and gait map

A selected group of participants at Pittsburgh will have brain MRI's and a gait map test to investigate the association between focal gray matter atrophy, white matter disease and mobility impairment in community-dwelling older adults.

#### 4.2 Procedure checklist and exit interview

At the end of the Year 11 clinic visit, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 11 Clinic Visit Workbook Procedure Checklist is completed; ie., the header information including the Health ABC Enrollment ID #; participant's first and last name; whether the CT was scheduled; whether the visit included scheduling an MRI; and permission to send test results to the physician (see Appendix 1). Confirm that all exams and measurements were completed. Review the Year 11 Clinic Visit Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected results (Appendix 4). Participants will be given the following results:
  - ⇒ Height. Standing height in feet and inches should be provided.
  - ⇒ Weight. Weight in pounds should be provided.
  - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
  - ⇒ Indication about whether or not their peroneal motor nerve conduction and monofilament tests were within the normal range.
  - ⇒ Laboratory tests: HgA<sub>1</sub>C, and CBC results (for those who didn't have this draw in Year 10) will be sent at a later date.
  - ⇒ Brain MRI: Important abnormalities will be reported to participants.

- ⇒ CT: Important abnormalities will be reported to participants.
- Tell participant that additional results and a summary will be sent to them within 8 weeks of their 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 Year 11 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 for angioplasty.
  - ⇒ Fracture. Any broken bone, excluding minor fractures of the ribs, toes, fingers, etc.
  - ⇒ Cancer. Any newly diagnosed cancer, excluding non-melanoma skin cancer.

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

### 4.3 Incomplete visits

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

#### Starred (★) items on data collection forms

The star (★) indicates priority questions and exams, and defines the minimum data to be collected during the clinic visit. Begin by administering the star questions/exams first only if the participant refuses to complete the entire clinic visit.

As always, the goal is still to administer the complete Year 11 Clinic Visit Workbook to all Health ABC participants. However, in the event that some participants may not be willing to complete the entire clinic visit, we have identified those questions and exams that are most important to administer. These priority questions/exams are identified by a star next to the question/exam. If the participant is unwilling to complete the entire clinic visit, complete the starred questions and exams first. Once the starred questions and exams have been completed, continue to complete the other non-starred questions and exams, if the participant is willing. Please mark "Refused" on all questions/exams that the participant is NOT willing to complete.

## 5. Alerts and notifications

At the clinic visit, participants will receive a report that includes height, weight, and blood pressure (see Appendix 4). Table 2 lists measures that have alert values; Appendices 5 and 6 contain examples of alert letters to physicians. Lab results will be sent to the participant within several weeks of the clinic visit.

<u>Defined Values</u>	<u>Examiner Discretion</u>
Blood pressure	Weight loss $\geq$ 10%
Fasting glucose	Teng mini-mental state
HgA <sub>1</sub> C	

### 5.1.1 Blood pressure

Page 1 of the Year 11 Participant Results Report includes a place for the participant's name and for their systolic and diastolic blood pressure values that can found in the Year 11 Clinic Visit Workbook. Record these results on the Year 11 Participant Results Report. Review the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommendations based on the participant's blood pressure (see below).

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

There are five categories to check on the blood pressure portion of the Year 11 Participant Results Report:

- If the participant's systolic blood pressure is normal, i.e., <120 systolic, and < 80 diastolic or prehypertension, 120-139 systolic, or 80-89 diastolic, check "Recheck blood pressure within 1 year" on the Year 11 Participant Results Report.
- If the participant's systolic blood pressure is 140 to 159, or their diastolic blood pressure is 90-99, check the box on the Year 11 Participant Results Report that says "Recheck blood pressure within 2 months." Suggest to the participant that they have their blood pressure rechecked within 2 months.
- If the participant's systolic blood pressure is 160 to 179, or their diastolic blood pressure is 100-109, check the box on the Year 11 Participant Results Report that says "See your

doctor in 1 month.” Suggest to the participant that they see their doctor within one month.

- If the participant’s systolic blood pressure is 180 to 209, or their diastolic blood pressure is 110-119, check the box on the Year 11 Participant Results Report that says “See your doctor in 1 week.” If the participant gives their permission, you can contact their primary care provider within one week, or instruct the participant to contact their primary care provider within one week.
- If the participant’s systolic blood pressure is  $\geq 210$ , or their diastolic blood pressure is  $\geq 120$ , check the box on the Year 11 Participant Results Report that says “See your doctor immediately.” If the participant gives their permission, you can contact their primary care provider immediately, or instruct the participant to contact their primary care provider immediately.

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

### 5.1.2 Weight change

Participants with weight loss of  $\geq 10\%$  that appears to be unexplained will have the weight change brought to the attention of their physician with the participant’s permission (see Appendix 5).

### 5.1.3 Teng mini-mental state

Although there are no alert values for this test, we know that a score of 80 or less is roughly comparable to a score of 24 on the 0-30 scale and is used as a screening cut point for cognitive impairment. This is a screening test that varies with age and education. Additional clinical evaluation is needed for diagnosis. The field center physician or designee should look at the MMSE score compared to baseline and in the context of what else is known about the person, discuss the results with the participant on an individual basis. This would include sending the results to their doctor with permission.

### 5.1.4 Labs

HgA<sub>1</sub>C results will be sent to the clinical sites from the Core Laboratory. Local labs will send clinical sites the CBC results. CBC results will be recorded on the CBC Results form and scanned into the data system. Participants will be sent a copy of their CBC and their HgA<sub>1</sub>C results.

Please see chart below for laboratory reference ranges.

**5.1.5 Lab reference ranges**

Analyte	Reference Range for Reports	Immediate Alerts*
Hg A <sub>1</sub> C	Less than 6%      Normal Less than 7%      Recommended 7 to 8%            Elevated Greater than 8%    Further action suggested	None
▲ White blood cells	See local lab reference range	**<2,000 or >15,000
▲ Red blood cells	See local lab reference range	None
▲ Hemoglobin	See local lab reference range	None
▲ Hematocrit	See local lab reference range	**<30% or >50%
▲ Platelets	See local lab reference range	**<100,000 or >600,000
▲ Mean corpuscular vol.	See local lab reference range	None
▲ Mean corpuscular hemoglobin	See local lab reference range	None
▲ Mean corpuscular hemoglobin content	See local lab reference range	None

\*Central 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 4) 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.

▲ Test done only on participants who did not have the CBC draw in Year 10

**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.

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

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

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

### 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 2 Year 11 Pre-Visit Instructions**

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

Your appointment for your Health ABC Year 11 Clinic Visit has been scheduled for: \_\_\_\_\_, \_\_\_\_\_ at \_\_\_\_\_ a.m. at XXXXXXXXXX, XXXXXXXXXX (a map is enclosed). Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

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

- Read all enclosed materials.
- 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.
- Drink plenty of water before you come into the clinic.
- Wear comfortable shoes for walking. It would be helpful if you wear a short-sleeved shirt, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles. You will be asked to change clothes for some tests.
- Do not wear jewelry to the clinic, if possible, since this may make it more difficult to do your bone scan.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.
- A plastic bag has been provided for all of your prescription medications and vitamins and minerals that you have taken in the last 30 days only. Please bring these with you to the clinic.

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 3 Data from Prior Visits Report****Year 11 Clinic Visit  
Data from Prior Visits Report**

Participant Name:  
Health ABC Enrollment ID# :  
Acrostic:

**VISIT HISTORY**

1. Date of last regularly scheduled contact:
2. Number of months since last regularly scheduled contact:
3. Missed Year 10 clinic visit?  
3a. Reason for missed Year 10 clinic visit:
4. Type of Year 10 contact:
5. Missed Year 10.5 phone interview?  
5a. Reason for missed Year 10.5 phone interview:
6. Has the participant ever had a proxy interview?  
6a. For which contact(s)?

**SPECIMEN COLLECTION**

Does participant require a CBC?

**HEIGHT**

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

**WEIGHT CHANGE ALERT**

1. Participant's weight at their Year 10 clinic visit:
2. Participant's weight at their Year 10 clinic visit minus 10%:

**BLOOD PRESSURE**

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

**ANKLE-ARM BLOOD PRESSURE**

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

**VIBRATION PERCEPTION THRESHOLD**

Which great toe was tested (and foot heated) at Year 4?

**PERONEAL MOTOR NERVE CONDUCTION**

1. Which leg was tested at Year 4?
2. Distance from ankle cathode to fibular head cathode?
3. Distance from ankle cathode to popliteal fossa cathode?

**MONOFILAMENT TESTING**

Which great toe was tested at Year 4?

**CT TRACKING – PITTSBURGH ONLY**

Does participant require a CT?

Which thigh was measured for the last CT scan?

**MEDICATION INVENTORY**

The following is a listing of prescription medications used by the participant in Year 10. Please use this list to confirm with the participant that they brought all of the medication they used in the past 30 days.

Medication Name	Formulation Code	Frequency	Still Using
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**EVENTS REPORTED**

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

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

**DATE OF DEATH**

## Appendix 4 Health ABC Examination Results



## Year 11 Participant Results

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

Date of Year 11 Clinic Visit: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

---

Height: \_\_\_\_ feet \_\_\_\_ inches

---

Weight: \_\_\_\_ pounds

---

Blood Pressure: \_\_\_\_ / \_\_\_\_ mm Hg

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

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

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

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



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### Year 11 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 test was not felt.
-



## Year 11 Participant Results

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### Memory tests

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

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### Muscle strength, flexibility, balance, and walking speed tests

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

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

(    ) \_\_\_\_\_.





**Appendix 5 Weight Change Alert Letter for Physician**

Date

Physician name

Address

City, State, Zip code

Dear Dr. <Physician name>:

On <Date>, \_\_\_\_\_ was seen at the Health ABC Research Clinic.

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

This weight is  $\geq 10\%$  less than two years 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,

<Name of Principal Investigator>  
Health ABC Principal Investigator

**Appendix 6 Sample Letter to Physician Regarding Laboratory Alert Value**

Date

Physician name

Address

City, State, Zip code

Dear Dr. <Physician name>:

On <Date>, \_\_\_\_\_ was seen at the Health ABC Research Clinic.

As part of the clinic visit, a <type of lab test> was obtained. The results of the <type of lab test> are <results of lab test, including units> <alert values: xxxxxx, including units>.

All tests 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 the Health, Aging and Body Composition Study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest 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 me at \_\_\_\_\_. Thank you for your support.

Sincerely,

<Name of Principal Investigator>  
Health ABC Principal Investigator