

YEAR 10 CLINIC VISIT OVERVIEW

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YEAR 10 CLINIC VISIT

1. Overview of measurements

All Health ABC participants who attend the Year 10 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Medication inventory
- Standing height
- Weight
- Radial pulse
- Blood pressure
- Grip strength
- Bone density (DXA) scan
- Isokinetic strength (Kin-Com)
- Pulmonary function test
- Chair stands
- Standing balance
- Balance walks
- Rapid Assessment of Adult Literacy in Medicine (REALM)
- Teng mini-mental state
- Digit symbol substitution test
- CLOX 1
- 20-meter walk
- Long distance corridor walk
- Phlebotomy

Subgroups of participants may have the following measurements:

- Energy expenditure
- Thigh, abdominal, spine CT
- Brain MRI

After the completion of each component of the Health ABC Year 10 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 10 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 10 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. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the Year 10 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 who regularly use an inhaler for a lung or respiratory condition, bring this with them to the clinic
- 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 and non-prescription medications 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 10 clinic visit preparation

At the time of the Year 10 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 10 clinic visit (see Appendix 3)
- Your HABC Participant Contact Information report from the Access system with the participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.)
- A Year 10 Clinic Visit Workbook preprinted with the acrostic and Health ABC enrollment ID number (this workbook includes the Year 10 Questionnaire). It is important to double-check the accuracy of the pre-printed acrostic at the top of the first page of the Year 10 Clinic Visit Workbook as compared with the participant's name. After you print the participant's name on the first page of the Year 10 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 10 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:

- A completed Pre-visit Screener for Energy Expenditure form and a Year 10 Energy Expenditure Visit 1 form for those participants who are part of the energy expenditure sub-study (and a Year 10 Energy Expenditure Visit 2 form for participants who come in 2 weeks later for their second energy expenditure visit).
- 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 10 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 10 CT Tracking form is completed only for participants who are eligible for a CT.

Table 1
Health ABC Year 10 Clinic Visit Forms

Year 10 Clinic Visit Workbook:	Year 10 Clinic Visit Workbook (cont.)
Year 10 Clinic Visit Procedure Checklist	Teng mini-mental state
Year 10 Questionnaire	Digit symbol substitution test
Medication inventory update	CLOX 1
Standing height	20-meter walk
Weight	Long distance corridor walk
Radial pulse	Phlebotomy
Blood pressure	Laboratory processing
Grip strength	
Bone density (DXA) scan	Prescreener for Energy Expenditure (completed before visit)
Isokinetic strength (Kin-Com)	
Pulmonary function test	Year 10 Energy Expenditure Visit 1
Chair stands	Year 10 Energy Expenditure Visit 2
Standing balance	Brain MRI Eligibility Assessment
Balance walks	Brain MRI Tracking Form
Rapid Assessment of Adult Literacy in Medicine (REALM)	Year 10 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 (DXA, height, weight, Kin-Com). 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

Blood pressure before isokinetic strength (Kin-Com)

Blood pressure before pulmonary function test

Blood pressure and radial pulse before long distance corridor walk

20-meter walk before long distance corridor walk

Standing height before pulmonary function test

Standing height before accelerometry setup (energy expenditure participants only)

Weight before energy expenditure (energy expenditure participants only)

Weight before accelerometry setup (energy expenditure participants only)

Preferable:

Blood draw before exams

Group together standing height, weight, and bone density scan

4.1.1 Year 10 in-clinic follow-up interview

The Year 10 Questionnaire will be administered during the Year 10 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.

4.1.3 Medication inventory

Over-the-counter medications will be recorded. This information is necessary to determine in finer detail the extent of participants' drug benefit in the Part D Medicare era and for drug exposure to determine the presence and direction of any misclassification bias.

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

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

See Medication Inventory operations manual for detailed procedures.

4.1.3 Anthropometry and physical measures

Two anthropometric and physical measurements will be made on all participants who attend the Year 10 clinic visit: standing height and 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 Standing Height and Weight operations manual chapters.

4.1.4 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 excluded from the isokinetic strength, pulmonary function, and long distance corridor walk tests and referred for medical care according to the protocol for referrals. Participants with extremely high or low radial pulse will be excluded from the long distance corridor walk test.

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

4.1.5 Grip strength

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

See Grip Strength operations manual for detailed procedures.

4.1.6 Bone density (DXA)

Bone mineral density of the whole body will be performed using the Hologic QDR 4500 instrument. Body composition measurements are obtained during the whole body scan. Participants should have the BMD of their hip obtained during Year 10 on the same side that was scanned at baseline, unless the participant has had a hip replacement on that side.

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

4.1.7 Isokinetic strength (Kin-Com)

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

See Isokinetic Strength operations manual for detailed procedures.

4.1.8 Pulmonary function test

Pulmonary function tests on each participant will include:

- Forced expiratory spirometry
- Slow vital capacity (only if a participant cannot perform the forced maneuver)

You will need the participant's height to do the PFT measurement. Refer to the participant's height on page 37 in the Year 10 Clinic Visit Workbook. Do not use the height from baseline.

See Pulmonary Function Test – EasyOne spirometer operations manuals for detailed procedures.

4.1.9 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 and standing balance.

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

4.1.10 Rapid Estimate of Adult Literacy in Medicine (REALM)

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

See Rapid Estimate of Adult Literacy in Medicine (REALM) operations manual for detailed procedures.

4.1.11 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.

4.1.12 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.

4.1.12 Executive control function - CLOX 1

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

See Executive Control Function – CLOX 1 operations manual for detailed procedures.

4.1.13 20-meter walk

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

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

See 20-meter Walk operations manual for detailed procedures.

4.1.14 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 Long Distance Corridor Walk operations manual for detailed procedures.

4.1.15 Blood collection and processing

This year, a maximum of 60 mL of whole blood will be collected for the main and ancillary studies.

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

4.1.16 CT

Pittsburgh participants will have CT scans. 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.

4.1.17 Accelerometry and energy expenditure

A subgroup of participants will have accelerometry and energy expenditure measurements. The combination of accelerometry, heart rate, and the criterion measure of free-living activity energy expenditure by doubly-labeled water will provide an unprecedented opportunity to understand physical activity in older adults.

See Accelerometry and Energy Expenditure operations manuals for detailed procedures.

4.2 Procedure checklist and exit interview

At the end of the Year 10 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 10 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 10 Clinic Visit Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected results (Appendix 4). Participants will be given the following results:
 - ⇒ Height. Standing height in feet and inches should be provided.
 - ⇒ Weight. Weight in pounds should be provided.
 - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.

- ⇒ Body Composition. The participant will receive a body composition results report that includes their percent body fat and where their results fit in the range of Health ABC participant results.
- ⇒ Bone mineral density (BMD). Their BMD will be plotted by the DXA technician on a sex and race-specific normative curve.
- ⇒ Pulmonary Function Test. Spirometry results will be given to each participant. These results include the percent predicted FVC, the percent predicted FEV1 and the ratio between the FEV1 and FVC. A brief explanation of what these values mean and what ranges are considered to be normal will also be included in the report.
- ⇒ Laboratory tests: Fasting glucose, HgA₁C, and CBC results will be sent at a later date.
- ⇒ Brain MRI: Important abnormalities will be reported to participants.
- ⇒ CT: Important abnormalities will be reported to participants.
- 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. It is not necessary to reweigh the participants who come in for a second clinic visit. For the DXA exam use the weight that is recorded on page 37 of the Year 10 Clinic Visit Workbook.

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 10 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, blood pressure, lung function, and DXA results (see Appendix 4). Table 2 lists measures that have alert values; Appendices 7, 8, and 9 contain examples of alert letters to physicians. Lab results will be sent to the participant within several weeks of the clinic visit.

Table 2	
<u>Health ABC Tests: Alert Values</u>	
<u>Defined Values</u>	<u>Examiner Discretion</u>
Blood Pressure	Weight loss \geq 10%
Bone Density	Teng mini-mental state
Pulmonary function	Symptoms during
Fasting glucose	long distance corridor walk
HgA1C	
White blood cells	
Hematocrit	
Platelets	

5.1.1 Blood pressure

Page 1 of the Year 10 Participant Results Report includes a place for the participant's name and for their systolic and diastolic blood pressure values that can be found on page 39 (Questions #6 and #7) in the Year 10 Clinic Visit Workbook. Record these results on the Year 10 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 10 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 10 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 10 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 10 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 10 Participant Results Report that says "See your doctor in 1 week." If the participant gives their permission, you can contact their primary care provider within one week, or instruct the participant to contact their primary care provider within one week.
- If the participant's systolic blood pressure is ≥ 210 , or their diastolic blood pressure is ≥ 120 , check the box on the Year 10 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.

5.1.3 Bone density (DXA)

The alert for DXA is loss of bone at a greater rate than 1.6 % a year since baseline. (See Appendix 6 for alert letter to participant and Appendix 7 for the alert letter to physician to be sent after confirmation of excess bone loss from the DXA Reading Center [see Appendix 5 - Excessive Bone Loss Form].)

5.1.3 Long distance corridor walk

If the participant develops chest pain or other symptoms, the clinic supervisor should be notified immediately.

5.1.4 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 8).

5.1.5 Pulmonary function test

The alert value is an FEV1 < 1.0 liter or < 40% of predicted (whichever is the smaller number).

5.1.6 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.

5.1.7 Labs

Fasting glucose and HgA₁C 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 fasting glucose and HgA₁C results.

Please see chart below for laboratory reference ranges.

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 10 Pre-Visit Instructions

Dear _____:

Your appointment for your Health ABC Year 10 Clinic Visit has been scheduled for: _____, _____ at _____ a.m. at XXXXXXXXXX, XXXXXXXXX (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.
- If you regularly use an inhaler for a lung or respiratory condition, be sure to bring this with you to the clinic.
- 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 the prescription AND non-prescription medications that you have taken in the last 30 days only. Include eye drops, shots, supplements, vitamins, pain medications, laxatives or bowel medicines, cold medications, cough medications, antacids or stomach medicines, and ointments or salves. 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 10 Clinic Visit
Data from Prior Visits Report**

Participant Name:
Health ABC Enrollment ID# :
Acrostic:

1. Date of last regularly scheduled contact:
2. Missed Year 8 clinic visit?
3. Reason for missed Year 8 clinic visit:
4. Type of Year 8 contact:
5. Missed Year 9.5 phone interview?
6. Reason for missed Year 9.5 phone interview:
7. Type of Year 9.5 contact:
8. Has the participant ever had a proxy interview?
9. For which contact(s)?

STANDING 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 8 clinic visit:
2. Participant's weight at their Year 8 clinic visit minus 10%:

BLOOD PRESSURE

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

BONE DENSITY (DXA) SCAN

1. Which hip was scanned at baseline (Year 1)?

ISOKINETIC QUADRICEPS STRENGTH (KIN COM)

1. Which leg was tested at the Year 8 clinic visit?
2. Which leg was tested at the baseline (Year 1) clinic visit?
3. Which hip was scanned at the baseline (Year 1) clinic visit?
4. Manual position for most recent quadriceps strength measurement:
 - 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

PULMONARY FUNCTION TEST

H=

R=

LONG DISTANCE CORRIDOR WALK

Were there abnormal Marquette ECG hardcopy references collected during the Year 4 ECG, or, if they didn't have the Year 4 ECG, during the baseline (Year 1) ECG?

ENERGY EXPENDITURE

Is participant in the Energy Expenditure cohort?

CT TRACKING – PITTSBURGH ONLY

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 6. Please confirm with the participant whether this information is still current and complete and update the MIF, being careful to determine whether medications listed below were used continuously or whether there is a new start date.

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

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
------------------------	---------------	---------------	---------------

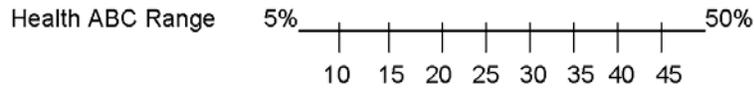
DATE OF DEATH

BODY COMPOSITION

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

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your body fat percentage is marked below 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 adults. As a participant in Health ABC, you are helping us to determine what percentage of body fat either maintains or improves health as we age or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %



BONE MINERAL DENSITY

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 10 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

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

What do bone density measurements mean?

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

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

What are my bone density results?

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

_____ Normal
_____ Low
_____ Osteoporosis

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

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

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

LUNG FUNCTION TEST

Lung Function Test	Your Value	Usual Normal Range
FVC: total amount of air you blew out of your lungs	_____ % of Predicted	80% and greater
FEV1: amount of air you were able to blow out in the first second)	_____ % of Predicted	80% and greater
FEV1/FVC: ratio of the other two volumes	_____	65% and greater

- The lung function test was not performed or lung function could not be determined accurately.
- Your values are within the normal range or above; your lung function is normal.
- Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.
- If either of your values is less than 50% of your predicted normal value, or if your FEV1/FVC ratio is less than 50%, your function is substantially reduced.

Laboratory (blood) tests

You will receive the results of your blood tests in several weeks. These results will include your fasting glucose and HgA₁C.

CT and MRI

Some Health ABC participants had CT and MRI exams. These images are being reviewed using special research techniques. These techniques take longer to complete than a standard clinical reading that is done by doctors, so results will not be available for a while. When results are available, you will be notified about important abnormalities.

Memory and reaction time tests

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

Muscle strength, flexibility, balance, and walking speed tests

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

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

() _____.

Women



Year 10 Participant Results

Participant Name: _____

Date of Year 10 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

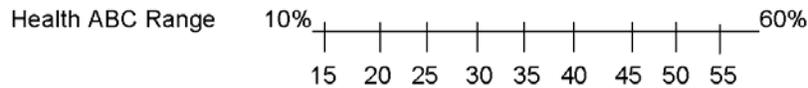
If you have any specific questions about your blood pressure, please talk with your doctor.

BODY COMPOSITION

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

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your body fat percentage is marked below 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 adults. As a participant in Health ABC, you are helping us to determine what percentage of body fat either maintains or improves health as we age or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %



BONE MINERAL DENSITY

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 10 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

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

What are my bone density results?

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

_____ Normal
 _____ Low
 _____ Osteoporosis

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

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

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

LUNG FUNCTION TEST

Lung Function Test	Your Value	Usual Normal Range
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FEV1: amount of air you were able to blow out in the first second)	_____ % of Predicted	80% and greater
FEV1/FVC: ratio of the other two volumes	_____	65% and greater

- The lung function test was not performed or lung function could not be determined accurately.
- Your values are within the normal range or above; your lung function is normal.
- Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.
- If either of your values is less than 50% of your predicted normal value, or if your FEV1/FVC ratio is less than 50%, your function is substantially reduced.

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You will receive the results of your blood tests in several weeks. These results will include your fasting glucose and HgA₁C.

CT and MRI

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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.

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:

() _____.



Year 10 Participant Lab Results

Participant Name: _____

Date of Year 10 Clinic Visit: ____ / ____ / ____
Month Day Year

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

Fasting glucose: ____ mg dL

Normal:	Less than 100 and greater than 50 mg/dL
Borderline:	100 to 125 mg/dL
Elevated:	126 or higher mg/dL

HgA₁C: ____ %

Normal range:	Less than 6%
Recommended:	Less than 7%
Borderline:	7 to 8%
Further action suggested:	Greater than 8%

6/28/06

HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

YEAR 10 CBC RESULTS

Examiner Note: Please record the following results sent by the local laboratory.

White blood count	<input type="text"/> <input type="text"/> . <input type="text"/> thousands/ μ L
Hemoglobin	<input type="text"/> <input type="text"/> . <input type="text"/> g/dL
Hematocrit	<input type="text"/> <input type="text"/> . <input type="text"/> percent
Mean corpuscular volume	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> fL
<p>Platelet: Was the laboratory able to provide an accurate platelet count?</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <input type="radio"/> Yes ↓ </div> <div style="text-align: center;"> <input type="radio"/> No ↓ </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%; border: 1px solid black; padding: 5px;"> <p>What was the platelet count?</p> <div style="text-align: center;"> <input type="text"/><input type="text"/><input type="text"/> thousands/μL </div> </div> <div style="width: 45%; border: 1px solid black; padding: 5px;"> <p>What were the results?</p> <p><input type="radio"/> Normal; sufficient; greater than or equal to 50,000 with a warning</p> <p><input type="radio"/> Insufficient; less than 50,000 with a warning</p> </div> </div>	

Appendix 5 Excessive Bone Loss Form



HABC Enrollment ID #	Acoustic	Date Form Completed	Staff ID #
H		/ /	
		Month Day Year	

EXCESSIVE BONE LOSS FORM

Suspected Excessive Bone Loss Checklist

(Examiner Note: Please make sure that this form is accompanied by all the items listed below.)

- Printouts of the baseline and all follow-up scans of the hip
- Printouts of the "rate of change" report(s) you created for the hip
- Copies of baseline and all follow-up scans of the hip on floppy disk

Be sure to follow all procedures for participants with suspected excessive bone loss.

Comments: _____

To be filled out by the UCSF DXA Reading Center

- Yes, we can confirm excessive bone loss.
The scans are technically correct and the analyses are performed appropriately.
- Yes, we can confirm excessive bone loss.
However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.
- The scans provided indicate possible excessive bone loss.
However, a second scan of the site was not performed in this participant. Excessive bone loss can only be confirmed after you have obtained a second scan of the region where bone loss is suspected. Please schedule the participant for a repeat measurement.
- After scan review we cannot confirm excessive bone loss.

Comments: _____

Signature of UCSF DXA Reading Center Reviewer _____ Date: _____



Version 1.0, 4/1/99

Appendix 6 Excessive Bone Loss Letter to Participant

Date

Participant's name

Address

City, State, Zip code

Dear Ms./Mr./Mrs. <participant's name>:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than 1.6 % per year since your baseline measurement was made.

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

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

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

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

Sincerely,

<Name of Principal Investigator>
Health ABC Principal Investigator

Appendix 7 Excessive Bone Loss Letter to Physician

Date

Physician name

Address

City, State, Zip code

Dear Dr. <Physician name>:

Your patient, _____, who has been a participant in the Health ABC study for the past 9 years, was here on ____/____/____ for his/her annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline, Year 3, Year 5, Year 8, and now at Year 10. The BMD scans of his/her total hip showed ____% bone loss since the start of the study. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as “excessive bone loss” by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma, but we cannot rule out the possibility of positioning or other measurement errors.

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

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

Sincerely,

<Name of Principal Investigator>
Health ABC Principal Investigator

Appendix 8 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 9 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