

YEAR 16 CLINIC VISIT OVERVIEW

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

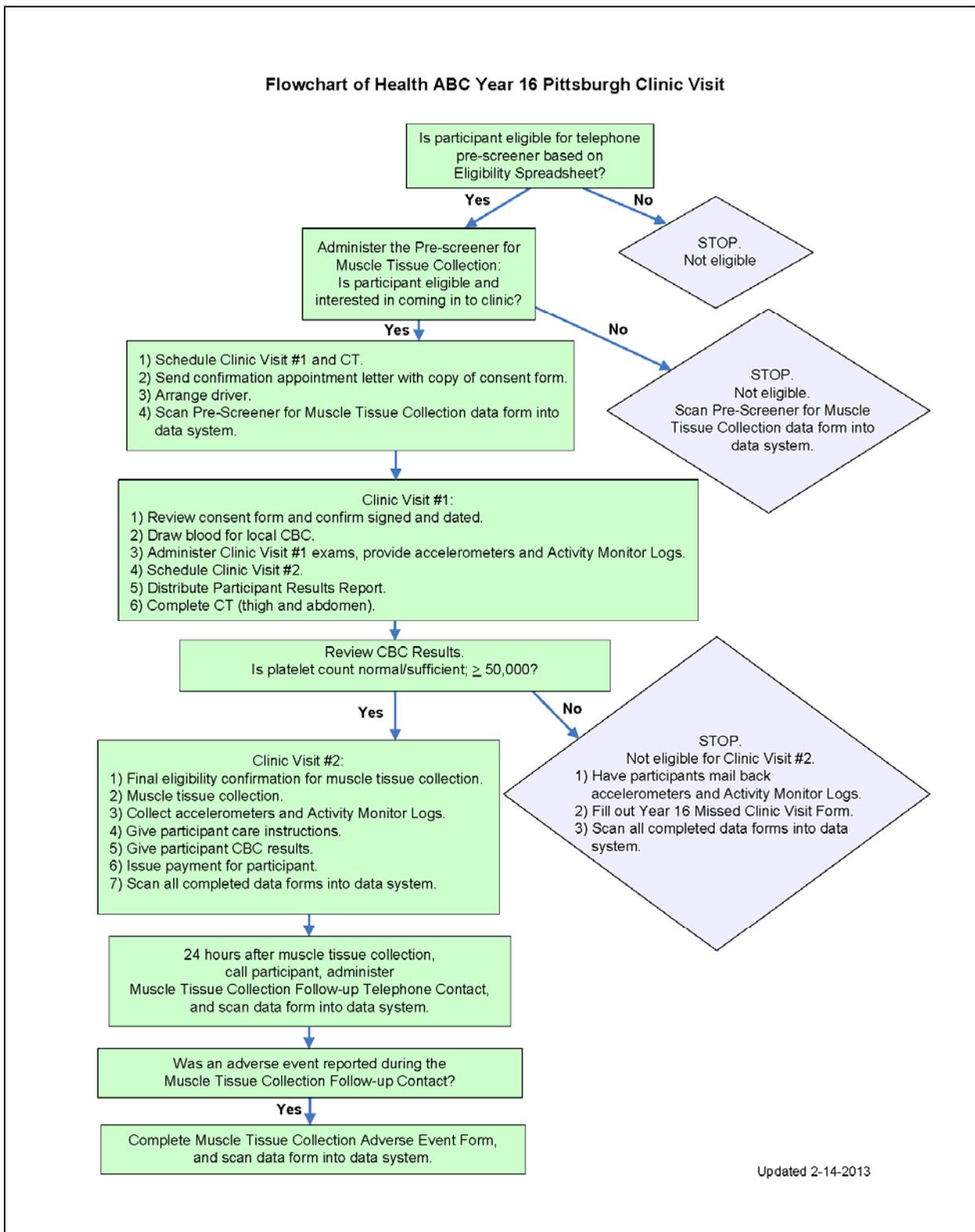
A subset of Pittsburgh participants will have a Year 16 clinic visit. Eligibility for muscle tissue collection will be assessed over the telephone to determine if a participant is eligible for a muscle tissue sample collection procedure. Those participants who are found to be eligible and agree to be part of the muscle tissue collection study will have two clinic visits during Year 16 of the Health ABC study. At the first visit participants will have the following measurements unless specifically excluded according to criteria described in each chapter:

- 20-meter walk
- Accelerometry (participant will be given the accelerometers to wear home with them)
- Blood pressure
- Blood test for CBC (to confirm eligibility for muscle biopsy)
- Balance walks
- Chair stands
- Grip strength
- Isokinetic strength (Kin-Com)
- Radial pulse
- Standing balance
- Standing height
- Weight
- CT scan – thigh and abdomen (day will be variable – may be a separate visit)

At the second clinic visit, if the participant is still eligible, muscle tissue will be collected from the participant's thigh, and the accelerometers (ActiGraphs) and monitor logs will be returned by the participant.

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

1.1 Flowchart of Health ABC Year 16 Pittsburgh Clinic Visit



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 forms, but they are free to modify the script in order for the presentation to sound natural, as long the same information is conveyed to the participants and is presented in the same order as the standardized script. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

2. Working with older participants

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

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

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

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

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

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

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

For Clinic Coordinators and Investigators

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

3. Equipment and supplies

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

4. Training and certification

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

5. Determining eligibility for prescreening

To be eligible for the Year 16 Pittsburgh Clinic a participant must be eligible for the muscle tissue collection procedure. The participants who will be seen in clinic need to not have difficulties with ADLs, need to not be cognitively impaired, need to be reliable when answering questions, and need to be available to come into the clinic. In order to decide whether or not to pre-screen a participant for the Year 16 Pittsburgh Clinic Visit, review the Health ABC – Year 16 Pittsburgh Clinic Visit Eligibility Spreadsheet for Participants who are Alive as of December 3, 2012 that was sent to the field center in December, 2012. If a "Yes" was entered into any of the categories (listed below), the participant is not eligible for prescreening. The exclusion categories are the following:

- Yr 15Q4 AND Yr 16Q1 interviews were "proxy" interviews
- Yr 15Q4 AND Yr 16Q1 interviews were missed
- On Year 16Q1 Missed Follow-up Contact Form, "Moved out of area", "Clinic Too Far", or "In nursing home/long-term care facility" noted as reasons for missed interview
- Difficulty with ADLs (Yr16Q1, Pg. 6, Q#12-#14)
- Lives in "facility where provided with assistance in most or all of daily needs" (Yr16Q1, Pg. 35, Q#100)
- TICS score less than 20 (Y15Q2 or Yr15Q4 Pg. 13-15)
- Last participant quarterly interview "not very reliable" (Yr16Q1, Pg. 41, Q#113)
- Cognitive difficulties or in nursing home, per Year 16Q1 Proxy interview (Pg.21, Q #65)
- Healthy Brain Substudy assessment determined participant should not be contacted for Year 16 clinic visit
- During Healthy Brain Substudy, participant reported taking Aricept, Namenda, Exelon, or Razadyne

6. Preparation for the Year 16 clinic visits

6.1 Participant preparation

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

- date and time of the first Year 16 clinic visit
- that participants take all of their regular medications, as usual
- that participants bring all of their prescription and non-prescription medications to clinic
- that participants 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

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

Participants should receive a reminder call for the muscle tissue collection visit that takes place about a week after their first visit. At their first clinic visit participants will already have been given an instruction sheet explaining how to prepare for their second visit. Ideally, reminder phone calls should be made two days before the second visit to remind them:

- to wear their accelerometers
- to continue writing in their activity monitor log the times they take off the accelerometers, the activity they were doing when the accelerometers were off, and the time they put the accelerometers back on
- date and time of the second Year 16 clinic visit
- to only take Tylenol for pain unless they are taking something else by prescription
- to not engage in strenuous exercise for 48 hours before the procedure
- 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
- that participants who wear hearing aids should bring or wear them to the clinic
- that participants remember to bring the accelerometers and monitor logs to clinic

Please see an example of instructions for the muscle tissue collection visit in Appendix 3.

6.2 Year 16 clinic visit preparation

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

- A Data from Prior Visits Report should be generated with information that will be needed for the Year 16 clinic visit (see Appendix 4)
- The participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.)
- A Year 16 Pittsburgh Clinic Visit Workbook preprinted with the acrostic and Health ABC enrollment ID number. It is important to double-check the accuracy of the pre-printed acrostic at the top of the first page of the Year 16 Pittsburgh Clinic Visit

Workbook as compared with the participant's name. After you print the participant's name on the first page of the Year 16 Pittsburgh Clinic Visit Workbook, look at the first letter of the first name and the first three letters of the last name to make sure that these match the pre-printed acrostic at the top of the page.

- A Year 16 Participant Results Report to give the participant at the end of their clinic visit (Appendix 5).
- The participant’s chart. Field centers should also keep “progress notes” in the participant’s chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

Table 1 [below] lists all the forms that are completed for both Year 16 clinic visits.

Table 1	
<u>Health ABC Year 16 Pittsburgh Clinic Visit Forms</u>	
<p>Pre-visit: Muscle tissue collection eligibility pre-screener</p> <p>Year 16 Pittsburgh Clinic Visit Workbook:</p> <p>First clinic visit: Radial pulse Blood pressure Grip strength Chair stands Standing balance Balance walks 20-meter walk Height Weight Isokinetic strength (Kin-Com) Accelerometer screener and distribution</p>	<p>Tracking forms and monitor logs: CT Tracking Activity Monitor Logs</p> <p>Second clinic visit: Muscle tissue collection eligibility confirmation Muscle tissue collection Muscle tissue processing Accelerometer return and reading CBC Results</p> <p>Post-second clinic visit: Muscle tissue collection follow-up telephone contact Muscle tissue collection adverse event form (rarely needed)</p>

7. Clinic flow and measurements

7.1 Overview of clinic flow

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

Mandatory first visit

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

Preferable first visit:

Group together standing height and weight

The second Year 16 clinic visit includes the muscle tissue collection. The participant's blood pressure will be taken to make sure they are still eligible for the procedure. The accelerometers and monitor logs will be returned at the second visit also.

Mandatory second visit

Blood pressure exams before muscle tissue collection

7.1.1 Year 16 Muscle Tissue Collection Eligibility Pre-Screener

The Year 16 Muscle Tissue Collection Eligibility Pre-Screener interviews will be administered over the telephone. After initial screening, and if participants agree to the muscle tissue collection procedure, they will be asked to come in for two clinic visits.

See Interviewing Guidelines chapter for interview guidelines. See Muscle Tissue Collection chapter for screening information and instructions.

7.1.2 Blood pressure and radial pulse

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

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

7.1.3 Blood collection

Blood will be collected in order to obtain a complete blood count measured at a local laboratory. The results must be obtained before the participant can have muscle tissue collected at their second clinic visit. If a participant has a platelet count less than 50,000 or labeled "insufficient" they are no longer eligible for muscle tissue collection.

7.1.4 Grip strength

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

See Grip Strength operations manual for detailed procedures.

7.1.5 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.

7.1.6 20-meter walk

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

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

See 20-meter Walk operations manual for detailed procedures.

7.1.7 Anthropometry and physical measures

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

See Standing Height and Weight operations manual chapters.

7.1.8 Computed tomography (CT)

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. Thigh and abdominal scans will be obtained.

See Computed Tomography (CT) operations manual for detailed procedures.

7.1.9 Isokinetic strength (Kin-Com)

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

See Isokinetic Strength operations manual for detailed procedures.

7.1.10 Muscle tissue collection

During this examination, we are asking eligible participants to donate approximately 150 mg (size of a few grains of rice) of muscle tissue from the thigh, specifically the vastus lateralis muscle. About 75 mg of this tissue will be used by Dr. Goodpaster's lab to determine mitochondrial energetics (high-resolution respirometry), oxidative stress (H₂O₂ emission), expression of proteins related to muscle growth and atrophy signaling, mitochondrial dynamics, and histochemistry for muscle fiber type and fiber size; these will be shared with the Health ABC investigators and will be available for use by others in the scientific community.

See Muscle Tissue Collection operations manual for detailed procedures.

7.1.11 Accelerometry

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

Participants will be given a wrist and hip accelerometer and monitor log during their first Year 16 clinic visit and will be instructed about how to wear these accelerometers and how to complete the monitor log. They will return the accelerometers and their monitor logs at their second visit when they return to clinic for the muscle tissue collection procedure.

See Accelerometry operations manual for detailed procedures.

7.2 Procedure checklist and exit interview

At the end of the Year 16 clinic visit (first and/or second visit), an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 16 Pittsburgh 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 muscle tissue collection was scheduled; and permission to send test results to the physician (see Appendix 1). Confirm that all exams and measurements were completed. Review the Year 16 Pittsburgh 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 5). 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.
 - ⇒ CBC results.
 - Determine if the participant would like their test results sent to their physician. Note consent for release of reports to physician (yes or no) on the Year 16 Pittsburgh Clinic Visit Procedure Checklist.
 - Summarize future contact with the study both for scheduled telephone contacts and endpoints. Participants should be reminded to immediately contact the clinic for any of the following events:
 - ⇒ Hospitalization. Any overnight stay in an acute care facility.
 - ⇒ Surgery. Any surgery requiring regional (e.g., spinal) or generalized anesthesia. This includes same-day surgery for angioplasty.
 - ⇒ Fracture. Any broken bone, excluding minor fractures of the ribs, toes, fingers, etc.
 - ⇒ Cancer. Any newly diagnosed cancer, excluding non-melanoma skin cancer.

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

7.3 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.

8. Alerts and notifications

At the clinic visit, participants will receive a report that includes height, weight, CBC, and blood pressure (see Appendix 5). Table 2 lists measures that have alert values; Appendix 6 contains an example of an alert letter to a physician.

Table 2
Health ABC Tests – Alert Values

Blood pressure
White blood cells
Hematocrit
Platelets

8.1.1 Blood pressure

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

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

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

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

doctor in 1 week.” If the participant gives their permission, you can contact their primary care provider within one week, or instruct the participant to contact their primary care provider within one week.

- If the participant’s systolic blood pressure is ≥ 210 , or their diastolic blood pressure is ≥ 120 , check the box on the Year 16 Participant Results Report that says “See your doctor immediately.” If the participant gives their permission, you can contact their primary care provider immediately, or instruct the participant to contact their primary care provider immediately.

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

8.1.2 Labs

The local lab will send the Pittsburgh clinical site the CBC results. CBC results will be recorded on the CBC Results form and scanned into the data system. Participants will be given a copy of their CBC results.

Please see chart below for laboratory reference ranges.

Analyte	Reference Range for Reports	Immediate Alerts*
General Chemistries:		
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 Center. 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 6) 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.

9. Clinic safety

9.1 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.

9.2 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.

9.3 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.

9.4 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.

9.5 Emergency plans in case of fire

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

Appendix 1 Year 16 Pittsburgh Clinic Visit Workbook Procedure Checklist



HABC Enrollment ID #

Acrostic

Visit Year
 16

Staff ID#



Date Visit #1 Completed: / /
Month Day Year

YEAR 16 PITTSBURGH CLINIC VISIT WORKBOOK

What is your...?

First Name M.I. Last Name

PROCEDURE CHECKLIST

Measurement	Page #	Yes: Fully completed	Yes: Partially completed	No: Participant refused	No: Other reason/ Not applicable
1. Radial pulse	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Blood pressure	3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Grip strength	4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Chair stands	6	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Standing balance	7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Balance walks	9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. 20-meter walk	10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Height	11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Weight	12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Isokinetic quadriceps strength (Kin-Com)	13	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. CBC with platelets	17	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Was eligibility for muscle tissue collection procedure reviewed?	18	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
13. Was muscle tissue collected?	19	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Was muscle tissue processed?	21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Was accelerometer(s) given to participant?	22	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
16. Was the Activity Diary given to participant?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>
17. Did participant agree to have a CT?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

Comments: _____

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



Appendix 2 Year 16 First Clinic Visit Instructions

Instructions for First Year 16 Clinic Visit

Dear _____

Your appointment for your Health ABC Year 16 Clinic Visit has been scheduled for _____ at _____ a.m. at xxxxxxxxxxxx, xxxxxxxxxxxx (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.
- Take all your regular medications, as usual.
- Bring all of your prescription and non-prescription medications to 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 you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.

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

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

Appendix 3 Year 16 Second Clinic Visit Instructions**Instructions for Second Year 16 Clinic Visit (given over telephone)**

We're looking forward to seeing you for your second Health ABC Year 16 Clinic Visit scheduled for: _____ at _____ a.m. at XXXXXXXXXXX, XXXXXXXXX.

We're calling to give you a few reminders. Please remember to . . .

- keep wearing your accelerometers and to keep completing your monitor log
- bring in your accelerometers and monitor logs to your next clinic visit.
- only take Tylenol for pain unless you are taking something else by prescription
- not engage in strenuous exercise for 48 hours before the next clinic visit
- fast for 12 hours before your next clinic visit (no eating or drinking, except for water and prescription medications)
- drink plenty of water before you come into the clinic.
- wear comfortable clothing (short sleeved) and footwear, and to not wear pantyhose or girdles.
- not wear jewelry to the clinic, if possible, since this may make it more difficult to do your bone scan.
- If you have a hearing aid, bring it with you.

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

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

Below are the instructions the participant will have been given at their first clinic visit for the muscle tissue collection.

Muscle Tissue Collection Instructions

The muscle tissue collection procedure is done to obtain a sample of muscle cells from the thigh area. This procedure will take approximately 1 hour, and will be completed by a physician or physician assistant.

Below are instructions that you should follow to prepare for the muscle tissue collection procedure. If you have any questions about the information below, please call our clinic staff at (xxx) xxx-xxxx.

BEFORE THE MUSCLE TISSUE COLLECTION:

1. DO NOT STOP taking your prescription medications.
2. Only take Tylenol for pain or cold symptoms for 1 week before the procedure. However, if you are taking aspirin under the direction of a doctor, keep taking it.
3. Do not engage in strenuous exercise for 48 hours before the procedure.
4. Do not eat or drink anything except water from midnight the night before your procedure until after the tissue collection has taken place. However, you should take your prescription medications.

DURING THE MUSCLE TISSUE COLLECTION PROCEDURE:

1. Your blood pressure will be taken before the test.
2. The physician will inject some numbing medication into the area of your thigh from where the tissue will be taken. You will feel a burning sensation from this medication for a short period of time. This medicine is very similar to the medicine the dentist uses to numb your teeth and gums.
3. Once the area is numb, the physician will make a small cut in the skin and then insert a needle into the muscle tissue. You should not feel anything except the pressure of the needle and perhaps a sharp pinch during the procedure.
4. Muscle tissue will be removed through this needle.
5. When the procedure is finished, either Dermabond or a steristrip and bandage will be placed over the site.

AFTER THE MUSCLE TISSUE COLLECTION PROCEDURE:

Plan to limit your activity for the rest of the day and do not shower until the next day. You should not take a bath for 72 hours after the procedure.

Appendix 4 Data from Prior Visits Report**Year 16 Pittsburgh Clinic Visit
Data from Prior Visits Report**

Participant Name:
Health ABC Enrollment ID#:
Acrostic:

YEAR 16Q1 INTERVIEW

1) Status of Year 16Q1 participant interview (participant completed; proxy completed; missed interview):

1a) If missed Year 16Q1 interview, reason for missed interview:

BLOOD PRESSURE

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

HEIGHT

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

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

ISOKINETIC QUADRICEPS STRENGTH (KIN COM)

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

Baseline or First Measurement of Isokinetic Quadriceps Strength

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

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

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

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

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

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

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

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

COMPUTED TOMOGRAPHY (CT)

10) Which thigh was measured during participant's last CT scan?

ACCELEROMETRY

11) Which hand does participant use to write with?

EVENTS

Appendix 5 Health ABC Examination Results



Year 16 Participant Results

 Participant Name: _____
(Please Print)

 Date of Year 16 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.



Year 16 Participant Results

Muscle tissue, CT, 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:

() _____.

HABC Enrollment ID #	Acrostic	Visit Year	Date of CBC Results			Staff ID#	
H <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"/>	● 16	<input type="text"/> / <input type="text"/> / 2013	Month	Day	Year	<input type="text"/> <input type="text"/> <input type="text"/>



YEAR 16 CBC RESULTS

1. White blood count	<input type="text"/> <input type="text"/> . <input type="text"/>	thousands/ μ L
2. Hemoglobin	<input type="text"/> <input type="text"/> . <input type="text"/>	g/dL
3. Hematocrit	<input type="text"/> <input type="text"/> . <input type="text"/>	percent
4. Mean corpuscular volume	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	fL
5. Platelet: Was the laboratory able to provide an accurate platelet count? <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <input type="radio"/> Yes <input type="radio"/> No </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; width: 45%;"> What was the platelet count? <input type="text"/> <input type="text"/> <input type="text"/> thousands/μL </div> <div style="border: 1px solid black; padding: 5px; width: 45%;"> What were the results? <input type="radio"/> Normal/sufficient; greater than or equal to 50,000 <input type="radio"/> Insufficient/less than 50,000 </div> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; text-align: center;"> Examiner Note: If platelet count is less than 50,000 or "insufficient," do NOT schedule muscle tissue collection procedure. </div>		

Appendix 6 Sample Letter to Physician Regarding Alert Values

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 eighties and nineties 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