# BLOOD COLLECTION

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## 1. Background and Rationale

The Health ABC study involves the collection of approximately 17 mL of blood from participants. Since the study depends on the voluntary return of participants over an extended period of time, every effort must be made to make the entire procedure as easy and painless as possible both for the participants and for the Field Center personnel.

A standard informed consent has been prepared for this study. With regard to laboratory procedures, the consent statement informs study participants that there is a small risk of bruising at the spot on the arm where the blood is taken and that about three tablespoons of blood are drawn. The consent statement also informs study participants that they will be contacted if clinically significant test results are discovered.

## 2. Equipment and Supplies

### 2.1 Sample ID Labels

You will be supplied with sheets of sample ID barcode labels to use for labeling forms, draw tubes, and cryovials. A sample sheet of barcode labels can be found in Appendix 1. All labels on each sheet have the same 6-digit sample ID number (the first digit identifies the clinic - Memphis = 1, Pittsburgh = 2).

There are 4 labels containing the ID number with no extension. Two are to be used for pre-labeling the 2 draw tubes, with 2 extras for backup vacutainers. These labels have no barcode, and they have 1-4 lines of text indicating which specimen container they are intended for, including the stopper color and volume, if applicable.

There are also 2 barcoded labels with the ID number, one called “Phlebotomy Form,” which is placed on the Phlebotomy Form (Appendix 2), and the other called, “Laboratory Processing Form” which is placed on the Laboratory Processing Form. *This process of matching the participant-specific ID (**already on the form brought to the lab by the participant)** to the sample-specific ID barcode is crucial to being able to use the data collected from laboratory tests.*

There are also 5 barcoded labels with the same ID number and the words "BDID Form." Use of these labels is detailed in the Lab Specimen Processing chapter. Finally, there are 13 labels intended for labeling cryovials (see Lab Specimen Processing chapter).

## 2.2 Blood Collection Trays and Tubes

Blood drawing trays are prepared in advance for the following day. Each tray is stocked with a full supply of blood drawing equipment for 6-9 participants and holds an ice bath and the individual blood collection tube rack for each participant. Several racks will also be prepared to hold various plastic tubes and vials for the final serum and plasma aliquots sent to the Laboratory for Clinical Biochemistry Research (LCBR) for analysis and to McKesson BioServices for storage. The blood collection tube racks and aliquot tube racks are prelabeled from the same sheet of sample ID barcode labels.

**2.2.1 Blood collection tray.** The collection tray itself is made of hard plastic which is unbreakable and can be easily cleaned. The tray has ten individual compartments which are filled with the following supplies:

- Alcohol swabs
- Band-Aids
- Gauze
- Tourniquets (2)
- Vacutainer holders
- Needle/sharps container
- Styrofoam ice bath filled ~10 min before draw
- 21G Butterfly needles with Luer adapter
- Smelling salts
- Timer/stopwatch
- Scissors
- Adhesive tape
- Pencils/pens
- Latex gloves

### 2.2.2 Blood Collection Rack: Labeling and Setup

A separate tube rack containing the necessary draw tubes is set up for each participant. They are arranged according to the priority of the draw. This rack will fit into the blood collection tray. The blood collection tubes should be prelabeled with sample ID labels. After the labels have been used for setting up the blood collection rack and the aliquot rack (see Lab Specimen Processing chapter), there will be 9 labels left: 2 "Backup Vacutainer" labels, 1 "Phlebotomy Form" label, 1 "Laboratory Processing Form" label, and 5 "BDID Form" labels. These can be

separated into 2 mini-sheets: The "Backup Vacutainer," "Phlebotomy Form," and "Laboratory Processing Form" labels should be clipped to the corresponding blood collection tray. The "BDID Form" labels should be clipped to the corresponding aliquot rack.

### 2.2.3 Description of Blood Collection Tubes

Each draw tube is color coded to aid in handling.

Tube #1 is a 7 ml lavender stoppered tube containing 15% liquid EDTA as the anticoagulant. After drawing, the tube should be mixed and immediately placed on ice. 1 mL of whole blood will be aliquoted before spinning. This 1 mL will be sent to LCBR for analysis of HbA1c. The cryovial cap is coded white. The remaining blood in the draw tube will be spun. Cryovial caps for this plasma are also coded white. The plasma will be used for archival purposes.

Tube #2 is a 10 ml siliconized red stoppered tube used to collect serum. This tube contains no anticoagulant so that the blood clots to form serum. After drawing, the blood is allowed to clot at room temperature for 40-45 minutes (Maximum = 90 minutes). Cryovial caps are coded red. The serum is used for analysis of fasting glucose, cholesterol and archiving.

## 3.1 Precautions for Handling Blood Specimens

In accordance with the OSHA regulations on blood borne pathogens (see OSHA regulations that are kept in the laboratory), the LCBR recommends the following laboratory safety protocol for the field center laboratories:

- Non-permeable lab coats, latex gloves, and face shields should be used when handling any blood in any situation where splashes, spray, spatter, or droplets of blood may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

- 'Universal Precautions' should be followed when handling any blood products.

- Contaminated needles and sharps shall be immediately placed in a puncture-resistant, leakproof container. Never recap or break needles.

- Hepatitis B vaccine should be offered to all unvaccinated technicians handling blood and documentation of vaccination or technicians' declining to be vaccinated should be kept.

## 3.2 Participant Precautions and Exclusions

### 3.2.1 Participant Phlebotomy Questionnaire

Following the questionnaire format on the Phlebotomy Form, each participant is asked whether they have a bleeding disorder before the blood is drawn (Ques. 1). If they have had any problems with excessive bleeding or bruising at a venipuncture site, use your own judgment to decide whether or not a clinic physician or nurse supervisor should be consulted.

If the participant has experienced fainting spells during phlebotomy (Ques. 2), ask the participant the frequency of fainting spells. If the participant frequently faints, again, use your own judgment to determine whether or not a consultation with the clinic physician or nurse supervisor is necessary. Provide smelling salts, basin, and a cold cloth if needed. See section below on precautions when a participant feels faint.

Questions 3 and 4 relate to rare, but important exclusions. If a participant has had a radical mastectomy, including removal of the axillary (armpit) lymph nodes, any damage to veins on the side from which the lymph nodes were removed could result in chronic edema and clotting problems. Therefore, it is safest to use the arm from which lymph nodes were not removed. If a participant has had a bilateral radical mastectomy, it is safest not to do the blood draw at all. If they aren't sure whether their mastectomy was radical or a modified procedure, it is safest to treat it like a radical mastectomy.

Similarly, if a participant has had a graft or shunt implanted to allow kidney dialysis, application of the tourniquet and venipuncture in the area of the graft could seriously compromise the graft. Again, it is safest to use the arm without the graft or, if the participant has had grafts in both arms, not to do the blood draw at all.

### 3.2.2 PRECAUTIONS WHEN A PARTICIPANT FEELS FAINT OR LOOKS FAINT FOLLOWING THE BLOOD DRAWING.

- Have the participant remain in the chair, if necessary have them sit with their head between their knees.
- Provide the participant with a basin if they feel nauseated.
- Have the participant stay sitting until the color returns and they feel better.
- Place a cold wet cloth on the back of the participant's neck.
- If the participant faints, use smelling salts to revive by crushing the ampule and waving it under the participant's nose for a few seconds.
- If the participant continues to feel sick, contact a medical (nursing) staff member who will advise you on further action.

### 3.3 Participant Refusal of Phlebotomy

Rarely, a participant will refuse phlebotomy. Please keep a list of Health ABC Enrollment ID #s of any of these participants and identify which test they refused.

## 4. Subject and Exam Room Preparation

### 4.1 Phlebotomy Room

The blood drawing should take place in an isolated room or participants should be separated by room dividers. The room should be equipped with all of the necessary blood drawing supplies. A separate counter or work table should be equipped with all of the materials and vials that are used in the blood handling and processing. The centrifuge, refrigerator, and freezer should be nearby.

### 4.2 Preparation for Phlebotomy

Preparation for phlebotomy is done in the following manner. Early morning, before any participants arrive:

- Check to make sure that blood collection tray is properly equipped. Every item on the checklist (Appendix 4) must be ready before proceeding.

- Check that each vacutainer tube is properly labeled with sample ID labels and numbered 1-2.

- Check that the sample processing station is properly equipped (see Lab Sample Processing chapter).

- Make sure the phlebotomy room is tidy and stocked with extra smelling salts, basin, and disposable wash cloths, and that blood mixer is functional.

Approximately 10 minutes before scheduled participant arrival:

- Fill styrofoam ice bath 3/4 full with crushed ice.

### 4.3 Preparation of Participants for Phlebotomy

It should be stressed that this study requires the voluntary cooperation of the participants. These people are donating both time and blood on a purely voluntary basis, with no reward other than the knowledge that they are contributing to progress in medicine. Thus, the whole experience must be made as pleasant as possible. Two tubes of blood are collected. The smaller tube contains slightly under 2 teaspoons (7 mL) of blood. The larger tube contains 2 teaspoons (10 mL) of blood. Any participants who are concerned about the volume of blood should be reassured that the total amount of blood drawn is less than 4 teaspoons, although it may look like more. The phlebotomist may also assure participants that they donate 26 times as much blood (450 mL) when they donate a unit of blood.

## 5. Detailed Procedures

### 5.1 Forms

An example of the Phlebotomy form is in Appendix 2. The purpose of this form is to provide a vital link between the sample ID# and the participant ID# and to facilitate the collection of plasma and serum samples from participants. The collection must be done in a rapid and efficient manner, with maximum protection for the participant. In addition, the process must facilitate the monitoring of phlebotomy and other quality assurance parameters. All forms must be completed in ink.

The Phlebotomy form has the following purposes:

1. Assure the most efficient and safest possible venipuncture for participants.
2. Allow the monitoring of the quality of the above procedures.
3. Allow more efficient processing of the samples at LCBR.
4. Provide information critical to the interpretation of the assay results

The participant will arrive at the phlebotomy station with their Health ABC participant ID# already filled in on their Phlebotomy and Laboratory Processing forms. The sample ID will be determined by the set of prelabeled tubes used to collect their samples. It is vital that this same sample ID be matched up with the participant ID on both the Phlebotomy and the Laboratory Processing forms (see Lab Specimen Processing chapter). There will be a small sheet of labels clipped to the rack of vacutainers. On it is a "Phlebotomy Form" label, to be affixed to the upper right corner of the Phlebotomy Form, and a "Laboratory Processing Form" label which should be affixed to the upper right corner of the Laboratory Processing Form. This should be done before drawing any blood, to insure that this critical task is not forgotten.

There are actually two parts to the Phlebotomy form associated with blood drawing. The first section contains questions that are important for participant safety; these questions should be asked immediately before phlebotomy and deal with any propensity to bleed or faint. The second part deals with details of the phlebotomy procedure, whether it went smoothly, how long it took, etc.

### 5.1.10 Return Visit Aliquots

Occasionally, participants return to the clinic just to have a fasting blood draw or because the were unable to give a sample at the regular clinic visit. There are new forms that must be filled out for return visits: the Return Visit Phlebotomy Form, and the Return Visit Lab Processing Form (see Appendix 3). Use a new set of sample ID bar code labels. Place the Phlebotomy Form label in the Bar Code Label space on the Return Visit Phlebotomy Form. Place a Laboratory Processing Form label in the Bar Code Label space on the Return Visit Laboratory Processing Form.

If the participant returned only because they were not fasting at the clinic visit, they should have had a complete draw during the clinic visit. You will therefore only have to draw a small amount of blood for a fasting serum sample. Do not draw tube #1. For tube #2, substitute a 3- or 5-mL siliconized red-stoppered tube (the 3-ml pediatric tubes may require a different adapter for the centrifuge). You will get more serum than you need for the fasting serum sample, but you should not fill more cryovials for storage. Fill cryovial 06 only. You may also fill one blind duplicate cryovial 06, if needed. The rest of the serum should be discarded.

Only if the participant did not have blood drawn at all during the clinic visit, use the draw tube labels for Draw Tube 1 and 2 and the cryovial labels for cryovials 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, and 13 as usual. If the participant had an incomplete draw, then draw the tube needed to complete the set of cryovials. For example, if the participant had an EDTA tube drawn at their clinic vist, but a serum sample could not be obtained, draw the regular 10 mL tube #2 and fill cryovials 06-13.

Be sure to fill out both Return Visit forms with the header information including the Health ABC ID #, Acrostic, Date Form Completed, and Staff ID #.

If you know that you are going to have a large number of re-draws just for one or both of the cryovials being sent to LCBR for immediate assay, then you can set aside a group of 20 label sets, along with the corresponding blind duplicate set and use this exclusively for the re-draws.

You should only create blind duplicates that match a real sample. Since none of the samples sent to LCBR this year (cryovials 1 and 6) should have a blind duplicate, you should not be creating blind duplicates for the re-draws. If you use the rest of the labels for blind duplicate cryovials from new participants (i.e., not those having redraws), you will end up with more duplicates than 5% of the total samples.

Therefore, you may discard the blind duplicate label set that goes with the group of 20 labels sets you have set aside. However, if you have not already removed and discarded the labels for cryovials 1 and 6 from the blind duplicate label set, you can also use that set for a redraw.

If you have already gotten out of sync by creating a set of blind duplicate samples for every 20 redraws, you may discard the next one or two blind duplicate label sets until you are back in sync. In other words, if you have had 40 redraws and created two extra sets of blind duplicates, just discard the next two blind duplicate label sets. When you fax the Blind Duplicate ID Forms to the Coordinating Center, just make a note on the fax cover sheet that you have discarded two sets of barcode labels, and record the barcodes from those sets.

While it would be better to have extra barcode labels to use for redraws, it is impossible to predict how many label sets you would need for this purpose. Normally, the need for redraws would be rare and sporadic.

## 5.2 Phlebotomy

### 5.2.1 General

Blood drawing is standardized for the sitting position.

The venipuncture is performed with a 21 gauge butterfly needle with 12 inches of plastic tubing between the venipuncture site and the blood collection tubes. A 23 gauge needle may be used, if necessary, for a difficult draw, *but this must be noted on the Phlebotomy form under "Comments on blood collection."* The butterfly has a small, thin-walled needle, which minimizes trauma to the skin and vein. The use of 12 inches of tubing allows tubes to be changed without any movement of the needle in the vein. If the participant is concerned about the venipuncture, they may be reassured to know such care is taken. The participant should be given enough time to feel comfortable both before and after the blood collection. In many cases the most memorable part of the experience for the participant will be the contact with the technician who draws the blood and their general attitude and competence.

If the participant is nervous or excited, the technician briefly describes the procedure. Sample script: *"I am going to be drawing about 4 teaspoons of blood. This blood will be used in tests for blood glucose and some new experimental tests. We hope to be able to use the results of these tests to better understand health and disease in older people."*

### 5.2.2 Handling participants who are extremely apprehensive about having blood drawn

*Do not under any circumstances force the participant to have blood drawn.* It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible. It is sometimes best to let the participant go on with another part of the visit. It may also be helpful to have the participant relax in the blood drawing chair just so the phlebotomist can check the veins in the participant's arms, without actually drawing blood. If the participant has "good veins" the phlebotomist can reassuringly say, "Oh, you have good veins; there should be no problem." Elderly participants are often aware of the difficulty they pose to phlebotomists and should receive extra consideration and detailed explanations as required.

### 5.2.3 Venipuncture Procedure

- Wear Latex gloves and a lab coat.
- Arrange draw tubes in order of draw (see Section 5.2.9) on the table top within easy reach. Assemble butterfly apparatus and vacutainer holders, gauze, and alcohol prep prior to tourniquet application.
- Apply tourniquet.
- Examine participant's arms for the best site for venipuncture. Generally the antecubital vein is preferred, if feasible. Release tourniquet.
- Cleanse venipuncture site. Prepare area by wiping with alcohol swab in a circular motion from center to periphery. Allow area to dry.
- Reapply tourniquet and start timer. Note the start time on the Phlebotomy form.
- Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches below the venipuncture site.
- With the needle bevel upward, enter the vein in a smooth continuous motion.
- Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the opposite hand and place it under the elbow for support.
- Grasp the flange of the vacutainer holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
- Note the blood flow into the first collection tube. If blood is flowing freely, the butterfly needle can be taped to the participant's arm for the duration of the draw. If the flow rate is very slow, the needle may not be positioned correctly.

- Remove the tourniquet at 2 minutes. Once the draw has started, do not change the position of the tube until it is withdrawn from the needle. If blood flow ceases after the tourniquet is removed, it may be reapplied for another 2 minutes. Note on the Phlebotomy form the total length of time the tourniquet was on.
- Keep a constant, slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow. Do not vary pressure or reintroduce pressure after completion of the draw.
- Fill each vacutainer tube as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a vacutainer tube fills only partially, remove the vacutainer and attach one of your extra, backup tubes of the same type without removing the needle from the vein. Be sure to place one of the "Backup Vacutainer" labels on that tube after completing phlebotomy.
- When the blood flow ceases, remove the tube from the holder. The shutoff valve re-covers the point, stopping blood flow until the next tube is inserted.
- After tube #1 is removed, mix by gently inverting before placing tube on the mixer. Note: do NOT mix red top tube # 2. (See section on Blood Mixing During Venipuncture below).
- Average venipuncture time is 2-3 minutes, but any difficulties may increase this time to 10 minutes. Be sure to note the time venipuncture is completed on the Phlebotomy form.

### 5.2.4 Removing the Needle

- To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard needle into puncture-proof sharps container.
- Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma.
- Remove tube #1 from the blood mixer and place in ice. Tube #2 should already be in the rack at room temperature.

### 5.2.5 Bandaging the Arm

Under normal conditions:

- Slip the gauze pad down over the site, applying mild pressure.
- Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
- Tell the participant to leave the bandage on for at least 15 minutes.

If the participant continues to bleed:

- Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
- Wrap a gauze bandage tightly around the arm over the pad.
- Tell the participant to leave the bandage on for at least 15 minutes.

### 5.2.6 Completing the Blood Drawing Procedure

- Dispose of needle and tubing in the appropriate biohazard needle sharps containers.
- Complete the Phlebotomy form. This includes rating the venipuncture as clean or traumatic and writing any comments about any difficulties with the phlebotomy under "Comments on Phlebotomy."
- Clean up the venipuncture area (if necessary).
- Bring blood collection tray to the processing area with the filled vacutainer tubes and Laboratory Processing form.

### 5.2.7 Procedures for Difficult Draw

If a blood sample is not forthcoming, the following manipulations may be helpful.

- If there is a sucking sound, turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
- If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm.
- Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.
- DO NOT attempt a venipuncture more than twice unless a participant encourages you to do so.
- Reassure the participant that the inability to obtain a clean venipuncture is not any sign of a medical problem on their part.
- If venipuncture is unsuccessful, participant should be rescheduled at a later date, preferably with a different Field Center phlebotomist.
- Document any problems with venipuncture and sample collection on the Phlebotomy form. In particular, note whether a vein other than one of the antecubital veins was used.

### 5.2.8 Other Possible Problems

1) Not all tubes are collected (blood flow ceases, difficult venipuncture, etc.): *Always fill the collection tubes in the order specified.* Make notations of difficulties on the Phlebotomy form. If the participant is willing, another attempt should be made to complete the draw.

2) Collection tube does not fill: First, try another tube of the same type. Partially filled plasma tubes are not acceptable if less than 2/3 full. Partial tubes for serum are okay, but will result in a reduced number of aliquots. Check "No" (not filled to capacity) and explain why under Question #10 of the Phlebotomy form if a tube is not completely filled.

### 5.2.9 Priority of Tubes

A total of approximately 17 mL of blood will be drawn from each participant in 2 tubes. Tubes are numbered 1-2 and arranged in the rack to be drawn in the following order of priority:

| | | |
|---|---|---|
| 1. | Whole blood / EDTA Plasma 7 mL | lavender top |
| 2. | Serum 10 mL | red top |

### 5.3 Blood Mixing During Venipuncture

Each tube should be treated as follows:

| | |
|---|---|
| #1 | EDTA: place on mixer for ~30 seconds, then place in ice bath |
| #2 | Serum: do NOT mix; place in rack at room temperature for AT LEAST 40 minutes |

## 6. Procedures for Performing the Measurements at Home

This examination can be done on home visits. The timing of the draw should be arranged so that there is sufficient time to be sure that the participant will not faint or bleed after the examiner has left the home, but late enough in the visit so that the samples can be returned to the lab for processing within two hours after the draw.

## 7. Alert Values/Follow-up

Laboratory results are reported by the central laboratory to the field centers by mail within 14 days. Two copies of the report are sent, one for the participant's file and one to be sent to the participant. If an abnormal value (see "Immediate Alerts" in the following table) is detected, however, the central laboratory notifies the field center by both phone and fax. If the participant has already been informed that they have elevated fasting glucose, you will not need to alert their physician again. However, you may wish to include a note with the participant report that informs the participant that an abnormal (high or low) value was found before and that the number remains high or low.

| **Analyte** | **Reference Range for Reports** | **Immediate Alerts*** |
|---|---|---|
| Glucose Metabolism: | | |
| Fasting Glucose | <110 and ≥50 mg/dL Normal<br>110-125 mg/dL Borderline<br>≥126 mg/dL Elevated** | **>350 mg/dL**<br>**OR <50 mg/dL** |
| General Chemistries: | | |
| Hg $A_1C$ | 4-6% Greater than 7% may indicate prior or current elevated glucose levels. | None |
| Lipids: | | |
| Total Cholesterol | <200 mg/dL Normal<br>200-239 mg/dL Borderline<br>>239 mg/dL Elevated** | None |

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

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

Occasionally, an error value is reported for a particular laboratory result. The two most common error values are:

-999, which indicates that no sample was received for that test. This may be expected, as when a fasting glucose sample is not sent because a participant was not fasting, or may indicate a shipping error by the field center. If the field center believes that a sample was sent, LCBR should be notified and the source of the error determined.

-777, which indicates that the test was run, but a valid result could not be obtained. This error may come about in a variety of ways. Sometimes an incomplete

aliquot may have been sent by the field center and there is insufficient sample to run the test. When -777 is reported for hemoglobin $A_1C$, it may either indicate that the whole blood sample was received in unusable condition (improper handling such as freezing) or that an abnormal hemoglobin variant was detected. The lab can identify S and F abnormalities and report a result. Hemoglobins C, D, E, G, and J cannot be differentiated except by further, more expensive testing beyond the scope of this study. Since hemoglobins D, E, G, and J shorten red blood survival and give erroneously low hemoglobin $A_1C$ values, samples with these hemoglobin variants are reported as abnormal with no result (-777). Although hemoglobin C does not shorten red blood cell survival, since it can't be positively differentiated from D, E, G, and J, the hemoglobin $A_1C$ value cannot verified and is also reported as -777.

## 8. Quality Assurance

### 8.1 Training Requirements

Clinical experience with phlebotomy is mandatory. Additional training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe procedure by experienced examiner)
- Discuss problems and questions with local expert or QC officer

### 8.2 Certification Requirements

- Complete training requirements
- Explain what to do for difficult venipuncture
- Recite measures to take for fainting participant
- Conduct phlebotomy on volunteer or participant while being observed by QC officer using QC checklist

### 8.3 Quality Assurance Checklist

Preparation:

☐ Blood collection trays properly prepared
☐ Blood draw tubes properly labeled

- ☐ Questions on Phlebotomy form asked
- ☐ Hepatitis B vaccination given or offered to all personnel handling blood

Venipuncture properly carried out:

- ☐ Script properly delivered
- ☐ Non-permeable lab coats, gloves, and face shields used
- ☐ Preparation of venipuncture site correctly done
- ☐ Venipuncture smoothly done
- ☐ Tubes filled in proper priority order
- ☐ Plasma tubes at least 2/3 full
- ☐ Tourniquet removed at 2 minutes
- ☐ Needle removed and arm bandaged correctly
- ☐ Needle and tubing appropriately disposed

Tubes mixed and handled correctly after filling:

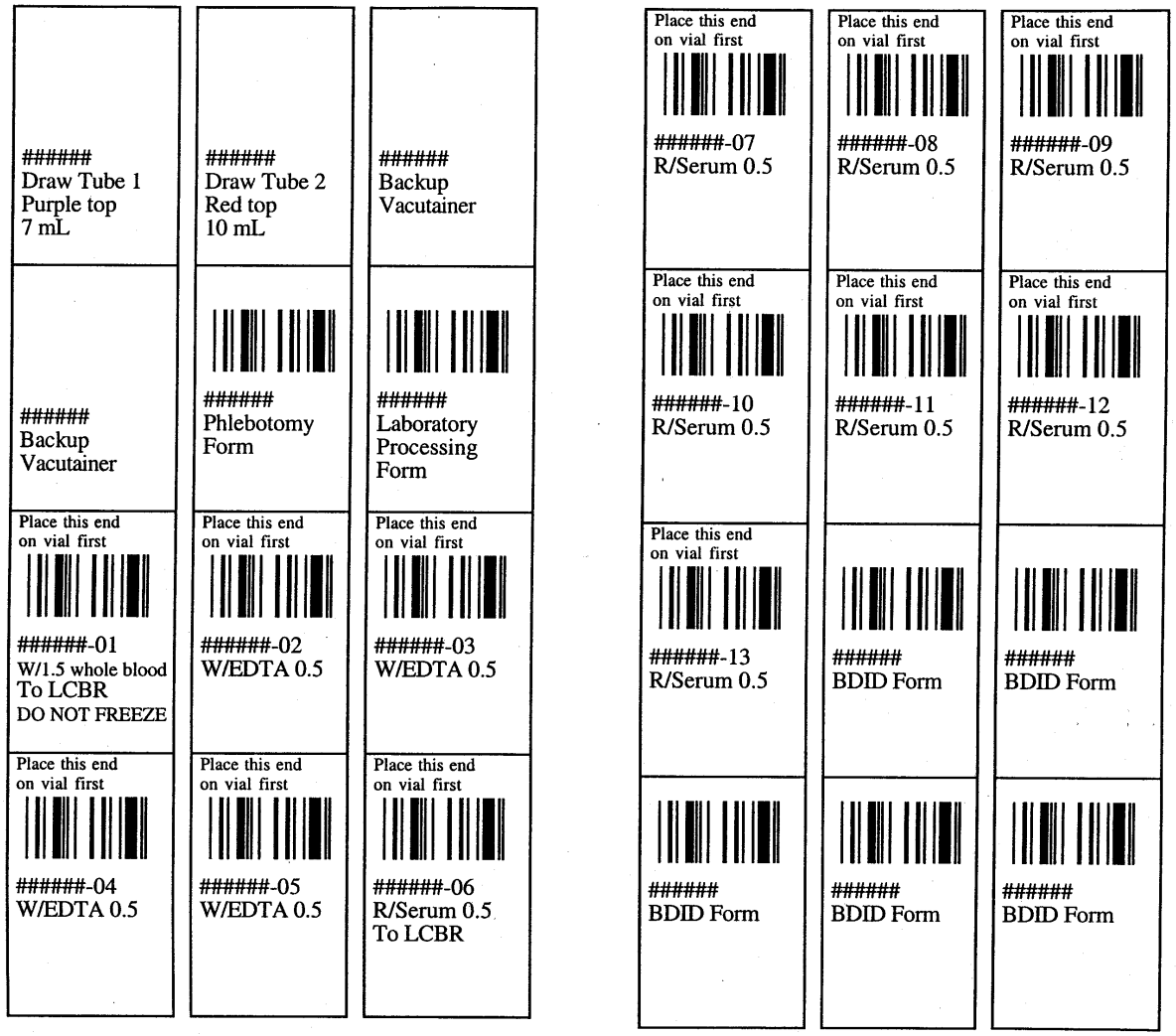
- ☐ Tube 1 mixed for at least 30 seconds, placed in ice bath
- ☐ Tube 2 NOT mixed, placed in rack at room temperature

Phlebotomy form properly filled out:

- ☐ Sample ID barcode label affixed to upper right corner (and to upper right corner of Lab Processing form)
- ☐ Time at start of venipuncture entered
- ☐ Time at end of venipuncture entered
- ☐ Total elapsed time with tourniquet entered
- ☐ Quality of venipuncture checked
- ☐ Total fasting time correctly calculated

# APPENDIX 1

## Sample Label Sheet (Bar Codes)



# APPENDIX 2

## Phlebotomy Form

Health ABC

HABC Enrollment ID # H

Acrostic

Date Form Completed: Month / Day / 2 0 0 Year

Staff ID #

## PHLEBOTOMY

Bar Code Label

❶ Do you bleed or bruise easily?

○ Yes ○ No ○ Don't know ○ Refused

❷ Have you ever experienced fainting spells while having blood drawn?

○ Yes ○ No ○ Don't know ○ Refused

❸ Have you ever had a radical mastectomy? **(Female Participants Only)**

○ Yes ○ No ○ Don't know ○ Refused

→ Which side?

→ ○ Right: Draw blood on left side.
→ ○ Left: Draw blood on right side.
→ ○ Both: Do NOT draw blood. Go to Question #10 on page 40.

❹ Have you ever had a graft or shunt for kidney dialysis?

○ Yes ○ No ○ Don't know ○ Refused

→ Which side?

→ ○ Right: Draw blood on left side.
→ ○ Left: Draw blood on right side.
→ ○ Both: Do NOT draw blood. Go to Question #10 on page 40.

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*Y4CVW Version 1.0, 6/06/2000 pjm*

Health ABC

## PHLEBOTOMY

❺ Time at start of venipuncture:

[ ][ ] : [ ][ ] ○ am ○ pm
Hours Minutes

❻ Time blood draw completed:

[ ][ ] : [ ][ ] ○ am ○ pm
Hours Minutes

❼ Total tourniquet time:
***(Examiner Note: If tourniquet was reapplied, enter total time tourniquet was on. Note that 2 minutes is optimum.)***

[ ][ ] minutes

Comments on phlebotomy:

❽ What is the date and time you last ate anything?

**a.** Date of last food: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
Month Day Year

**b.** Time of last food: [ ][ ] : [ ][ ] ○ am ○ pm
Hours Minutes

**c.** How many hours have passed since the participant last ate any food?

[ ][ ] hours **(Question 6 minus Question 8b. Round to nearest hour.)**

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Health ABC

## PHLEBOTOMY

9 Quality of venipuncture:

○ Clean ○ Traumatic

***Please describe. Mark all that apply:***

- ○ Vein collapse
- ○ Hematoma
- ○ Vein hard to get
- ○ Multiple sticks
- ○ Excessive duration of draw
- ○ Leakage at venipuncture site
- ○ Other ***(Please specify:)*** _____

10 Was any blood drawn?

○ Yes ○ No

Please describe why not: _____

Were tubes filled to specified capacity? If not, comment why.

| Tube | Volume | Filled to Capacity? Yes | No | Comment |
|---|---|---|---|---|
| 1. EDTA | 7 ml | ○ | ○→ | _____ |
| 2. Serum | 10 ml | ○ | ○→ | _____ |

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# APPENDIX 3

## Return Visit Laboratory Forms

Health ABC

| HABC Enrollment ID # | Acrostic | Date Form Completed | Staff ID # |
|---|---|---|---|
| H | | Month / Day / 2 0 0 Year | |

**YEAR 4 RETURN VISIT PHLEBOTOMY**

Bar Code Label

❶ Do you bleed or bruise easily?

○ Yes ○ No ○ Don't know ○ Refused

❷ Have you ever experienced fainting spells while having blood drawn?

○ Yes ○ No ○ Don't know ○ Refused

❸ Have you ever had a radical mastectomy? **(Female Participants Only)**

○ Yes ○ No ○ Don't know ○ Refused

→ Which side?

→ ○ Right: Draw blood on left side. ○ Left: Draw blood on right side. ○ Both: Do NOT draw blood. Go to Question #10 on page 3.

❹ Have you ever had a graft or shunt for kidney dialysis?

○ Yes ○ No ○ Don't know ○ Refused

→ Which side?

→ ○ Right: Draw blood on left side. ○ Left: Draw blood on right side. ○ Both: Do NOT draw blood. Go to Question #10 on page 3.

***Examiner Note: If the participant is having a repeat blood draw only because they were not fasting during their Year 4 clinic visit, only draw a 3 to 5 ml serum tube. In Question #10.2, mark "Yes" when asked whether the serum tube was filled to capacity (even though the volume is less than 10 ml).***

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## Health ABC YEAR 4 RETURN VISIT PHLEBOTOMY

❺ Time at start of venipuncture:

[ ][ ] : [ ][ ] Hours Minutes ○ am ○ pm

❻ Time blood draw completed:

[ ][ ] : [ ][ ] Hours Minutes ○ am ○ pm

❼ Total tourniquet time:
***(Examiner Note: If tourniquet was reapplied, enter total time tourniquet was on. Note that 2 minutes is optimum.)***

[ ][ ] minutes

Comments on phlebotomy:

❽ What is the date and time you last ate anything?

**a.** Date of last food: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] Month Day Year

**b.** Time of last food: [ ][ ] : [ ][ ] Hours Minutes ○ am ○ pm

**c.** How many hours have passed since the participant last ate any food?

[ ][ ] hours **(Question 6 minus Question 8b. Round to nearest hour.)**

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## YEAR 4 RETURN VISIT PHLEBOTOMY

**9** Quality of venipuncture:

○ Clean ○ Traumatic

***Please describe. Mark all that apply:***

- ○ Vein collapse
- ○ Hematoma
- ○ Vein hard to get
- ○ Multiple sticks
- ○ Excessive duration of draw
- ○ Leakage at venipuncture site
- ○ Other ***(Please specify:)*** _____

**10** Was any blood drawn?

○ Yes ○ No

Please describe why not: _____

Were tubes filled to specified capacity? If not, comment why.

| Tube | Volume | Filled to Capacity? Yes | No | Comment |
|---|---|---|---|---|
| 1. EDTA | 7 ml | ○ | ○→ | _____ |
| 2. Serum * | 10 ml | ○ | ○→ | _____ |

***Examiner Note: If the participant had a repeat blood draw only because they were not fasting during their Year 4 clinic visit, mark "Yes" to Question #10.2 when asked whether the serum tube was filled to capacity (even though the volume is less than 10 ml).***

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Health ABC

| HABC Enrollment ID # | Acrostic | Date Form Completed | Staff ID # |
|---|---|---|---|
| H | | Month / Day / 2 0 0 Year | |

## YEAR 4 RETURN VISIT LABORATORY PROCESSING

Bar Code Label

Time at start of processing: : ○ am ○ pm

| Collection Tubes | Cryo # | Vol. | Type | To | Fill in Bubble | Problems | Not Filled |
|---|---|---|---|---|---|---|---|
| #1 whole blood | 01 | 1.0 | W/1.5 | L | ○ | ○H ○P ○B | ○ |
| #1 EDTA plasma | 02 | 0.5 | W/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 03 | 0.5 | W/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 04 | 0.5 | W/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 05 | 0.5 | W/0.5 | M | ○ | ○H ○P ○B | ○ |
| #2 serum | 06* | 0.5 | R/0.5 | L | ○ | ○H ○P ○B | ○ |
| | 07 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 08 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 09 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 10 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 11 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 12 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |
| | 13 | 0.5 | R/0.5 | M | ○ | ○H ○P ○B | ○ |

***Examiner Note: If the participant had a repeat blood draw <u>only</u> because they were not fasting during their Year 4 clinic visit, only fill cryovial #06.***

L=LCBR; M=McKesson; H=Hemolyzed; P=Partial; B=Both; R=red; W=white

**LCBR Use only: Received Date:** _____ **Time:** _____

Frozen? ☐ Yes ☐ No

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## APPENDIX 4

## Phlebotomy Checklist

Blood Collection Tray Checklist

Per Tray:

- ☐ 10 21G Butterfly needles with Luer Adapters
- ☐ 10 Alcohol Swabs
- ☐ 15 Band-Aids
- ☐ 15 Gauze pads
- ☐ 5 Vacutainer holders
- ☐ complete set of extra, unlabeled collection tubes
- ☐ 2 Tourniquets
- ☐ 1 Smelling salts
- ☐ 1 Timer or stopwatch
- ☐ 2 Pencils / pens
- ☐ Latex gloves
- ☐ 1 Hemostats
- ☐ 1 Adhesive tape
- ☐ 1 Scissors

~10 min before draw:

- ☐ 1 styrofoam ice bath filled with ice

Per participant:

- ☐ 1 Blood tube rack with 2 draw tubes labeled and numbered.

At the Phlebotomy Station:

- ☐ Basin
- ☐ Cold cloth
- ☐ Tube mixer
- ☐ Biohazard containers
- ☐ Needle / Sharps container
- ☐ Paper towels

## APPENDIX 5 Sample Letter to Physician Regarding Alert Values

June 7, 2000

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

Dear Dr. Friedman:

On June 1, 2000, we performed a surveillance visit on your patient _____ at the Health ABC Clinic. [A fasting glucose was obtained and the results of the fasting glucose are 48 mg/dL. (Alert values are <50 mg/dL or >350 mg/dL.)]

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

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

Sincerely,

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

/sa