ADMINISTRATIVE INFORMATION

0a. Completion Date: [ ] / [ ] / [ ]
   Month  Day  Year
0b. Staff ID: [ ] [ ]

Instructions: This form should be completed during the participant’s clinic or home visit.

CLINIC VISIT  □
HOME VISIT  □

A. URINE SAMPLE

1. Urine sample collected?
   Yes..... □
   No ...... □ → Go to Item 6

2. Time/date of urine sample:
   a. Time of urine sample: ........................................... [ ] [ ] : [ ] [ ]
   b. AM or PM?
      AM ....... □
      PM ....... □
   c. Date of urine sample collection: ......................... [ ] [ ] / [ ] [ ] / [ ] [ ] [ ]

B. URINE PROCESSING

3. Volume adequate for processing?........................................... □
   Yes (≥ 30mL)......................................................... Y
   Yes (< 30 mL but at least 15 mL) ......................... B
   No (<15 mL, discard).................................................. N → Go to Item 6
4a. Urine pH adjustment made? ...........................................☐

Yes, pH adjustment made ........................................... A
No, pH adjustment not made ...................................... B → Go to Item 6

Date/time that the pH adjustment is made and technician ID for urine sample

b. Date ..............................................................................
   M  M  D  D  Y  Y  Y  Y

c. Time .............................................................................
   h  h  m  m

d. AM or PM?
   AM ........ ☐
   PM ........ ☐

5. Technician ID for urine sample: ..................................... ☐ ☐ ☐

C. BLOOD DRAWING

6. Do you have any bleeding disorders other than easy bruising which is often caused by medications like aspirin or plavix?

   Yes ................ ☐
   No ................. ☐ → Go to Item 7

   a. Please specify the nature of the bleeding disorder:

      ______________________________________________________________
      ______________________________________________________________

7. When was the last time you ate or drank anything other than water?

   a. Time .............................................................................
      h  h  m  m

   b. AM or PM?
      AM ........ ☐
      PM ........ ☐
8. Time/date of blood drawing:
   a. Time of blood drawing: ................................ h : h m : m  
   b. AM or PM?
      AM .......... □  
      PM .......... □  
   c. Date of blood drawing: ................................ M / M D / D Y / Y  

9. Number of venipuncture attempts: ....................  

10. Code number of phlebotomist: ..........................  
   a. Code number of assistant: .........................  

11. Any blood drawing incidents or problems?  
   Yes ................ □  
   No ................. □  → Go to Item 13  
   [Blood drawing incidents: Document problems with venipuncture in this table. Place an “X” in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 12.]

<table>
<thead>
<tr>
<th>Tube</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Sample not drawn</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>b. Partial sample drawn</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>c. Tourniquet reapplied</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>d. Fist clenching</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>e. Needle movement</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>f. Participant reclining</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
</tbody>
</table>

12. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here:  
   ________________________________________________________________  
   ________________________________________________________________  
   ________________________________________________________________
D. BLOOD PROCESSING

13. Date/time of processing specimen tubes 4, 5, 6, and 7:
   a. Date specimen tubes 4, 5, 6, and 7 were spun:  
      
   b. Time specimen tubes 4, 5, 6, and 7 were spun:  
      
   c. AM or PM?
      AM....□ PM....□

14. Code number of technician processing blood (tubes 4, 5, 6, 7):  

15. Date/time of processing specimen tubes 1, 2, 8, and 9:
   a. Date specimen tubes 1, 2, 8, and 9 were spun:  
      
   b. Time specimen tubes 1, 2, 8, and 9 were spun:  
      
   c. AM or PM?
      AM....□ PM....□

16. Code number of technician processing blood tubes 1, 2, 8 and 9:  

17. Date/time specimens from tubes 1, 2, 4, 5, 6, 7, 8 and 9 were placed in freezer:
   a. Date specimens were placed in freezer:  
      
   b. Time specimens were placed in freezer:  
      
   c. AM or PM?
      AM....□ PM....□

18. Date/time of processing specimen tube 3:
   a. Date specimen tube 3 was spun:  
      
   b. Time specimen tube 3 was spun:  

c. AM or PM?

AM ....... ☐
PM ....... ☐

d. Code number of technician processing blood tube 3:  ☐ ☐ ☐

19. Date/time tubes 3, 10 and 11 were packaged for daily shipment out:
   a. Date tubes (3, 10 and 11) were packaged for daily shipment out:

         ☐ ☐/ ☐ ☐/ ☐ ☐ ☐ ☐
   M     M     D     D     Y     Y     Y     Y

   b. Time specimens were packaged for daily shipment out: ☐ ☐: ☐ ☐

   c. AM or PM?

      AM ....... ☐
      PM ....... ☐

d. Code number of technician packaging specimens for daily shipment out:  ☐ ☐ ☐

20. Any blood processing incidents or problems?

      Yes ............... ☐  No  ☐ FINISHED

[Blood processing incidents: Document problems with the processing of specimens in this table. Place an “X” in box(es) corresponding to the tubes in which the processing problem(s) occurred. If a problem other than those listed occurred, use Item 21.]

<table>
<thead>
<tr>
<th>Tube</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<th>8</th>
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<th>10</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Broken tube</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. Clotted</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Hemolyzed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. Lipemic</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>e. Other</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
</tr>
</tbody>
</table>

21. Comments on blood processing or other problems in blood processing: (attach a sheet if needed)

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
INSTRUCTIONS FOR THE BIOSPECIMEN COLLECTION (BIO) FORM

I. General Instructions
The BIOSPECIMEN COLLECTION FORM is completed during the participant's clinic or home visit to record information on the collection and processing of blood and urine samples. Technicians performing venipuncture and processing blood and urine samples must be certified and should have a working knowledge of the relevant Manuals of Operations. Technicians should also be familiar with and understand the document entitled "General Instructions for Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Code Number of person completing this form (described in the General Instructions) should be completed prior to the arrival of the participant.

If not all of the 11 blood sample tubes can be drawn at the initial visit and the participant is willing to return to collect the missing tubes, collect only those tubes not drawn at the initial visit. Go back into the BIO form in the DMS and update it with the information on the newly collected tubes.

If a full set of tubes was lost or destroyed and the participant is willing to return to collect the samples again, call the data coordinating center at least 5 business days in advance of the re-draw visit to get another set of labels. Enter another occurrence of the BIO form for this participant’s re-draw (see instructions on completing a second occurrence of a form is located on the ARIC website under ‘Training’, ‘DMS’, ‘Occurrences Instructions’).

Mark all re-draw tubes with the capital letter, “R” and highlight. Use a black permanent marker that will not bleed.

II. Detailed Instructions for Each Item

Administrative Information

0a. Enter the date the biospecimen samples were collected. The date the urine and blood samples were collected are completely separate in items #2 and 8.

0b. Enter the technician code of the person completing this form.

0c. Check the appropriate box for Clinic Visit or Home Visit

A. URINE SAMPLE

At the reception station (clinic visits) or upon arrival at the home visit the participant is told that a urine specimen will be collected when it is convenient for the participant. This is best done early during the clinic/home visit, e.g., when the participant changes clothes, but can be done anytime during the examination sequence if the participant is not able to provide a specimen before blood drawing and the snack. In the latter case, it is useful to encourage the participant to drink one or two glasses with the snack and alert the technician when he/she wishes to empty his/her bladder. If a urine specimen has not been obtained over the course of the examination visit, the technician asks the participant again to provide a specimen at the end of the examiantion.

1. Indicate whether a urine sample was collected. If NO, urine sample was not collected, go to Item 6; if YES, continue.

2a-c. Record the time and date the urine was collected.
B. URINE PROCESSING

3a-c. Note if urine volume is adequate for processing. Choose either A ≥30 mL (desired). B between 30 mL and 15 mL (do not pH adjust) or C <15 mL (discard and collect at a different date, go to item #6).

4a-d. 4a. Note if a pH adjustment is made. If the answer is no, go to item # 6. 4b. Note the date that the pH adjustment is made. 4c. Note the time the pH adjustment is made. 4d. Enter whether it is morning, a.m. or afternoon, p.m. 5. Enter technician ID for urine sample.

C. BLOOD DRAWING

6 – 6a. For the clinic and home visits: Ask if the participant has a bleeding disorder that is not related to the use of medications such as aspirin and plavix. If the participant’s answer is NO, check the box indicating the negative answer and proceed to item #7. If the answer is YES, ask that he/she specify the nature of the bleeding disorder and record in 6a. Proceed with caution by executing pressure at the venipuncture site for a prolonged period. You may have the participant assist by elevating the arm and holding the gauze firmly on the venipuncture site. You must check that clotting has occurred and bleeding stopped before applying a band aid and releasing the participant. If the participant does not know whether he/she has a bleeding disorder, offer the explanation, "If you have a bleeding disorder you would have symptoms like excessive nose bleeds, or very easy bruising, or problems with bleeding after tooth extractions, or any type of surgery and continue as described above for NO or YES responses.

7a-b. Enter the last time the participant ate or drank anything (other than water or coffee/tea without cream and sugar). If the participant is rescheduled for another day, a new BIO form under a new sequence number should be entered.

8a-c. Record the time and date of venipuncture. This is the time when the vein is punctured and date blood is drawn for specimens.

9. Enter the number of venipuncture attempts.

10 - 10a. Enter the code number of the technician who performed the venipuncture and the blood drawing assistant. If more than one technician attempts to draw the blood, enter the code of the first technician. The same technician should not attempt a venipuncture more than twice.

11a-f. Note any blood drawing incidents or problems, and document in the table provided. Place an “X” in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If an incident/problem is not listed below, document it on Item 12. If no incidents or problems occurred while drawing, skip to Item 13.

Blood drawing incidents or problems:
- a. Sample not drawn
- b. Partial sample drawn
- c. Tourniquet reapplied
- d. Fist clenching
- e. Needle movement
- f. Participant reclining

12. Document any other blood drawing problems not listed in Item11.
D. BLOOD PROCESSING

13a-c. Record the date/time at which the centrifuge containing tubes 4, 5, 6, and 7 began to spin.

14. Enter the code number of the technician who began processing blood tubes 4, 5, 6, and 7.

15 a-c. Record the date/time at which the centrifuge containing tubes 1, 2, 8 and 9 began to spin.

16. Enter the code number of the technician who began processing blood tubes 1, 2, 8 and 9.

17a-c. Record the date/time at which samples from tubes 1, 2, 4, 5, 6, 7, 8 and 9 were placed in the freezer.

18a-d. Note the date/time tube 3 was spun and the code number of the technician processing tube 3.

19a-d. Note the date/time and code number of technician tubes 3, 10, and 11 were packaged for shipment out.

20a-e. Note any blood processing incidents or problems listed below.
   a. Broken tube
   b. Clotted
   c. Hemolyzed
   d. Lipemic
   e. Other

Document any other blood processing problems not listed in Item 20. For example, centrifuge or freezer problems.

21. Record comments on blood processing or other problems in blood processing and shipping such as lost shipments or broken tubes. Attach a sheet if more space is needed for notations.