
FORM:	100 - BLOOD COLLECTION AND PROCESSING
Version:	1.5 – July 1, 1997
Description:	Completed by Clinical Center (CC) staff; 2-page form key-entered at CC.
When Used:	Each time CC or other facility collects blood for local lab analysis or specimen repository at McKesson.
Purpose:	To assign a unique blood sample number to each blood sample collected, document conditions of blood draw and processing, and identify blood aliquots obtained.

GENERAL INSTRUCTIONS

BLOOD REQUEST

1. Include a form in the Screening Visit 1 (SV1) and appropriate annual visit packets.

BLOOD COLLECTION

2. At the visit, affix the participant ID label to the form.
3. Determine which specimens to collect by indicating the visit type. Mark the line indicating the type of specimens to collect in the Blood Request portion of the form.

If you need to redraw one or more tubes due to insufficient sample, breakage, or recheck of CBC results, complete a new *Form 100*, following the steps below as for a new blood draw.

4. Complete the Blood Collection Checklist portion of the form by asking the participant Questions 6-7.
5. Complete the remaining items in the Blood Collection portion of the form when you draw the blood sample. See the instructions in *Vol. 2 - Procedures, Section 11.2.4.5 - Participation Preparation, step 3*, for specific directions for asking the questions.
6. Label the filled blood collection tubes and affix the blood sample number label "form" to both the front and back of the form in the spaces indicated for the routine label.
7. Review the front of the form for completeness.
8. Bring the filled blood collection tubes, form, and remaining blood sample labels to the blood processing area.

BLOOD PROCESSING

9. Complete the blood processing section of the form. Process samples as indicated on the Blood Request section of the form. Send samples to your local lab as needed.
10. Review the back of the form for completeness.
11. Process and key-enter the form in a manner that best fits the flow of forms in your CC. Options include:
 - Key-enter the *entire* form after receiving the blood results from the lab. To do this:
 - Store the form in the participant's file or in a central holding area with other "waiting for result" specimen forms.

- When you receive the blood results from the lab, attach the lab results to the form and send the form and results to Data Entry for key-entry.
- Key-enter the form after completing the form, and key-enter the blood results when you receive them from the local lab.
 - Send the form to Data Entry for key-entry after completing the processing portion of the form. Store the form in a central holding area to await the blood results from the lab.
 - When you receive the blood results from the lab, attach the lab results to the form, and send the form and results to Data Entry for key-entry of the lab results.

Data Entry: Regardless of which processing option is chosen, review the form for completeness and return to the responsible staff person with any problems and questions. Key-enter after you resolve any questions.

12. Initial the first page when you complete the key-entry. If you key-enter the form before blood results are available, initial the form key-entered twice, once when you key enter questions and again when you key-enter the blood results.
13. File the form and any results in the participant's file.
14. If you are unable to draw a blood sample for CBC, platelet count, or triglyceride level at your CC, you can use an outside laboratory to draw and process the blood sample for these tests. Note you cannot use an outside lab to draw and process blood for samples you send to McKesson. An "outside CC" can be used to draw and process a blood sample for CBC, platelet count, triglyceride level and for blood samples that are sent to McKesson.

To key-enter the CBC, platelet count, or triglyceride level you have on a participant from an outside lab or outside CC, treat the blood sample results as you would treat results from a blood sample you drew in your CC. Use the following procedures:

- Ask the Data Coordinator to create a new employee ID, giving the employee name as "Outside employee" or "Outside CC." You can use this same "Outside employee" or "Outside CC" ID number for future blood results you receive from an outside lab.
- Create a *Form 100 - Blood Collection and Processing* for the blood sample. Record as much information on the form as you have:
 - Record the date the outside lab or outside CC drew the blood sample as the date drawn.
 - Record the staff ID number your Data Coordinator assigned to "Outside employee" or "Outside CC."
 - Record contact type and visit type as appropriate.
 - Answer the time drawn and other questions if known; otherwise leave blank.
 - Affix a WHI Blood Sample Number label to the form in Question 8 and Question 14 just as you would for a blood sample you drew in your CC.
 - In Question 9, record the staff ID number your Data Coordinator assigned to "Outside employee" as the employee who processed the blood sample.
 - Leave Questions 10-13 on time processed blank.
 - Mark the appropriate cryovial numbers in Question 16.
- Attach the blood sample results report to the *Form 100* as usual.
- Key-enter the form and results as usual.

Item Instructions

Blood request	The combination of blood collection tubes to draw and aliquot samples to process. Use the grid to help you determine which combination of tubes to draw and process. Base your decision on: <ul style="list-style-type: none"> • type of study: Clinical Trial (CT) or Observational Study (OS), • visit type and timing: SV1, 1st Annual, 3rd Annual, etc.
1. Date blood drawn	Date sample drawn.
2. Drawn by	Standard 3-digit WHI employee ID of person drawing the blood sample. (See common data items.)
3. Contact type	Mark appropriate box. (See common data items.)
4. Visit type	Mark the appropriate box. Write the visit number as needed. (See common data items.)
5. Time drawn	Time blood draw completed. Record time from a 12-hour clock (not a 24-hour clock) and mark the appropriate box for AM or PM.
6. Hours since participant last ate	<p>The number of hours since the participant last ate. Include any intake of food or drink.</p> <p>Round time to the nearest whole hour by rounding increments of 30 or more minutes up to the next hour and dropping increments of 29 or fewer minutes. For example, round:</p> <p style="padding-left: 40px;">0 hr. 20 min. to 00 hr. 0 hr. 45 min. to 01 hr. 2 hr. 20 min. to 02 hr. 2 hr. 30 min. to 03 hr.</p>
7.1. Physical activity	No/Yes
7.2. Aspirin or anti-inflammatory agents	No/Yes
8. WHI routine blood sample number	<p>Unique 7-digit blood sample number from the blood sample label set you used to collect the blood. Attach the blood sample label printed "form" in the Routine label space indicated on the form.</p> <p>Data Entry: Scan the barcode on the blood sample number label rather than key-entering it.</p>
9. Processed by	Standard 3-digit WHI employee ID of person processing the blood sample. (See common data items.) If the sample was drawn only for a CBC, use the ID of the staff person who labeled the CBC tube and completed the paperwork for the local lab.
10. Time centrifuged	Time you started centrifuging the blood collection tubes. Use the time from a 12-hour clock (not a 24-hour clock) and mark the appropriate box for AM or PM. If you centrifuge the tubes at different times, use the time you centrifuge the 10 ml lavender tube. (Skip if you drew only a CBC and had no tubes to centrifuge.)

11. Lipemic No/Yes. Answer only if the participant is interested in HRT or HRT+DM. Check the study component(s) of interest to confirm if lipema needs to be determined. Indicate if the serum in the 7 ml royal blue tube appears lipemic Use the laminated Test Print card and the two photographs showing tubes with serum with normal, 300 mg/dl and 500 mg/dl triglyceride. If you cannot read the print through the 7 ml royal blue, mark the answer "1-Yes."

12. Time sample place in aliquot vials Time you put the plasma and serum into the aliquot tubes to be sent to McKesson in the freezer. (Skip if you drew a blood sample only for a CBC.) Use the time from a 12-hour clock and mark the appropriate box for AM or PM.

If you aliquot samples from more than one type of blood collection tube, use the time you place the plasma from the 10 ml lavender tube into the cryovials -10 to -12.

13. Time placed samples in freezer Time you put the serum and plasma cryovials to be sent to McKesson in the freezer. (Skip if you have no samples to send to McKesson.) Use the time from a 12-hour clock and mark the appropriate box for AM or PM.

If you have multiple specimen types, use the time you place the plasma from the 10 ml lavender tube into the freezer.

14. WHI routine blood sample number Unique 7-digit blood sample number from the blood sample label set you used to collect the blood. It should be the same number the blood collection person put on the front of the form in Item 8 - Routine Blood Sample Number.

15. Cryovial number The number of the cryovial indicating type of aliquot.

Cryovial Number	Blood Coll. Tube	Specimen	Size	Test
02	Royal Blue	serum	1.8 ml	
03	Royal Blue	serum	1.8 ml	
04	Royal Blue	serum	1.8 ml	
05	Royal Blue	serum	1.8 ml	
06	Light Blue	plasma	1.8 ml	
07	Light Blue	plasma	1.8 ml	
08	Light Blue	plasma	1.8 ml	
09	Royal Blue	serum	0.5 ml	triglyceride
10	10 ml Lavender	plasma	1.8 ml	
11	10 ml Lavender	plasma	1.8 ml	
12	10 ml Lavender	plasma	1.8 ml	
13	10 ml Lavender	buffy coat	—	
14	10 ml Lavender	RBC	1.8 ml	
16	2 ml Lavender	whole blood	1.8 ml	CBC
20	Light Blue	buffy coat	—	

Data Entry: Key-enter the cryovial number printed on the form in Item 15 - Cryovial Number if the corresponding box in Item 16 is marked.

16. Sample placed in cryovial Mark the box if you processed a cryovial for the indicated cryovial number.

Blood Results From Local Laboratory

Data Entry: Key-enter the blood results listed below from the lab reports attached to the form. The order and format of the results depends on the format of the CC's local lab report. All the tests may be listed on one lab report or may be listed on different reports for the CBC results (WBC, hematocrit, and platelet count) and the triglyceride value.

For each result, enter in the format and units listed below:

CBC results (cryovial #16)

WBC ___ ___ . ___ thousand cells/ml (Kcell/ml)
Hemoglobin ___ ___ . ___ gm/dl
Hematocrit ___ ___ . ___ %
Platelet Count ___ ___ ___ . ___ thousand cells/ml (Kcell/ml)

Note: As of 3/15/96 hemoglobin is not required for eligibility, and you do not need to key-enter this value.

Triglyceride results (cryovial #9)

Triglyceride Level ___ ___ ___ . ___ mg/dl