

	Title:	Collection of Random Urine Specimens		
	Version Date:	2015-JAN-21	Document Number:	SOP_BCP_0002
	Effective Date:	2015-MAR-31		
Data Collection Site (DCS)	Version:	3.0	Number of Pages:	4

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for obtaining a random urine specimen from a study participant.

2.0 Scope:

This document is to be used by all DCS staff and DCS laboratory staff when asking a study participant for a random urine specimen.

3.0 Responsibilities:

It is the responsibility of DCS staff and DCS laboratory staff to perform procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- **SOP_BCP_0003** - Biospecimen Post Collection Processing SOP
- **SOP_BCP_0001** - Collection of Blood by Venipuncture SOP
- **SOP_BCP_0011** - Personal Protective Equipment (PPE)
- **SOP_BCP_0406** – Site Specific Waste Disposal SOP
- **SOP_BCP_0031** - Brady Code Reader 3500 – Operation, Maintenance & Calibration
- **DOC_BCP_0001** - Daily Zero Times for Collection of Blood and Urine Samples
- **MAN_BCP_0217** – LabWare Guide

5.0 Definitions:

- **Random Urine:** Urine collected at any time.

6.0 Equipment:

- Barcode scanner, Brady Code Reader 3500; and,
- LabWare.

7.0 Supplies:

- Biospecimen barcode label;
- Urine container, sterile;
- Hand sanitizer or hand soap; and,

- Paper towels or hand dryer.

8.0 Procedure Steps:

8.1 Urine Collection

- 8.1.1** Check the interview ID badge for consent for urine collection. Proceed if there is a red- or a yellow-colored dot on the badge. **Do not if the dot is blue.**
- 8.1.2** Obtain an empty, sterile urine container.
- 8.1.3** Using a permanent marker copy the interview ID for the participant onto the urine container.
- 8.1.4** Provide the labeled urine container to the participant
NOTE: To avoid a dilute specimen it is preferable if the study participant has not used toilet facilities in several hours.
- 8.1.5** Give the following instructions for urine collection verbally to the participant
1. Wash hands with soap and water for 15 seconds and thoroughly dry.
 2. Remove the lid from the container but do not touch the inside of the container.
 3. Void urine directly into the container.
 4. Place the lid on the container and firmly tighten to seal the container and prevent leakage.
 5. Wipe off the exterior of the container with a paper towel and discard the paper towel.
 6. Wash hands with soap and water for 15 seconds and thoroughly dry.
- Note:** Please ensure the instructions in section 8.1.5 are posted in the washroom.
- 8.1.6** Direct the participant to the designated washroom.

If the participant needs to use the washroom prior to the Biospecimen Collection stage in the DCS.

- 8.1.7** Follow procedural steps for urine collection found in section 8.1.
- 8.1.8** Return the urine container to the Biospecimen Collection and Processing (BCP) room.
- 8.1.9** Record the time zero for the urine collection on the *DOC_BCP_0001 - Daily Zero Times for Collection of Blood and Urine Samples*.
- 8.1.10** When the participant has completed all the other interviews in the DCS, have them return to the BCP room. The Onyx stage and/or the blood collection needs to be completed.
- 8.1.11** Ensure that the DCS Lab Tech is prepared to interview and take blood from the participant.
- 8.1.12** Please follow either sections 8.2, 8.3 or 8.4 as applies.

8.2 If the participant has a contraindication for blood donation or chosen to donate urine only.

- 8.2.1** Follow procedural step for urine collection found in section 8.1.
- 8.2.2** Open the **Urine Only** stage in Onyx. Complete the series of questions in Onyx. If Onyx is not available, obtain *CRF_BCP_0002 - Urine Collection Only Case Report Form* and complete the information on the paper form.
- 8.2.3** In LabWare, in **Assign Sample Labels**, click on **Sample Label Assignment**. This will generate a dialog box. Scan the participant's interview ID. Complete the field "Time of urine collection". Answer YES to "Urine collected?" and NO to "Blood collected?" Press **OK**.

If the sample was collected earlier in the DCS visit, enter the time of sample collection from the *DOC_BCP_0001 - Daily Zero Times for Collection of Blood and Urine Samples* ensuring the correct participant sample for the interview ID.

- 8.2.4** Apply a barcode label for a participant from the specimen collection barcode labels. Remember that one column of barcodes is specific for all specimens of a single participant (interview ID). **Discard all unused labels from that column.**
- 8.2.5** Apply the label to the surface of the urine container so the surface is free of wrinkles and the barcode is clearly visible.
- 8.2.6** Scan the linear barcode.
- 8.2.7** Thank the participant for the sample donation and ensure that they are directed to another DCS staff member to conclude the DCS visit.
- 8.2.8** Place the urine container on the work bench for biospecimen post collection processing.

8.3 If the participant has provided a urine sample but decided to return for blood donation.

- 8.3.1** Discard the urine sample provided by the participant, so that they can provide a urine sample at the same time that they give a blood sample.

8.4 Urine Collection after Blood Collection

- 8.4.1** Follow procedural step for urine collection found in section 8.1.
- 8.4.2** Apply a barcode label for a participant from the specimen collection barcode labels. Remember that one column of barcodes is specific for all specimens of a single participant (interview ID). Discard all labels from that column.

8.4.3 In LabWare, make sure that you are within the given participant's folder. In **Assign Sample Labels** tab click on **View Collection Samples**. If you are not in the participant's folder, click on **Rebuild** and scan any barcode label already assigned to a sample for this participant. Then, in the **Assign Sample Labels**, click **Urine** and scan the urine barcode label for the urine sample. This will generate a dialog box. Ensure that the date and time are correct for "Time of urine collection". Answer YES to "Urine collected?" and Press **OK**.

8.4.4 Thank the participant for the sample donation and ensure that they are directed to another DCS staff member to conclude the DCS visit.

8.4.5 Place the urine container on the work bench for biospecimen post collection processing.

9.0 Documentation and Forms:

- **CRF_BCP_0002** - Urine Collection Only Case Report Form
- LabWare

10.0 References:

Clinical and Laboratory Standards Institute (CLSI) GP16-A3 Urinalysis: Approved Guideline – Third Edition. Vol. 29 No. 4

Revision History:

New Version #	Revision Date	Revision Author	Content Approval
3.0	2015-JAN-21	Chetna Naik	Cynthia Balion
Summary of Revisions			
Added reference to <i>MAN_BCP_0217 – LabWare Guide</i> to Related Documents.			
Section 8.3 updated to state that urine provided should simply be discarded if the participant decides to return to give a blood sample.			
Step 8.4.3 rewritten.			
Various steps within document reorganized or edited for clarity			
Reviewed and updated Purpose, Scope, and Responsibilities sections.			

New Version #	Revision Date	Revision Author	Content Approval
3.0	2013-OCT-31	Chetna Naik	Cynthia Balion
Summary of Revisions			
Section 4.0 Added time zero to document			
Section 5 added definition for CVS and hematoma and vascular graft			
Section 6 added 2D scanner and Brady code reader to the equipment			
8.1.1- Moved needle size recommendation			
8.3.3 - Added info for contraindications to be checked			
8.4.1 -Removed tourniquet cannot be reused info			
8.5.2 - Added info to check for exclusions			
8.8.6 – Added collection of time zero information			
8.8.9 – Removed the blood not flowing recommendation info			
8.9.4 to 8.9.7 – Label Vacutainers and using information added			
8.9.8 – Added direct the participant to the reception			

8.10 Addition of instructions for labeling biospecimens and scanning into LabWare.
8.11 – Renumbered section for completing the interview
8.12 – Renumbered cleaning the bleeding station section
8.2 Added instruction regarding returning for blood on a different date than urine donation

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New Version #	Revision Date	Revision Author	Content Approval
2.0	2012-JUN-12	Lori Dewar	Cynthia Balion
Summary of Revisions			
Updated table 1			
New Version #	Revision Date	Revision Author	Content Approval
1.0	2012-MAY-03	Lori Dewar	Cynthia Balion
Summary of Revisions			
NOTE: Due to clerical error released version 1.0 a second time			
Added document numbers in section 4.0			
Reworded PICC line definition			
Updated section 7.0			
Updated step 8.1.1, 8.5.2 to correct contain correct consumables			
Updated table 1			
Updated 8.8.1 to include all needle types			
Removed section 8.9 Perform Venipuncture using BD Vacutainer Eclipse Blood Collection Needle with pre-attached holder			
Removed steps 8.10.5 – 8.10-9 and 8.11.1			
Added steps 8.9.6 and 8.9.8			