Instructions for Collecting and Storing Your Urine Samples

I)	Introduction	1	
II)	Urine Collection Instructions		
	a. Urine collection supply kit: The "Whiz Pops"		
	b. When to collect daily urine samples		
	c. What to do if you miss a collection		
	d. How to collect urine		
III)	How to store your samples	3	
IV)	Record keeping and labeling instructions		
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I) Introduction

Thank you for participating in the **Perimenopausal Night Sweats Study.** Remember that hormonal data and other information about you are strictly confidential. It would be impossible for anyone other than the study investigators and assistants to link your data with your individual name.

This document outlines the step-by-step procedures to follow in the collection and storage of urine samples. You will start collecting first morning urines as soon as you start the study, continue during one full menstrual cycle, and continue until 5 days into your second menstrual cycle. You can see a picture below shown in **Figure 1**.

Figure 1. Collect urine samples each morning, starting when you enter the study and continuing until 5 days into Cycle 2. The cycles are also described on the Study Overview sheet, and the Daily Perimenopause Diaries are numbered.

Cycle 0	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5
•					
from when	first 5				
study starts	days				

The number of samples you will take depends on how long your menstrual cycles are, and when you start the study.

Please keep these instructions in a convenient location so that you can refer to them as needed. You can call 604-875-5232 or email Vesna. Stajic@vch.ca if you have any questions about this study or these instructions. Dr. Stajic will contact you as soon as possible.

II) Urine Collection Instructions

a. Urine collection supply kit

You will receive a cooler bag, an ice pack, 50 Whiz Pops with Ziplock bags to store them in, and 50 labels for recording sample collection date and ID. This should be enough material for you to collect all of your samples. If you are getting to the end of your supplies and you still have not had your second period, please call and we will arrange for you to get more. A 'Whiz Pop' is an easy to use urine sample collector consisting of a vial and a dry sponge attached to a screw-cap (See Figure 2, page 3).

b. When to Collect Urine

Your first morning urine will be most helpful for measuring hormones because it is more concentrated. Therefore it is important to collect your first urination after getting up in the morning. We realize that you may urinate during the night or early morning, but we prefer that you only collect urine when you're up for the day. Collect your first urine when you are finally up and about after sleeping.

c. What if you miss a urine collection

If you miss the first urine of the day, collect a later one if you can, and make a note on the sample and your diary. If you miss a day altogether, please sample the next morning and go back to your regular schedule. If you miss a day, when you resume urine collection the next day, please remember to mark the label with the correct cycle and date).

d. How to collect urine

- 1. Before you urinate in the morning, get a urine collection vial (Whiz Pop). (It is handy to keep the Ziploc bag of collection vials in the bathroom closet or cupboard.)
- 2. Unscrew the cap of the vial and remove the cap with attached sponge from the vial (See Figure 2, next page). (Do not remove the sponge from the cap! The cap is designed to be a holder for the sponge).
- 3. When you sit on the toilet to urinate, hold the top of the cap with your hand, and position the sponge directly in your urine stream. You will notice that sponge expands greatly. Saturate the sponge well, until urine has "wicked" up the sponge and the sponge has expanded to fill the cap (See Figure 3 at the bottom); this should take about 8-12 seconds.
- 4. After the sponge is saturated, wait two or three seconds to prevent dripping.

- 5. Insert the sponge back into the collection vial and screw the cap on tightly.
- 6. Write the date on the label provided, circle which cycle this is, and write down which cycle day this is (at the top of your diary). Your id number should already be on the label. Peel it off, and attach it firmly around the body of the vial, *not the cap*. You may wish to attach the label to the vial just prior to urinating on the sponge— you may find it makes things easier to handle to have it in place first.

NOTE: Use a ball-point pen or a permanent marker (sharpie). Gel pen inks come off in the freezer.

- 7. Place the labeled, loaded vial first into a Ziploc bag. Then put the vial in the bag into the cooler bag and place the cooler bag in your home freezer.
- 8. If the sponge falls out of the cap and into the toilet or onto the ground, please discard it. Try to get another sample (then or later) with a new urine collection vial. We have provided an extra whiz pop and labels should such a situation arise.

Figure 2

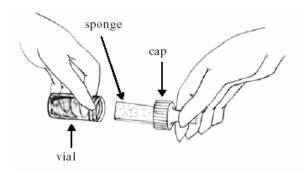
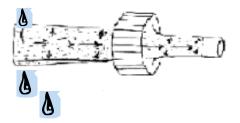


Figure 3



III) How to store your samples

Your urine samples should be kept frozen or as cold as possible at all times including when you are removing samples from your freezer to transport to the laboratory. Keeping samples frozen or cold is important for preserving the reproductive hormones in the urine.

You may store samples in your freezer in the cooler bag we have provided, or you may use a different container such as a plastic bag or any other container that is convenient for you.

Please try to get the sample into the freezer as soon as possible. If there is a significant delay (for example, the sample was inadvertently left out for the day), please make a note of it on the label and on your diary.

The collection vials seal tightly (as long as the caps are screwed on tightly), so there should be no problem with leaking or spilling of urine in your freezer. A major advantage of the sponges is that the urine is held in the sponge, making leakage highly unlikely.

To prevent drying out of sponges (and loss of urine sample), please make sure the caps of the vials are sealed tightly.

IV) Record keeping and transport of frozen urine samples

We have provided a sheet of labels with your study ID already printed, on which you will write the date, circle which cycle you are in (0 1 or 2), and the cycle day. It may be easier and more convenient for you to have this already filled out and stuck onto the Whiz Pop prior to collecting your urine sample. If you need to comment on the urine sample (for example, it had been inadvertently left out of the freezer, or the urine sample had been taken later in the day), you can make a note of it on another blank label and place it on the Whiz Pop the comment refers to. Finally, there is a box on the Daily Perimenopause Diary record to record an 'X' to indicate that you collected a urine sample on that day.

You will be bringing the frozen urine samples to us in the cooler bag we provided (with a frozen ice pack). If you have room and are willing to store them, you can bring them to the office for your final study visit. Otherwise, speak with the study coordinator to make other arrangements.

Thanks for your good work on this study! CeMCOR

