





# **DLMO Pilot Study**

## **At-Home Study Kit Instructions**

## Study Kit Components Checklist

### Electronics

- ☐  Actiwatch (1)
- ☐  Bottle and time stamp lid (1) with cotton collection swabs (20)
- ☐  Light Meter (1)
- ☐  Battery Operated Tea Lights (18)

### Collection Tools

- ☐  Melatonin Collection Tubes (18)

### Other Study Materials

- ☐ Ice Pack (2)
- ☐ Toothbrush (1)
- ☐ Blue Light Blockers (1)
- ☐ Single Use Tylenol (2)
- ☐ Medical Tape
- ☐ Masking Tape
- ☐ Sample Collection Bags (2)
- ☐ Sticker Labels
- ☐ Aluminum Foil

### Shipping Materials

- ☐ Fedex Return Label (1)
- ☐ Fedex Label Pouch (1)
- ☐ Silver Insulated Pouches (3)
- ☐ Shipping Tape
- ☐ Shipping Box (1)

## Melatonin Sample Collection: Preparation Tip Sheet

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### 24 Hours

Prior to  
Collection

**No** alcohol, caffeine, or recreational drug consumption



### Day of Collection

**No** alcohol, caffeine, or recreational drug consumption.

*Avoid the following:*  
Food: Turkey, bananas, citric acid, foods containing Red 40 (see Foods to Avoid)



### 6 Hours

Prior to  
Collection

**No** alcohol, caffeine, or recreational drug consumption.

**No** nicotine or tobacco products including but not limited to cigarettes, vaping, chewing tobacco, pipes, cigars.

Do **NOT** consume the following:

Drinks: Coffee, energy drinks, caffeinated tea, caffeinated soda,

Food: Turkey, bananas, citric acid, foods containing red 40, chocolate (see Food Items to Avoid)



### Immediately before and during collection
















**No** toothpaste when brushing teeth.

**No** lip products such as chap stick, lip balm, or lip stick.



## Melatonin Sample Collection: Food Items to Avoid

The following is a list of food items to avoid when preparing for the melatonin sample collection. Melatonin levels can be affected by food; therefore, it is very important to avoid any food or drink that may influence your melatonin levels. The following list is for guidance but is not exhaustive. Contact the study team if you are unsure whether a snack or drink is compliant with the study protocol.

<b>Food Containing Red 40</b>	Cereal	<i>Fruity Pebbles, Fruity Cheerios, Trix, Cap'n Crunch Berry Flavor</i>		 
	Food	<i>Pickles, some cherry pie fillings, some barbecue sauces</i>		 
	Drinks	<i>Powerade Orange, Crush, Sunny Delight Orange Strawberry</i>		
	Candy	<i>M&amp;Ms, Reese's Pieces, Strawberry Twizzlers, Skittles, Peeps, Candy Corn, Jellybeans</i>		
<b>Food Containing Citric Acid</b>	Drinks	<i>Orange Juice, Grapefruit Juice</i>		 
	Fruits	<i>Lemons, limes, oranges, grapefruits, tangerines, pomelos, pineapple, strawberries, raspberries, cranberries, cherries, tomatoes</i>		 
	Other	<i>Ketchup</i>		
<b>Food and Drink Containing Caffeine</b>	Drinks	<i>Coffee, Soda, Energy Drinks, Tea (Black, Green, White)</i>		 
	Food	<i>Chocolate, Chocolate Flavored Cereal, Chocolate Pudding, Chocolate Cake, Icecream (Chocolate, Coffee flavors)</i>		 
	Other	<i>Excedrin Pain Reliever</i>		

## Melatonin Sample Collection: Acceptable Food Options

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The following is a list of acceptable food options in case you are hungry and choose to eat during the sample collection. Melatonin levels can be affected by food; therefore, it is very important to choose snacks and drinks that are compliant with the study protocol. The following list is for guidance but is not exhaustive. Contact the study team if you are unsure whether a snack or drink is compliant with the study protocol.

### Drinks

Caffeine-free herbal teas

*Mint tea*

*Chamomile*

Caffeine-free sodas

*Ginger-Ale*

*Root-beer*

Milk, Plain or Chocolate

*Cow Milk*

*Almond Milk*

*Soy Milk*

*Coconut Milk*

Flavored Seltzer or Sparkling Water



### Snacks

Cup Snacks

*Apple sauce*

*Vanilla pudding*

Crackers

*Triscuits*

*Cheez-Its*

*Goldfish Crackers*

*Rice Thins (gluten-free)*

*Staufer's Animal Crackers*

*Graham Crackers*

Granola bars

*Kashi Granola Bars (Honey*

*Almond Flavor)*

*Nature Valley Brand (Oats n*

*Honey, Cinnamon, Peanut*

*Butter)*

String Cheese

Light butter popcorn



### Fruits

Apples

Pears

Watermelon

Raspberries

Blueberries

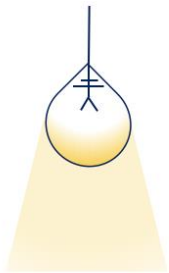
Cantaloupe



## Melatonin Sample Collection: Guidance on Light Intensity

The diagram below depicts different light settings and their approximate lux. Lux is a measure of light intensity, equal to one lumen per square meter. That means that in a darkened room, one lux is approximately equal to the light emitted from one lit candle. Melatonin levels are diminished by higher lux levels; therefore, it is important for the melatonin sample collection to collect samples in dim light conditions.

### Internal Light Lux Measures



Low Light  
50 Lux



Living Room  
200 Lux



Office Space  
200 Lux



Supermarket  
200 Lux

### External Light Lux Measures



Rain  
10,000 Lux



Cloudy  
20,000 Lux



Bright  
50,000 Lux



Direct Sun  
100,000 Lux



Dim Light  
<10 Lux

**For the melatonin sample collection, samples must be collected in dim light conditions.**

**Dim light conditions are defined as a collection space with light measuring below 10 lux.**

## Dim Light Melatonin Saliva Sample Collection Kit

**Overview:** The Dim Light Melatonin Saliva Sample Collection kit is designed to collect saliva samples in one-hour intervals for 8 hours under dim light conditions and overlapping with your bedtime. The samples will be analyzed for melatonin concentration, which provide us insight on your biological bedtime. Melatonin is a hormone that regulates your sleep-wake cycle. **Melatonin levels are affected by light.** For this sample collection, it is extremely important to follow directions carefully to ensure samples are not affected by light levels. We will be tracking the times of saliva collection so please make every effort to follow scheduled sample times and to open and close the bottle with time stamp lid containing the sample collection cotton swabs fully after each use.

**Protocol Duration:** ~8 hours

**Attention:** Icepacks must be **frozen** prior to start of sample collection

### Preparing for Collection: Dim Light Melatonin Saliva Samples

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#### Part 1: Preparing your Environment

This protocol needs to be conducted in an area of rest, where you won't be disturbed or exposed to bright light for the entirety of the collection period, about 8 hours. For this protocol a dim light environment below 10 lux must be maintained. A light meter and tea lights have been provided to facilitate maintaining dim light conditions. Blue light blocking glasses have been provided to minimize exposure to blue light. The following instructions will prepare your area of rest to ensure proper dim light conditions are maintained for the duration of the protocol:

1. Using the provided tape, tape down light switches in your collection space, nearest restroom, and any other areas where light may be accessed during the protocol. You may need to place aluminum foil over windows to block light.
2. Place up to 16 of the provided battery-operated tea lights in your collection space and one battery-operated tea light in your bathroom. This will ensure dim light is maintained if the bathroom is needed during the protocol.
3. The provided light meter is handheld. When you are ready to begin sample collections and you have set your environment to dim light conditions, use the light meter to measure your light exposure. The meter should read below 10 lux.
4. When dim light conditions under 10 lux have been achieved and you are ready to begin the protocol. Confirm set up completion by texting the study number.
5. You may only use electronics such as a TV or cellphone if they have been dimmed to the lowest setting. If using either of these devices, change their settings to the dimmest light setting before beginning the sample collection. Electronics such as tablets (iPad, Kindle) and laptops are not allowed.

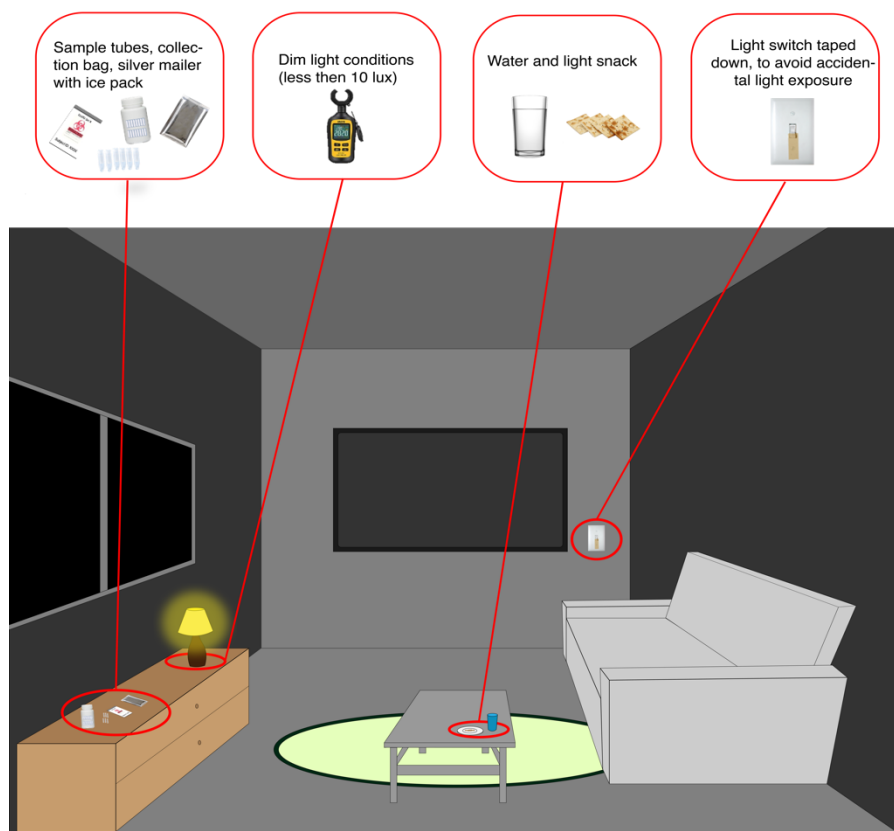


## Part 2: Preparing for Collection

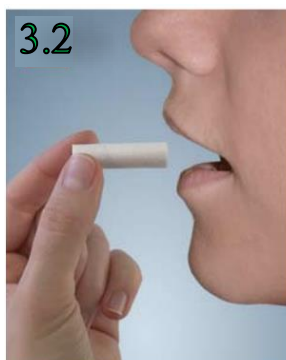
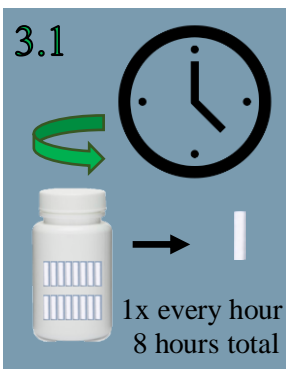
This protocol requires that you maintain a resting position for the duration of the protocol. The following instructions will prepare you to ensure resting conditions are maintained for the duration of the protocol:

1. You may place water and a snack near you in case you are thirsty or hungry during the protocol. Please see the provided guidance sheets for a list of study protocol appropriate food. *You may drink water or eat immediately **AFTER** a saliva sample collection, giving at least 30 minutes prior to your next collection and using a wet toothbrush with NO toothpaste to clean mouth and teeth.*
2. Two bags of collection tubes have been provided; each bag contains 9 tubes. Additional tubes have been provided should you need them. Take one bag of tubes and place the bag near you where tubes can be accessed easily.
3. You will label tubes as you collect samples during the protocol. In the kit you will find a set of labels titled “Dim Light Melatonin Collection Labels”. Place one set of labels near you, preferably next to your bag of collection tubes.
4. Two plastic biohazard bags have been provided, with an attached label to write the date of collection. Take one bag and write the date of collection on the bag, then place the dated bag near you where it can be accessed easily.
5. Collected saliva samples will need to remain cold during the protocol. An ice pack and silver mailer were provided with the collection kit. Place the frozen ice pack into the silver mailer and place it near you, where it can be accessed easily.

### Example Room Set Up







## Collecting Dim Light Melatonin Saliva Samples

### Goal 1: Provide hourly melatonin saliva samples in a dim light environment

1. Open the bottle with time stamp lid at the scheduled sample collection time and remove **one** cotton collection swab then replace the cap and close it fully. The cap will automatically track the time opened and closed.
2. Place the cotton collection swab in your mouth, letting it sit under your tongue until it becomes saturated with saliva, approximately 3-4 minutes.
3. Once the cotton is fully saturated, remove it from your mouth and place it into a collection tube. Using the provided marker, mark the tube label with the sample number, for example 1 for Sample 1.
4. Securely fasten the cap onto the tube.
5. Place the completed sample into the dated biohazard bag, then place and keep the bag inside of the silver pouch with the ice pack.
6. Repeat steps 1-6 every hour on the hour until all nine samples are collected. At the end of the protocol, you should have nine samples labeled "Sample 1; Sample 2; Sample 3..."
7. Place completed samples into the biohazard bag. Place that bag into the silver pouch containing a frozen icepack. Continue adding collected samples until all nine samples are completed. Place the silver pouch containing the icepack and biohazard bag with samples into your freezer.



- Store all saliva samples in the silver pouch with frozen icepack
- Once ALL 9 samples are complete, place entire silver pouch with icepack and samples in your **FREEZER**
- Keep samples in freezer until ready to return samples
- Mark each collection complete in the portal

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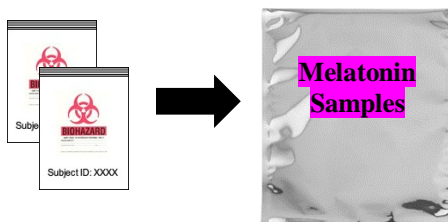
## Study Completion: Returning Samples and Electronics

The following instructions are provided to ensure collected samples are shipped appropriately. Before beginning sample return, ensure provided icepacks are fully frozen and returned in the foam and cardboard box used to originally ship the at-home kit to your address. Please **ONLY** package samples on the same day as planned return shipping.

### Melatonin Collection Samples

Place the frozen icepack into the silver, insulated envelope labeled “Melatonin Samples”. Place the two bags of completed, frozen melatonin collections into the silver envelope labeled “Melatonin Samples”. Place the silver envelope containing icepack and collection samples inside the foam box nested in the cardboard box.

Shipping Temperature:  
**Frozen**



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### Electronics

Place electronics in the provided silver, padded envelope labeled “Electronics”. Use the “Electronics Checklist” for guidance on which electronics to return. Once all electronics are in the silver padded envelope, seal the envelope and place in the foam box.

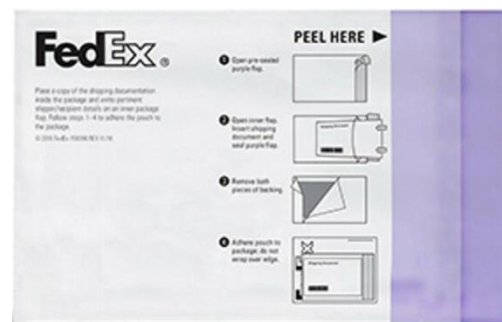
Shipping Temperature:  
**Room Temperature**



## Study Completion: Shipping Samples and Electronics

*The following instructions are provided to ensure collected samples are shipped appropriately. Please package samples on the same day as shipping.*


- 1) Once samples and electronics are in their respective insulated mailers and inside the foam box, close the foam box using the foam lid. Then seal the cardboard box using the provided shipping tape.
- 2) Place the provided FedEx shipping slip into the FedEx pouch as shown below. Remove the sticker from the back of the FedEx pouch and adhere it to the top of the sealed box.







- 3) Bring the kit to your nearest Fedex center. If you need help finding your nearest Fedex center, please reach out to the study team and we will happily assist you. The Fedex center will scan the kit and mail it to our study team **at no cost to you.**
- 4) In the participant portal, navigate to the "Returning Samples and Electronics" tab and check off that you have returned the kit.

## Return Shipping: Item Checklist

### Collected Samples:

- ☐  Completed Melatonin Collection Samples  
(2 Sets: 9 sample tubes, 18 samples total)

### Electronics:

- ☐  Actiwatch (1)
- ☐  Bottle with time stamp lid (1)
- ☐  Light Meter (1)
- ☐  Battery Operated Tea Lights (18)