SPECIMEN COLLECTION

1. Background and Rationale

The Second MrOS Sleep Visit (Sleep V2) involves the collection of approximately 10 mL of blood and a urine specimen from each participant. Since the study depends on the voluntary return of participants over an extended period of time, every effort must be made to make the entire procedure as easy and painless as possible both for the participants and for the clinic center personnel.

A standard informed consent has been prepared for this study. With regard to laboratory procedures, the consent statement informs study participants that there is a small risk of bruising at the spot on the arm where the blood is taken and that about one to two tablespoons of blood are drawn.

More information regarding the urine collection is also provided in the Urine Collection Protocol.

2. Equipment and Supplies

2.1 Sample ID Labels

You will be supplied with sheets of sample ID barcode labels to use for labeling form, draw tube, cryovials, and the shipping grid sheet. A sample sheet of barcode labels can be found in Appendix 1. All labels on each sheet have the same 6-digit sample ID number (the first two characters identify the clinic: BI = Birmingham, MN = Minneapolis, PA = Palo Alto, PI = Pittsburgh, PO = Portland, SD = San Diego). Each label contains a barcode with the ID and sample type embedded in the barcode.

There are 15 labels per participant, containing the ID number and specimen information. The labels identify the draw tube (1), urine collection container (1), specimen collection Teleform (1), each of the cryovials (4 for serum, 2 for urine), and the location on the shipping grid sheet (6).

Please see directions for participants without pre-printed labels for directions for participants without labels.

2.2 Blood Collection Trays and Tubes

Blood drawing trays are prepared in advance for the following day. Each tray is stocked with a full supply of blood drawing equipment for 8-12 participants and the

individual blood collection tube rack for each participant. Several racks will also be prepared to hold various plastic tubes and vials for the final serum and urine aliquots sent to Biomedical Research Institute (BRI) for storage.

Please note all blood must be collected in the morning, before 11 am.

2.2.1 Blood Collection Tray

The collection tray itself is made of hard plastic which is unbreakable and can be easily cleaned. The tray has ten individual compartments, which are filled with the following supplies:

Alcohol swabs	Smelling salts
Band-Aids	Scissors
Gauze	Adhesive tape
Tourniquets (2)	Pencils/pens
Vacutainer holders	Latex gloves
Needle/sharps container	21G Butterfly needles

2.2.2 Blood Collection Rack: Labeling and Setup

A separate tube rack containing the necessary draw tubes is set up for each participant. This rack will fit into the blood collection tray. The blood collection tubes and urine cup should be pre-labeled with sample ID labels. The "Specimen Collection Form" label should be clipped to the corresponding blood collection tray.

2.2.3 Description of Blood Collection Tube

Draw tube # 1 is a 10 mL siliconized red stoppered tube used to collect serum. These tubes contain no anticoagulant, so the blood will clot to form serum. After drawing, the blood is allowed to clot at room temperature for 40-45 minutes (Maximum = 90 minutes). Cryovials #1 - #4 will be used to collect serum for future analyses.

3. Safety Issues and Exclusions

3.1 Precautions for Handling Blood Specimens

In accordance with the OSHA regulations on blood borne pathogens (see Appendix 7 for complete OSHA regulations), we recommends the following laboratory safety protocol for the field center laboratories:

- Non-permeable lab coats, latex gloves, and face shields should be used when handling any blood in any situation where splashes, spray, spatter,

or droplets of blood may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

- 'Universal Precautions' should be followed when handling any blood products.

- Contaminated needles and sharps shall be immediately placed in a puncture-resistant, leakproof container. Never recap or break needles.

- Hepatitis B vaccine should be offered to all unvaccinated technicians handling blood and documentation of vaccination or technician's declining to be vaccinated should be kept

3.2 Participant Precautions and Exclusions

3.2.1 Specimen Collection Questionnaire

Before the blood draw, each participant is asked whether they have a bleeding disorder. If they have had any problems with excessive bleeding or bruising at a venipuncture site, use your own judgment to decide whether or not a clinic physician or nurse supervisor should be consulted.

There is no action to take if the participant has been told they have a coagulation disorder.

In addition, ask each participant if he is fasting before coming to clinic and record it on the Blood Collection & Processing Form. Also, please record the time of the last meal.

If the participant has experienced fainting spells during phlebotomy, ask the participant the frequency of fainting spells. If the participant frequently faints, again, use your own judgment to determine whether or not a consultation with the clinic physician or nurse supervisor is necessary. Provide smelling salts, basin, and a cold cloth if needed. See section below on precautions when a participant feels faint.

3.2.2 PRECAUTIONS WHEN A PARTICIPANT FEELS FAINT OR LOOKS FAINT FOLLOWING THE BLOOD DRAWING

- Have the participant remain in the chair, if necessary have them sit with their head between their knees.
- Provide the participant with a basin if they feel nauseated.
- Have the participant stay sitting until their color returns and they feel better.

- Place a cold wet cloth on the back of the participant's neck.
- If the participant faints, use smelling salts to revive by crushing the ampoule and waving it under the participant's nose for a few seconds.
- If the participant continues to feel sick, contact a medical (nursing) staff member who will advise you on further action.

3.3 Participant Refusal of Phlebotomy

Rarely, a participant will refuse phlebotomy. Please mark 'No' for 'Was any blood drawn' on the Blood Collection & Processing Form to identify any of these participants.

4. Subject and Exam Room Preparation

4.1 Phlebotomy Room

The blood drawing should take place in an isolated room or where room dividers can separate participants. The room should be equipped with all of the necessary blood drawing supplies. A separate counter or work table should be equipped with all of the materials and vials that are used in the blood handling and processing. The centrifuge, refrigerator, and freezer should be nearby.

4.2 Preparation for Phlebotomy

Preparation for phlebotomy is done in the following manner. Early morning, before any participants arrive:

- Check to make sure that blood collection tray is properly equipped.
- Check that each vacutainer tube and urine cup is properly labeled with ID labels.
- Check that the sample processing station is properly equipped.
- Make sure the phlebotomy room is tidy and stocked with extra smelling salts, basin, and disposable wash cloths.

4.3 Preparation of Participants for Urine Collection

See the Urine Collection Protocol for more information.

4.4 Preparation of Participants for Phlebotomy

It should be stressed that this study requires the voluntary cooperation of the participants. These people are donating both time and blood on a purely voluntary basis, with no reward other than the knowledge that they are contributing to progress in medicine. Thus, the whole experience must be made as pleasant as possible. One tube of 10 mL contains less than 3 teaspoons of blood. The phlebotomist may also assure participants that they donate 45 times as much blood (450 mL) when they donate a unit of blood.

5. Detailed Procedures

5.1 Forms

The purpose of this form is to facilitate the collection of serum and urine samples from. The collection must be done in a rapid and efficient manner, with maximum protection for the participant. In addition, the process must facilitate the monitoring of phlebotomy and other quality assurance parameters. All forms must be completed in ink. Please refer to the 'Scannable Forms Guidelines' protocol for more information.

The participant will arrive at the phlebotomy station with their Mr. OS participant ID # already filled in on their Blood Collection & Processing and Urine Collection & Processing Forms. Make sure that the draw tubes are labeled with the correct MrOS ID number. It is very important that the participant's MrOS ID number matches the ID numbers listed on each of the draw tubes and each of the cryovials. There will be a small sheet of labels clipped to the rack of vacutainers. There is a "Specimen Collection Form" label which should be affixed to the Blood Collection & Processing Form. This should be done before drawing any blood, to insure that this critical task is not forgotten.

5.1.1 Return Visit Aliquots

Occasionally, participants return to the clinic just to give a urine sample or have a blood draw. Follow the procedure as for a regular clinic visit. Be sure to fill out forms with the header information including the MrOS ID #, Acrostic, Date of Specimen Collection, and Staff ID #. Double check to make sure that the MrOS ID listed on the forms matches the ID numbers on the draw tubes and cryovials.

Blood must be collected before 11 am.

5.2 Phlebotomy

5.2.1 General

Blood drawing is standardized for the sitting position.

The venipuncture is performed with a 21 gauge butterfly needle with 12 inches of plastic tubing between the venipuncture site and the blood collection tubes. A 23 gauge needle may be used, if necessary, for a difficult draw. The butterfly has a small, thin-walled needle, which minimizes trauma to the skin and vein. The use of 12 inches of tubing allows tubes to be changed without any movement of the needle in the vein. If the participant is concerned about the venipuncture, he may be reassured to know such care is taken. The participant should be given enough time to feel comfortable both before and after the blood collection. In many cases the most memorable part of the experience for the participant will be the contact with the technician who draws the blood and their general attitude and competence.

If the participant is nervous or excited, the technician briefly describes the procedure. Sample script: "*I am going to be drawing about 2 teaspoons of blood. We hope to be able to use the results of these tests to better understand health and disease in older people.*"

5.2.2 Handling participants who are extremely apprehensive about having blood drawn

Do not under any circumstances force the participant to have blood drawn. It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible. It is sometimes best to let the participant go on with another part of the visit. It may also be helpful to have the participant relax in the blood drawing chair just so the phlebotomist can check the veins in the participant's arms, without actually drawing blood. If the participant has "good veins" the phlebotomist can reassuringly say, "Oh, you have good veins; there should be no problem." Elderly patients are often aware of the difficulty they pose to phlebotomists and should receive extra consideration and detailed explanations as required.

5.2.3 Venipuncture Procedure

- Wear Latex gloves and a lab coat.
- Apply tourniquet.
- Examine participant's arms for the best site for venipuncture. Generally the antecubital vein is preferred, if feasible. Release tourniquet.
- Cleanse venipuncture site. Prepare area by wiping with alcohol swab in a circular motion from center to periphery. Allow area to dry.
- Reapply tourniquet and note the start time on the Blood Collection & Processing Form.
- Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches below the venipuncture site.
- With the needle bevel upward, enter the vein in a smooth continuous motion.

- Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the opposite hand and place it under the elbow for support.
- Grasp the flange of the vacutainer holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
- Note the blood flow into the first collection tube. If blood is flowing freely, the butterfly needle can be taped to the participant's arm for the duration of the draw. If the flow rate is very slow, the needle may not be positioned correctly.
- Keep a constant, slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow. Do not vary pressure or reintroduce pressure after completion of the draw.
- Fill each vacutainer tube as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a vacutainer tube fills only partially, remove the vacutainer and attach one of your extra, backup tubes of the same type without removing the needle from the vein.
- When the blood flow ceases, remove the tube from the holder. The shutoff valve re-covers the point, stopping blood flow until the next tube is inserted.
- Do NOT mix red top draw Tube # 1.

5.2.4 Removing the Needle

- To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard needle into puncture-proof sharps container.
- Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma.

5.2.5 Bandaging the Arm

Under normal conditions:
- Slip the gauze pad down over the site, applying mild pressure.
- Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
- Tell the participant to leave the bandage on for at least 15 minutes.

If the participant continues to bleed:
- Apply pressure to the site with a gauze pad. Keep the arm elevated until bleeding stops.
- Wrap a gauze bandage tightly around the arm over the pad.
- Tell the patient to leave the bandage on for at least 15 minutes.

5.2.6 Completing the Blood Drawing Procedure

- Dispose of needle and tubing in the appropriate biohazard needle sharps containers.
- Complete Blood Collection & Processing form.
- Clean up the venipuncture area (if necessary).
- Bring blood collection tray to the processing area with the filled vacutainer tubes.

5.2.7 Procedures for Difficult Draw

If a blood sample is not forthcoming, the following manipulations may be helpful.

- If there is a sucking sound, turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
- If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm.
- Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.
- DO NOT attempt a venipuncture more than twice unless a participant encourages you to do so.
- Reassure the participant that the inability to obtain a clean venipuncture is not any sign of a medical problem on their part.
- If venipuncture is unsuccessful, all efforts should be made to have the participant rescheduled at a later date, preferably with a different clinic center phlebotomist.

5.2.8 Other Possible Problems

Collection tube does not fill: First, try another tube of the same type. Partial tubes for serum are okay, but will result in a reduced number of aliquots.

5.3 Blood Mixing During Venipuncture

Each draw tube should be treated as follows:

# 1	Serum: do NOT mix; place in rack at room temperature for AT LEAST 40 minutes

6. Quality Assurance

6.1 Training Requirements

Clinical experience with phlebotomy is mandatory. Additional training should include:

- Read and study manual
- Attend MrOS training session on techniques (or observe procedure by experienced examiner)
- Discuss problems and questions with local expert or QC officer

6.2 Certification Requirements

- Complete training requirements
- Explain what to do for difficult venipuncture
- Recite measures to take for fainting participant
- Conduct phlebotomy on volunteer or participant while being observed by QC officer using QC checklist

6.3 Quality Assurance Checklist

Preparation:

- Blood collection trays properly prepared
- Blood draw tubes properly labeled
- Proper instructions given for urine collection
- Hepatitis B vaccination given or offered to all personnel handling blood

Venipuncture properly carried out:

- Script properly delivered
- Non-permeable lab coats, gloves, and face shields used
- Preparation of venipuncture site correctly done
- Venipuncture smoothly done
- Collection tubes at least 2/3 full
- Tourniquet removed at 2 minutes
- Needle removed and arm bandaged correctly
- Needle and tubing appropriately dispose

Draw Tube mixed and handled correctly after filling:

- Draw Tube # 1 is NOT mixed, placed in rack at room temperature

Specimen collection forms properly filled out:

- Sample ID barcode label affixed
- Blood draw time and time of last meal entered
- Urine collection time recorded

LAB PROCESSING GUIDELINES

1. Equipment and Supplies

A complete supply list with ordering information can be found in Appendix 6. Necessary supplies include:

- Horizontal centrifuge
- -20° Freezer space is required
- Dry Ice
- Pipets and tips: 1.0 mL volumes
- Lab coat and gloves
- Biohazardous waste disposal container
- Balance tubes for the centrifuge
- Lab mat
- 10% bleach solution
- Freezer boxes with 9 x 9 cell grid (for 1.8 mL serum cryovials)
- Freezer boxes with 9 x 9 cell grid (for 4.5 mL urine cryovials)
- Rubber bands

1.1 Sample ID Labels

Each cryovial label also has a 1-digit vial # (1 to #6) that serves as a unique identifier for each cryovial with MrOS ID #. The labels for cryovials have bar codes to help track the repository. See Appendix 4 for proper orientation of the barcode label.

Beneath the ID number, cryovial labels also have lines of text: vial #, cap color, and type of specimen (serum, urine). This line of text is intended to increase accuracy in the labeling and filling of the cryovials. The cryovial cap information is coded (C= clear, Y=yellow, etc.).

There are a total of 15 labels for each participant. One is to be used for pre-labeling the draw tube and one label for the urine specimen cup.

2. Laboratory Room Preparation

All items that are required for sample processing should be on hand before processing starts.

Aliquot racks will be set up to correspond to each blood collection tube rack. Rack setup is completed the previous day. All tubes and vials are labeled with sample ID

bar codes (see Label Orientation diagram in Appendix 4) and arranged in appropriate working order.

3. Detailed Procedures

3.1 Processing

The draw tubes may be held at room temperature for up to 90 minutes (Draw Tube # 1). Personal protective equipment (non-permeable lab coats, double-gloves with at least one latex pair, splatter shields) MUST BE worn for processing.

3.1.1 Immediate Processing

Draw Tube # 1 must remain at room temperature for a minimum of 40 minutes. Room temperature is 21° C (the range of 15.5° → 23.5° is acceptable), 70° F (the range of 60° → 75° is acceptable). Allowing the tubes to stand longer may increase the yield of serum. The maximum allowable time before centrifugation is 90 minutes.

If the urine specimen cannot be immediately, place the filled urine cup into the refrigerator until the processing can begin. UV light may damage the specimen.

3.1.2 Aliquots per Sample Type

The following is a summary of the processing. Detailed instructions follow (volume indicates sample size, not cryovial size). Please see Appendix 2 for a flow chart that illustrates this graphically.

Serum: The serum from 10 mL tube # 1 is aliquoted into four 1.0 mL samples, which are contained in 1.8 mL cryovials.
The total number of aliquots is: 4
4 x 1.0 mL (Clear cap, cryovial # 1-4)

Urine: Please see the Urine Collection Protocol for more information.

3.1.3 Centrifugation of Serum Samples

Draw Tube # 1 should be left at room temperature for at least 40-45 minutes (maximum 90 minutes) after they are drawn. The tubes should display a clot by this time.

Use a horizontal centrifuge; angle heads are not satisfactory.

Centrifuge the blood for 10 minutes at room temperature at a setting known to yield a relative centrifugal force (RCF) of at least 1000 **x** g at the bottom of the tubes. The table below gives those combinations of centrifuge speed in revolutions per minute (rpm) and rotating radius (r) that will yield an RCF value of 1000 **x** g. RPM should be read from a tachometer or rev counter when the centrifuge is normally loaded. Radius (r) is measured in centimeters from the center of the rotor shaft to the bottom of the vacutainer tube when the tube is in a horizontal position.

r (cm)	12	14	16	18	20	22.5	26
rpm	2800	2600	2400	2250	2100	2000	1900

Do not use a brake to slow down the centrifuge.

3.1.4 Making Serum Aliquots

Allow the centrifuge to come to a complete stop. Carefully remove the tubes from the centrifuge, being careful not to shake the tubes, and place them on ice. All cryovials will contain 1.0 mL of serum.

If the volume requirement is met for the cyrovial, fill in the circle in the column titled "Ok" on the Blood Collection & Processing Form. If the tube is only partially filled, mark the circle labeled P (for partial). If a sample is hemolyzed, mark the circle marked H. If the serum is reddish in color, determine if it is hemolyzed or simply contaminated with red blood cells. One can tell the difference by recentrifuging the vacutainer tube. This will pellet any contaminating red cells and the serum will clear. If the sample is hemolyzed the red color will remain in the serum. If the tube is both hemolyzed and partially filled, mark the circle labeled B (for both.) If you are unable to fill the designated cryovial, fill in the circle labeled "not filled."

3.1.5 Making Urine Aliquots

See Urine Collection Protocol for more information.

3.1.6 Freezing

Upon completion of the processing steps, serum and urine aliquots must be frozen at -20° or on dry ice within 30 minutes.

After aliquoting is complete, the rack containing the cryovials should be placed upright in the freezer at -20° C (or on dry ice or colder) for at least half an hour (preferably until the end of the day). Make sure the aliquots are not wet when placed

in the freezer. If a freezer is not immediately available, place the rack of samples on dry ice.

3.2 End of the Day Procedures

- Frozen cryovials in racks are packaged into freezer boxes by numeric order of cryovials per participant. The serum cryovials will be placed into the boxes with the 9 x 9 grid. Do not leave empty spaces in the boxes. Samples from one participant may overlap into two boxes, and box will have samples from more than one participant. Complete the shipping grid sheet (see Appendix 5) for each box as the boxes are filled with specimens.
- Re-stock blood collection trays with supplies.
- Label the next day's draw tubes and cryovials.
- Arrange draw tubes and aliquots in their proper racks.
- Wipe down all work areas with 10% Clorox solution.

3.3 Shipping the Blood Samples

3.3.1 General

Frozen blood and urine samples are shipped on a regular basis to BRI by Federal Express overnight delivery. Ideally shipments would occur about every 2 months, but for the second sleep visit we aren't seeing enough participants per month for this to be a realistic option. If we shipped specimens every 2 months, the serum and urine boxes would not be full. Please only ship full serum and urine boxes. We recommend that sites ship specimens at least every 6 months. This should allow sites to have a couple of serum/urine boxes to include in a shipper.

Do not ship on Thursdays or Fridays to avoid delivery of shipments during a weekend.

Shipments to BRI are charged to your local Federal Express account number.

This shipping protocol follows the procedures mandated by the International Air Transport Association's Dangerous Goods Regulations-Packaging Instructions 650 and 904.

3.3.2 Methods for shipping frozen samples

The frozen blood cryovials are already packaged in prelabeled freezer boxes and stored in the -20° C freezer by consecutive box number.

A grid sheet detailing the contents of the shipment will be completed as the samples are stored in the box. The grid will use barcode labels for each square.

Samples should be prepared for shipping as follows:

- Wrap each freezer box in paper towels to absorb possible leakage. Put a rubber band around the towel-wrapped box or bag. Using two rubber bands, put a rubber band in each direction (horizontally and vertically), forming a cross with the rubber bands.
- Put the individual freezer boxes containing the samples into a leakproof zip-lock plastic bag and then the outer envelop.
- Place approximately one third of the dry ice on the bottom of the mailer.
- Carefully place the freezer boxes into the styrofoam mailer. Place no more than a total of 4 L of sample into the styrofoam shipping container. Use two or more styrofoam mailers for the BRI shipment when necessary. (In this case, label the mailers "1 of 2" and "2 of 2").
- Place the remaining dry ice (approximately 7 - 14 lbs. total) on top and around the samples to fill the styrofoam container.
- Enclose the styrofoam container in the outer cardboard sleeve.
- Enclose the completed grid sheet with cryovial information and a copy of the Blood Collection & Processing Form. Carefully fold the completed grid to ensure that no barcodes are damaged by the fold. Folding between the labels is preferable.

The BRI mailing address is:

Chris Kennell
Biomedical Research Institute
12264 Wilkins Avenue
Rockville, MD 20852

E-mail (preferred method) specimenstorage@aol.com or FAX (301) 770-9811 the following information to BRI when a shipment is sent:

Date of shipment
Expected arrival date
Number of styrofoam mailers shipped
FedEx airbill number

4. Quality Assurance

4.1 Training Requirements

Clinical experience with processing of blood samples is strongly recommended. Additional training should include:

- Read and study manual
- Attend MrOS Sleep Visit 2 training session on techniques (or observe processing by experienced examiner)
- Discuss problems and questions with local expert or QC officer

4.2 Certification Requirements

- Complete training requirements
- Recite shipping schedule for applicable field center
- Process samples from volunteer or participant while being observed by QC officer using QC checklist.

4.3 Quality Assurance Checklist

Preparation

- Aliquot racks correctly set up
- Cryovials correctly labeled
- Hepatitis B vaccination given or offered to all personnel handling blood
- Non-permeable lab coats, gloves, and face shields used

Processing urine

- Urine correctly aliquoted

Processing serum tubes

- Centrifuge correctly balanced with water tube(s)
- Serum correctly aliquoted

Freezing

- Rack placed upright in -20° C freezer or samples placed on dry ice

End of day procedure

- Frozen aliquots removed from rack and placed in appropriate freezer boxes
- Freezer boxes correctly labeled

Shipment procedures -- dry ice

- Freezer boxes correctly wrapped -- absorbent material, rubber band, and zip-lock bag
- Styrofoam mailers correctly packed -- absorbent material, dry ice, top sealed with tape
- Grid and forms included in package
- Styrofoam mailer sealed in cardboard sleeve
- FedEx airbill correctly filled out
- Labels correctly affixed

Special directions for participants without pre-printed labels

For participants who do not have pre-printed labels available, sites should create labels locally (note that sites should contact the Coordinating Center to ensure that a participant is eligible for the second sleep visit before scheduling a participant not included on the provided recruitment lists.). We suggest that 8 labels be created for each participant: The labels identify the draw tube (1), urine collection container (1) and each of the cryovials (4 for serum, 2 for urine). Note that locally created labels for the Blood Collection & Processing TELEform and shipping grid are not required. All labels should include the 6-digit ID number, visit, tube information and the sample type. For example, the label for storage tube #1 for participant BI0001 will include BI0001, MrOS Sleep 2, Clear #1, 1.0 mL Serum (please see appendix 1 for more examples).

For these participants, no label is required for the Blood Collection & Processing TELEform. Note that a missing edit will appear on the MrOS website. This edit can be commented out as 'irretrievable'.

For these participants, no labels are required for the Specimen Shipping Grid. However, sites should hand-enter all information from the specimen label (ID, visit, tube information and sample type). For example, the following information should be entered on the shipping grid for storage tube #1 for participant BI0001: BI0001, MrOS Sleep 2, Clear #1, 1.0 mL Serum. Please take extra care when hand-entering information and please arrange your storage boxes so that those vials with no label for the shipping grid are at the end or beginning of the box. This will make data entry easier for BRI.

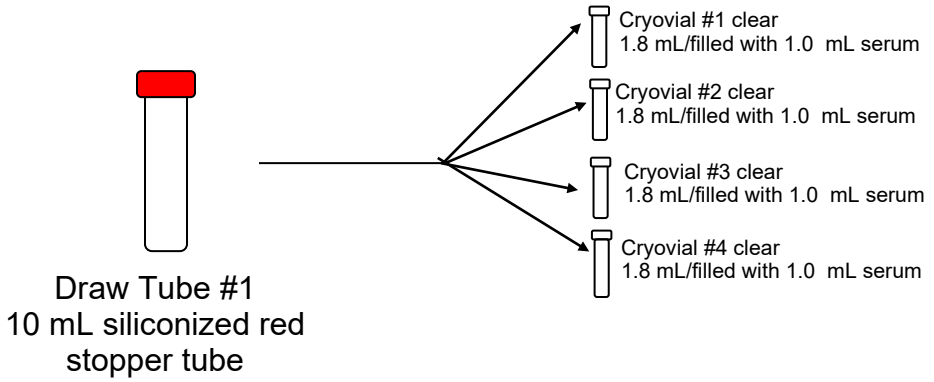
APPENDIX 1
MrOS Sleep Visit 2

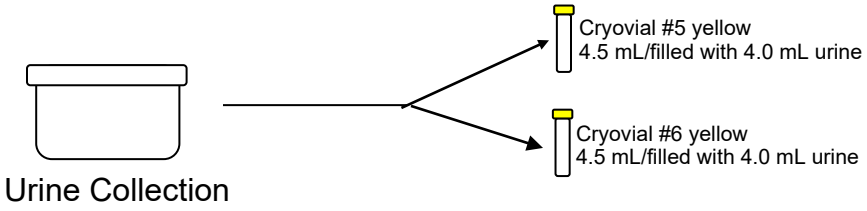
Sample Collection Labels: Samples

BI0001 MrOS Sleep 2 Draw Tube #1 Serum Red 10 mL	BI0001 MrOS Sleep 2 Specimen Collection Form
BI0001 MrOS Sleep 2 Urine Collection	
BI0001 MrOS Sleep 2 Clear #1 1.0 mL serum	BI0001 MrOS Sleep 2 Clear #1 1.0 mL serum Grid
BI0001 MrOS Sleep 2 Clear #2 1.0 mL serum	BI0001 MrOS Sleep 2 Clear #2 1.0 mL serum Grid
BI0001 MrOS Sleep 2 Clear #3 1.0 mL serum	BI0001 MrOS Sleep 2 Clear #3 1.0 mL serum Grid
BI0001 MrOS Sleep 2 Clear #4 1.0 mL serum	BI0001 MrOS Sleep 2 Clear #4 1.0 mL serum Grid
BI0001 MrOS Sleep 2 Yellow #5 4.0 mL urine	BI0001 MrOS Sleep 2 Yellow #5 4.0 mL urine Grid
BI0001 MrOS Sleep 2 Yellow #6 4.0 mL urine	BI0001 MrOS Sleep 2 Yellow #6 4.0 mL urine Grid

→ And so on for the next participant

APPENDIX 2
MrOS Sleep Visit 2 Study
Specimen Collection Flow Chart





APPENDIX 3
Phlebotomy Checklist

Blood Collection Tray Checklist

Per Tray:

- 10 21G Butterfly needles
- 10 Alcohol Swabs
- 15 Band-Aids
- 15 Gauze pads
- 5 Vacutainer holders
- complete set of extra, unlabeled collection tubes
- 2 Tourniquets
- 1 Smelling salts
- 1 Timer or stopwatch
- 2 Pencils/pens
- Latex gloves
- 1 Hemostats
- 1 Adhesive tape
- 1 Scissors

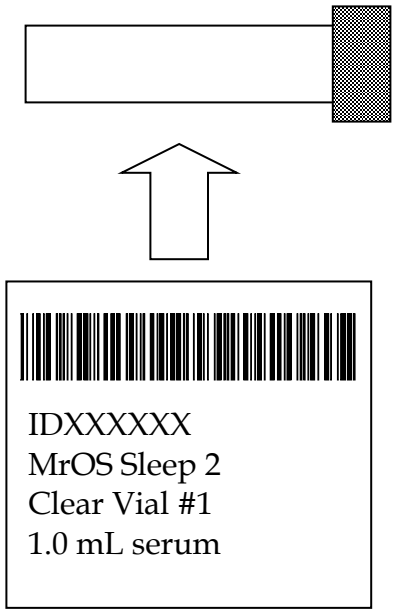
Per participant:

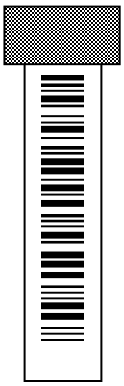
- 1 Blood tube rack with 1 draw tube labeled
- 1 MrOS Blood Collection & Processing Form
- 1 MrOS Urine Collection & Processing Form
- 1 3 oz urine collection cup labeled

At the Phlebotomy Station:

- Basin
- Cold cloth
- Tube mixer
- Biohazard containers
- Needle/Sharps container
- Paper towels

APPENDIX 4
Label Orientation on Cryovial





APPENDIX 5
MrOS Sleep Visit 2 Specimen Shipping Grid Sample

The following information must be included on the specimen shipping grid:

Visit (MrOS Sleep V2) Type of specimen
cryovial # (should correspond with form) Cap color
ID#

This information is included on the label for the grid sheet. If the label for the grid sheet is lost or damaged, this information may be hand written on the grid sheet. Please use Appendix 8 as a template for the grid sheet. Print it to 2 8.5 x 11 pieces of paper. Ensure when the page is folded that the fold does not go through any of the labels.

Please separate the 4.0 mL cryovials and 1.0 mL cryovials into different storage boxes. Use 3 inch tall storage boxes for the 4.0 mL cryovials and 2 inch tall storage boxes for the 1.0 mL cryovials.

1.0 mL cryovial in 2 inch tall box:

BI9001 MrOS Sleep 2 Clear #1 1.0 mL serum Grid	Clear #2 1.0 mL serum Grid	Clear #3 1.0 mL serum Grid	Clear #4 1.0 mL serum Grid	BI9003 MrOS Sleep 2 Clear #1 1.0 mL serum Grid	Clear #2 1.0 mL serum Grid	BI9005 MrOS Sleep 2 Clear #1 1.0 mL serum Grid	Clear #2 1.0 mL serum Grid	Clear #3 1.0 mL serum Grid

4.0 mL cryovial in 3 inch tall box:

BI9001 MrOS Sleep 2 Yellow #5 4.0 mL Urine Grid	Yellow #6 4.0 mL Urine Grid	BI9002 MrOS Sleep 2 Yellow #5 4.0 mL Urine Grid	Yellow #6 4.0 mL Urine Grid	BI9003 MrOS Sleep 2 Yellow #5 4.0 mL Urine Grid	Yellow #6 4.0 mL Urine Grid			

Note in this example, fictional participant BI9001 had all samples drawn, BI9002 only had urine drawn, BI9003 is missing serum cryovials #3-4, BI9004 has no specimens, and BI9005 is missing serum cryovials #4 and is missing both urine cryovials.

With permanent marker or a label, include the following information on **each individual freezer box:**

MrOS **Sleep V2** Study
Your Site's Name
The range of ID#s included in the box

E-mail Chris Kennell at specimenstorage@aol.com before you make shipment. Include the following information:

The fed-ex tracking number

date of shipment
expected arrival date
number of styrofoam mailers shipped

APPENDIX 6
MrOS Sleep Visit 2
Cryovials and Processing Equipment

Vendor: Fisher Scientific (800) 766-7000

Cryovials/Caps	**# per participant**	**Sample Type**	**Fisher Catalog #**
1.8 mL and 4.5 mL	4 2	Serum Urine	12-565-171N 12-565-161N
Cap - yellow	2	Urine	12-565-246
Cryovial Racks (if needed)	1 (can be reused)	All	07-200-618
Other	**# per participant**	**Sample Type**	**Fisher Catalog #**
Transfer pipets (built-in bulbs)	1 or 2	All	13-711-5A
Cryotube storage boxes – 2 ins	NA	Serum	11-678-24A
Cryotube storage boxes – 3 ins	NA	Urine	11-678-24B
81 cell cyrotube insert	NA	All	13-989-218
Urine collection cup (3 oz)	1	Urine	02-544-3
Blood Collection			
Vacutainer Blood Collection Set 21 G 3/4 "	1		02-664-1
Vacutainer Blood Collection Set 23 G 3/4 "	optional		02-664
Needle holders	1		02-665-110
10 mL siliconized red stopper tube, no additive	1	Serum	02-685A

Shipping material:
Secondary pressure vessel system (for 2 inches boxes): STP 710 including poly bag and outer envelope

Secondary pressure vessel system (for 3 inches boxes): STP 730 including poly bag and outer envelope
Absorbent strip: STP 150 3 inches with capacity 50 mL
The Saf-T-Pak secondary pressure vessel system comes in a case of 50. To order the system, please contact Saf-TPak
at 1-800-814-7484.

APPENDIX 7
OSHA
Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030
(15 pages)

1910.1030 - Bloodborne pathogens.

* Standard Number: 1910.1030
* Standard Title: Bloodborne pathogens.
* SubPart Number: Z
* SubPart Title: Toxic and Hazardous Substances

Produced by USDOL OSHA - Directorate of Safety Standards &
Directorate of Health Standards
Maintained by USDOL OSHA - OCIS

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.
"Blood" means human blood, human blood components, and products made from human blood.
"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.
"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
"Contaminated Laundry" means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.
"Contaminated Sharps" means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Engineering Controls" means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Handwashing Facilities" means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

"Licensed Healthcare Professional" is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

"HBV" means hepatitis B virus.

"HIV" means human immunodeficiency virus.

"Occupational Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

"Other Potentially Infectious Materials" means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

"Parenteral" means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective

equipment.

"Production Facility" means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

"Regulated Waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

"Research Laboratory" means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

..1910.1030(c) (c) Exposure Control. (1) Exposure Control Plan. (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure. (ii) The Exposure Control Plan shall contain at least the following elements: (A) The exposure determination required by paragraph (c)(2), (B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and (C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard. (iii) Each employer shall

ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e). (iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. ..1910.1030(c)(1)(v) (v) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying. (2) Exposure Determination. (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following: (A) A list of all job classifications in which all employees in those job classifications have occupational exposure; (B) A list of job classifications in which some employees have occupational exposure, and (C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard. (ii) This exposure determination shall be made without regard to the use of personal protective equipment. (d) Methods of Compliance. (1) General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials. ..1910.1030(d)(2) (2) Engineering and Work Practice Controls. (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used. (ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. (iii) Employers shall provide handwashing facilities which are readily accessible to employees. (iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible. (v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. (vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials. ..1910.1030(d)(2)(vii) (vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of

contaminated needles is prohibited. (A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure. (B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique. (viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) puncture resistant;

(B) labeled or color-coded in accordance with this standard;

..1910.1030(d)(2)(viii)(C)
(C) leakproof on the sides and bottom; and

(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. (x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present. (xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances. (xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited. (xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping. ..1910.1030(d)(2)(xiii)(A) (A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility. (B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing,

storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard. (C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics. (xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. ..1910.1030(d)(2)(xiv)(A) (A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated. (B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken. (3) Personal Protective Equipment. (i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. ..1910.1030(d)(3)(ii) (ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future. (iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided. (iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee. ..1910.1030(d)(3)(v) (v) Repair and Replacement. The employer shall repair

or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee. (vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible. (vii) All personal protective equipment shall be removed prior to leaving the work area. (viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal. (ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces. (A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
..1910.1030(d)(3)(ix)(B) (B) Disposable (single use) gloves shall not be washed or decontaminated for re-use. (C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised. (D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall: {1} Periodically reevaluate this policy; {2} Make gloves available to all employees who wish to use them for phlebotomy; {3} Not discourage the use of gloves for phlebotomy; and {4} Require that gloves be used for phlebotomy in the following circumstances: [i] When the employee has cuts, scratches, or other breaks in his or her skin; [ii] When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and [iii] When the employee is receiving training in phlebotomy.
..1910.1030(d)(3)(x) (x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. (xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated. (xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic

surgery). (4) Housekeeping. (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area. ..1910.1030(d)(4)(ii) (ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. (A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning. (B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift. (C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination. ..1910.1030(d)(4)(ii)(D) (D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps. (E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. (iii) Regulated Waste. (A) Contaminated Sharps Discarding and Containment. {1} Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: [a] Closable; [b] Puncture resistant; [c] Leakproof on sides and bottom; and [d] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. {2} During use, containers for contaminated sharps shall be: [a] Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries); [b] Maintained upright throughout use; and [c] Replaced routinely and not be allowed to overfill. ..1910.1030(d)(4)(iii)(A){3} {3} When moving containers of contaminated sharps from the area of use, the containers shall be: [a] Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; [b] Placed in a secondary container if leakage is possible. The second container shall be:

[i] Closable; [ii] Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and [iii] Labeled or color-coded according to paragraph (g)(1)(i) of this standard. {4} Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury. (B) Other Regulated Waste Containment. {1} Regulated waste shall be placed in containers which are: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. ..1910.1030(d)(4)(iii)(B){2} {2} If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. (C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories. (iv) Laundry. (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. {1} Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use. ..1910.1030(d)(4)(iv)(A){2} {2} Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions. {3} Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior. (B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment. (C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i). ..1910.1030(e) (e) HIV and HBV Research Laboratories and Production Facilities. (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration,

experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard. (2) Research laboratories and production facilities shall meet the following criteria: (i) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. (ii) Special Practices (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress. (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area. ..1910.1030(e)(2)(ii)(C) (C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms. (D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard. (E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench. (F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered. ..1910.1030(e)(2)(ii)(G) (G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable. (H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. (I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary. (J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when

handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal. ..1910.1030(e)(2)(ii)(K) (K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials. (L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person. (M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them. (iii) Containment Equipment. (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols. ..1910.1030(e)(2)(iii)(B) (B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually. (3) HIV and HBV research laboratories shall meet the following criteria: (i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area. (ii) An autoclave for decontamination of regulated waste shall be available. (4) HIV and HBV production facilities shall meet the following criteria: (i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area. ..1910.1030(e)(4)(ii) (ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination. (iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area. (iv) Access doors to the work area or containment module shall be self-closing. (v) An autoclave for decontamination of regulated waste shall be available within or as near as

possible to the work area. (vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area). ..1910.1030(e)(5) (5) Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix). (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up. (1) General. (i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident. (ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are: (A) Made available at no cost to the employee; (B) Made available to the employee at a reasonable time and place; (C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and (D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f). ..1910.1030(f)(1)(iii) (iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee. (2) Hepatitis B Vaccination. (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons. (ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination. (iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time. (iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A. ..1910.1030(f)(2)(v) (v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii). (3) Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a

confidential medical evaluation and follow-up, including at least the following elements: (i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred; (ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law; (A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented. ..1910.1030(f)(3)(ii)(B) (B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated. (C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual. (iii) Collection and testing of blood for HBV and HIV serological status; (A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained. (B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible. (iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service; ..1910.1030(f)(3)(v) (v) Counseling; and (vi) Evaluation of reported illnesses. (4) Information Provided to the Healthcare Professional. (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation. (ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information: (A) A copy of this regulation; (B) A description of the exposed employee's duties as they relate to the exposure incident; (C) Documentation of the route(s) of exposure and circumstances under which exposure occurred; (D) Results of the source individual's blood testing, if available; and (E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain. (5) Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. ..1910.1030(f)(5)(i) (i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the

employee has received such vaccination. (ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information: (A) That the employee has been informed of the results of the evaluation; and (B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment. (iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report. (6) Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section. (g) Communication of Hazards to Employees. (1) Labels and Signs. (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G). ..1910.1030(g)(1)(i)(B) (B) Labels required by this section shall include the following legend:

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. (D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. (E) Red bags or red containers may be substituted for labels. (F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g). ..1910.1030(g)(1)(i)(G) (G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement. (H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated. (I) Regulated waste that has been decontaminated need not be labeled or color-coded. (ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other

responsible person.)

..1910.1030(g)(1)(ii)(B) (B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color. (2) Information and Training. (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours. (ii) Training shall be provided as follows: (A) At the time of initial assignment to tasks where occupational exposure may take place; (B) Within 90 days after the effective date of the standard; and (C) At least annually thereafter. (iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided. (iv) Annual training for all employees shall be provided within one year of their previous training. (v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created. ..1910.1030(g)(2)(vi) (vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used. (vii) The training program shall contain at a minimum the following elements: (A) An accessible copy of the regulatory text of this standard and an explanation of its contents; (B) A general explanation of the epidemiology and symptoms of bloodborne diseases; (C) An explanation of the modes of transmission of bloodborne pathogens; (D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan; (E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials; (F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment; ..1910.1030(g)(2)(vii)(G) (G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment; (H) An explanation of the basis for selection of personal protective equipment; (I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge; (J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials; (K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available; (L) Information on the post-exposure evaluation and follow-up that the employer is required to

provide for the employee following an exposure incident; (M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and ..1910.1030(g)(2)(vii)(N) (N) An opportunity for interactive questions and answers with the person conducting the training session. (viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address. (ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements. (A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV. (B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV. (C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated. ..1910.1030(h) (h) Recordkeeping. (1) Medical Records. (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020. (ii) This record shall include: (A) The name and social security number of the employee; (B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2); (C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3); (D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and (E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D). (iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are: ..1910.1030(h)(1)(iii)(A) (A) Kept confidential; and (B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law. (iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020. (2) Training Records. (i) Training records shall include the following information: (A) The dates of the training sessions; (B) The contents or a summary of the training

sessions; (C) The names and qualifications of persons conducting the training; and (D) The names and job titles of all persons attending the training sessions. (ii) Training records shall be maintained for 3 years from the date on which the training occurred. (3) Availability. (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying. ..1910.1030(h)(3)(ii) (ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary. (iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020. (4) Transfer of Records. (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h). (ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period. (i) Dates. ..1910.1030(i)(1) (1) Effective Date. The standard shall become effective on March 6, 1992. (2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992. (3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992. (4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992. [56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996]

APPENDIX 8
MrOS Sleep Visit 2
Shipping Grid Sheet

Box Number :

Samples begin in the upper left corner and move left to right and lowest to highest.
This grid is prepared as if one is looking down on the sample box from above.

START

