Sleep Study
UAB Biobehavioral Pain Research Lab (BPRL)
Session One: Research Assistant Instructions and Information

Date ___/___/___

Brief Title: The Impact of Insomnia on Pain in HIV (the HIPPI study)

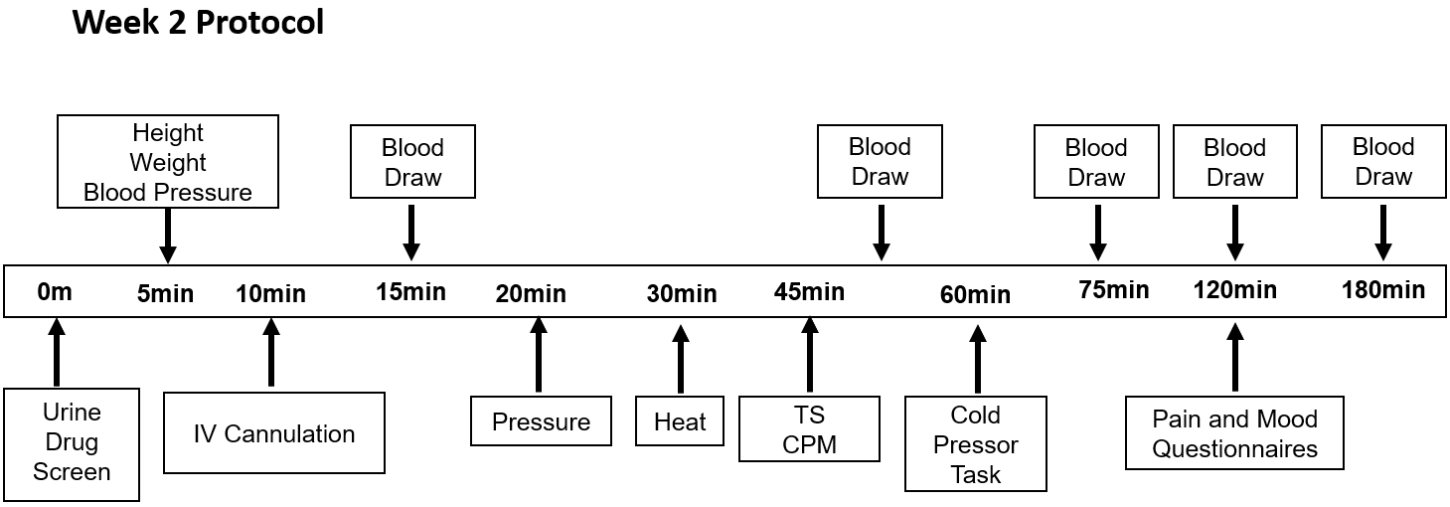
NCT Number: NCT04298658

Date: 7/31/2025

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Figure 2: Graphical depiction of the Week 2 protocol



Week 2 Protocol

Plan to be at the BPRL at least 45 minutes prior to the start of session one in order to complete the following:

- Call participant to ensure they are still able to make the session on time and answer any questions they may have pertaining to the session (directions, location, what to bring, etc.)
- Organize the subject packet (checklist, surveys & diaries, MD note)
- Collect the equipment (Laptop, clipboard, stop watch, checklist, acti-watch dock station, UDS)

Plan to arrive at the CRU at least 30 minutes prior to the start of the session in order to complete the following:

- Confirm room and participant with the nurses for the study
  - Double check the name/PID on the tubes
- Ensure all the study material is set up within the room
  - QST Devices – Cold Pressor / TSA Machine / BP Machine / Algometer / Touch Test
- If subject is driving to the CRU for participation, you will need to be prepared to meet him/her in 6th Ave. Parking Deck if necessary. Make sure you have the laminated "Sleep Study" sign.
- If subject is being dropped off at street entrance (19th Street), you will need to be prepared to meet him/her at street level entrance. Make sure you have the laminated "Sleep Study" sign.

When Participant arrives:

6th Ave. Parking Deck *(instructions for participants and guiding RAs)**:***

- Enter the hospital on the 2nd floor entrance through the blue double doors.
- Follow Concourse D (Jefferson Towers) to the first elevator bank.
- Take elevator to the 15th Floor.
- Have the participant check in at the nurse's station then show them to their room.

19th Street South Entrance *(instructions for participants and guiding RAs)***:**

- Go up the steps and enter through the double doors.
- The elevators will be on your left. Take it up to the 15th floor.
- Have the participant check in at the nurse's station then show them to their room.

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RA Note: No additional consent form needs a signature. The original informed consent that the participant completed at week 1 covers the remainder of their study participation. Inform participant of everything that will be performed during this session and provide participant with bottle of water. Answer any questions the subject has.

Starting the Session

Before Blood Draw

- Collect participant's actiwatch and retrieve data. Let this charge to configure and return to INSOMNIA ONLY participant at the end of this session.
- Assess subject readiness for session ensure participant doesn't have any questions or concerns. Ask them to wait on using the restroom for the urine drug test.
- Place the blood pressure cuff on the dominant arm. (Place cuff and position subject's arm for accurate blood pressure readings.) Ask subject to keep his/her arm in the same position. We will be taking blood pressure three separate times and the readings will be very different if the arm is moving or in a different position. If the readings are a little high, give the participant a couple minutes to adjust to the room, and then try again. **At least one reading should be below 150/95.**
- Take the participant's temperature using digital thermometer provided by the CRU. If the participant's temperature is above 104^0F then they must be rescheduled to a time when they no longer have a fever. **All participants must have temperature below 100.4^0F**.
- Provide participant with urine cup (UDS) and ask the participant to fill no more than half way. They may leave the cup beside the toilet when they leave. With a gloved hand, place the specimen cup on a sanitation wipe in our study room for approximately 5 minutes and record the results on the QST data recording sheet.
- After the participant has had a chance to use the bathroom, have the participant fill out the questionnaire **"Pain Intensity and Interference".**

RA Note: If all three blood pressure readings are above 150/95 or the temperature is above 100.4^0F then the participant will be disqualified from further participation and provided with $25 on their clincard.

Blood Draw: Inserting IV Cannula (Nurse)

- Go to the nurse's station and ask the nurse to place IV cannula into the subject's non-dominant arm. Only two attempts will be made to place the IV cannula. One more attempt may be made with participant permission, if not successful than a butterfly needle will be used to collect blood draw #1 and blood draw #5. **Only the nurse should touch cannula and tubes for blood**. If you must touch a tube, **BE SURE TO PUT ON GLOVES FIRST.**
    - 2 - 4mL lavender top (Outreach CD4/Hema) – **HIV Participants Only**
    - 1 - 6 mL lavender top (Outreach viral load) **– HIV Participants Only**
    - 1 - 10 mL plain red top (CRU)
    - 1 – 4 mL plain red top (CRU)
    - 1 – 4 mL blue top (Outreach)
    - 1 – 10 mL yellow top ACD (CRU/BARB)

RA Note: Should the IV Cannula ever become uncomfortable or painful after being inserted, the participant may ask for it to be removed and the RA will note in data sheets but continue with the rest of

the protocol. We will only collect the final blood draw # 5 via butterfly with their permission after the cannula's removal. If the IV cannula could not be successfully placed, then continue with the remainder of session 2.

QST Procedures: Pain Testing

RA Note: Play the audio instructions to the participant telling him/her how we want him/her to rate pain intensity using the 0-100 numeric rating scales.

RA Note: Play audio instructions for how to complete the Punctate Mechanical Stimuli.

Punctate Mechanical Stimuli (Von Frey Monofilament Touch Test)

- Use the **6.65 300g** Touch Test Sensory Evaluator. When applying the probe-tip on the skin, make sure that only the tip touches the skin. The probe must be oriented perpendicular to the skin. The RA must assure that her/his arm is stabilized, so there will be no lateral movement of the probe-tip as it touches the skin.

- Hold the probe just above the intended stimulation site, and bring it down to make gentle contact with the skin, without jabbing. After contacting the skin, press the monofilament at a 90 degree angle against the skin until it bows. Apply pinprick stimulator for approximately **1 second** and then remove.

- The test stimuli will be applied, in randomized order, to the back of the **Non-Dominant hand and the Non-Dominant trapezius**. First perform a single trial (one tap). Have the subject report the intensity of pain experienced (0-100) with the single trial and record on datasheet. Following the single trial, perform the series of 10 trials the same skin area. The size of this area should be about 1 cm^2. Apply the stimuli 10 times at a rate of one contact per second. Ask the subject to give a pain intensity rating representing the highest amount of pain they felt during the 10 contacts (0-100).

**Have subject close their eyes or look away when you are delivering the stimuli.

- Order of testing: Whether or not the RA begins the testing at the hand or trapezius should be determined randomly (i.e., a coin flip). Once this is determined, then the task proceeds in two full rotations in alternating fashion by body site using the same monofilament (e.g., hand, trapezius, hand, and trapezius, or vice versa). Discontinue the procedure at any time if the subject says "STOP".

RA Note: There will be a 2 minute break between the end of the punctate mechanical stimuli and when you begin the heat pain testing.

Heat Pain Testing

- For both Heat Threshold and Tolerance tasks, lightly place thermode on the skin surface. Three (3) sites along ***medial portion of the non-dominant forearm*** will be used for assessment of threshold and tolerance. To begin with, place the thermode 1 inch above where the wrist creases. (Max 50°C)

RA Note: Play audio instructions for how to complete the Heat Pain Threshold.

- **Heat Pain - Threshold** – Make sure to slightly move the location of the thermode on the forearm just a little so that the exact same spot is not stimulated each time. Record temperatures of heat pain thresholds on datasheet. (Max 50°C)

RA Note: Play audio instructions for how to complete the Heat Pain Tolerance.

- **Heat Pain - Tolerance** – Make sure to slightly move the location of the thermode on the forearm just a little so that the exact same spot is not stimulated each time. Record temperatures of heat pain tolerance on datasheet.

RA Note: There will be a 2 minute break between the end of the heat pain threshold/tolerance and when you begin the temporal summation of heat pain.

RA Note: Play audiotape instructions for how to complete the Heat Pain Temporal Summation.

- **Temporal Summation of Heat Pain** - you will practice the temporal summation of heat procedure on each participant using the 44^0C temperature on the dorsal side of the **non-dominant** forearm. Afterwards, use the ventral side of the **non-dominant** arm for testing. All subjects will be tested at 46ºC and 48ºC. Record 0-100 ratings given for each heat pulse on the datasheet. Discontinue task if subject rates the pain as 100 or asks to stop.
- **46^0C on ventral forearm –** Randomize 46 and 48 task order. Lightly place thermode about two to three inches above the wrist on ventral side of the non-dominant forearm. Record 0-100 ratings given for each heat pulse on the datasheet. Discontinue task if subject rates the pain as 100 or asks to stop.
- **48^0C on ventral forearm** – Randomize 46 and 48 task order. Lightly place the thermode two to three inches below the crease of the elbow on ventral side of the non-dominant forearm. Record 0-100 ratings given for each heat pulse on the datasheet. Discontinue task if subject rates the pain as 100 or asks to stop.

RA Note: There will be a 2 minute break between the end of the temporal summation of heat pain procedure and when you begin the punctate pinprick stimuli.

RA Note: Play audio instructions for how to complete the Baseline Pressure Pain Thresholds.

Baseline Pressure Pain Thresholds (Algometer)

- Start Medoc into Algometer Testing.
- Start with site listed on datasheet (starting site will be randomly selected and circled). Gently apply the tip of the Algometer to either the subject's **Dominant** forearm or ipsilateral trapezius and gradually increase the pressure. Subjects are to report when the pressure produced by the Algometer first produces a painful sensation. Be sure that the subject cannot read the laptop used for the algometer (face the laptop away from subject). Ideally, readings for each site should be within 100 kPa of each other. **Maximum pressure for the forearm and trapezius is 1000 kPa; discontinue pressure application at 1000 kPa**. If subject tolerates pressure to 1000 kPA, record as 1000.1 on the data sheet to indicate maximum pressure applied.
- **Dominant Forearm:** Position arm on well-supported surface. Have participant make a fist to identify muscle (approximately 8cm distal to the elbow, just lateral to midline of dorsal forearm). Apply evenly increasing pressure to this muscle.
- **Trapezius:** Feel for the thick trapezius muscle just above the scapula on participants back and shoulder. Apply evenly increasing pressure to this muscle until the participant indicates it has become painful.
- Obtain 3 pressure pain thresholds for each site (forearm, trapezius) in alternating fashion.

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RA Note: At this time, ask for the nurse to come perform blood draw #2. (10mL plain red, 6mL plain red, 4mL light blue)

RA Note: Play audiotape instructions for how to complete the CPM trials.

Conditioned Pain Modulation (CPM)

- For each participant, the cold water temperature will be set at 10^0C. Make sure there is a towel available for the participants to dry their hands off in between water submersion.
- Have subject remove rings, bracelets and watch on the hand to be submerged.
- Begin the CPM protocol by asking the subject to immerse his/her **Non-Dominant hand** into the cold water bath up to the wrist. As soon as the subject has immersed the hand, start the stopwatch. At 30 seconds following hand immersion, ask subject to rate the pain intensity of their submerged hand and record it. If subject needs to remove hand prior to one minute, record their withdrawal time and record it. If subject is able to keep hand submerged for entire 60 second period, withdrawal time will be recorded as "60". **As soon as the subject removes his/her hand from the cold water**, re-administer the Algometer to either the **Dominant** forearm or trapezious and have the subject report when they first feel pain as a result of the Algometer. Once pressure pain threshold has been reported, the subject may then dry the hand off with the towel. **Following completion of the first CPM trial, begin a 2 minute rest period**.
- Repeat entire procedure for the second, third, and fourth CPM trials with a 2 minute rest period between each. Keep in mind that the site of Algometer testing will randomly go back and forth between the forearm and the trapezius

RA Note: Ask participant to take this opportunity to try using the restroom and getting some water/snacks.

RA Note: Drop the temperature on the cold pressor to 4^0C, without informing participant. While participant is out of room, take the smaller of the two buckets and collect ice from the CRU Nurses closet (with a nurse's permission) and dispense the ice into cold pressor to help obtain the proper temperature before proceeding with repeated measures.

RA Note: Prepare the grey timer to 15 minutes and have it ready to start. When you start the stopwatch for the first 30 seconds of the cold pressor, also press start on the 15 minute timer and set it to the side. This is the count down for blood draw #3.

RA Note: After participant returns, play audio instructions for how to complete the Repeated Cold Pressor Task.

Repeated Cold Pressor Task

- Once the cold pressor reaches 4^0C ask participant to immerse the hand, just as they have before into the water and start the stopwatch. **At 24 seconds following hand immersion, ask subject to rate the pain intensity of their submerged hand and record it.** Ask participant to remove their hand from the water at 30 seconds, then give them **15 seconds to dry their hand off with the provided towel.** When the 15 seconds are over, ask the participant to once again place their hand into the water for the second submersion.
- Repeat this procedure of 30 seconds hand in the water and 15 seconds out of the water a total of five times. If subject needs to remove hand prior to one minute, record their withdrawal time in seconds and give them 15 seconds to dry off before attempting to submerge their hand again.

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Final Blood Draws and Questionnaires

- For the remainder of the study, provide the participant with the rest of the questionnaires to fill out while they wait for the last 3 blood draws to be performed. **Questionnaires include Pain Interference and Intensity, Sorge 24 Hour Food Record, Sorge Dietary Habits, Drug Abuse Screening Test, State-Trait Anxiety Inventory, Penn State Cigarette Dependence Index – Cigarettes, Penn State Cigarette Dependence Index – E-cigarettes, Alcohol Use Disorders Identification Test – C, Alcohol Smoking and Substance Involvement Test, Anger PROMIS, Perceived Stress Scale, Pain Catastrophizing Scale, HIV Stigma Mechanisms, Heightened Vigilance Scale, Experience of Discrimination, Adverse Childhood Experiences.**
- Ask participant to please answer the questions in the questionnaire packet. Tell him/her to answer every question – there is no right or wrong answers. Allow them to ask questions if needed and tell them to let the experimenter know when they are finished
- Double check the questionnaires every so often to ensure that no questions are accidently skipped or double marked. If participant chooses not to answer a question, simply initial by that question and note this down in the RA Notes.
- Should the participant finish all questionnaires before the full two hours have passed, then they can be given a remote for the television in the room or they can use their own forms of entertainments. They must however remain seated in the room until their time has completed.

RA Note: When the 15 minute timer sounds off, ask a nurse to perform blood draw #3. As the nurse collects the next time point, record the time in military standard and reset the timer for 45 minutes and start it. (10mL plain red, 6mL plain red, 4mL light blue)

RA Note: When the 45 minute timer sounds off, ask a nurse to perform blood draw #4. As the nurse collects the next time point, record the time in military standard and reset the timer for 60 minutes and start it. (10mL plain red, 6mL plain red, 4mL light blue)

RA Note: When the 60 minute timer sounds off, ask a nurse to perform blood draw #5. Record the time the nurse gives you in military time and ask her to remove the cannula as this is the last blood draw for this session. (10mL plain red, 6mL plain red, 4mL light blue, 10mL yellow)

End of Session

- Non Insomnia Participants: Make sure subject does not have any questions and that they are well enough to leave. If they are feeling a little uneasy, offer them snacks and beverages provided by the CRU Kitchen (nurses can help give them something to eat or drink if needed). Remind them that their payment will be processed within the next 3 business days.
- Insomnia Participants: Confirm follow up session for the next week (**week 3**) with participant. Make sure subject does not have any questions and that they are well enough to leave. If they are feeling a little uneasy, offer them snacks and beverages provided by the CRU Kitchen (nurses can help give them something to eat or drink if needed). Remind them that their payment will be processed within the next 3 business days.

Clean Up

- Collect all of the paperwork and make sure everything that everything has been filled out, signed, dated, and/or time stamped appropriately. Collect the blood flow sheet from the nurse.
- **Using a glove, wipe down all of the equipment used during the session with a Sani wipe** (located on the door). Everything must be cleaned and packed before asking a nurse to open up the storage areas for the black rolling cart and the cold pressor.

- After the QST equipment has been packed and stored at the CRU, bring the remainder of the study's belongings back to BPRL and store in appropriate locations.