Informed Consent

Please read this informed consent carefully before you decide to participate in the study. Consent Form Key Information:

- Complete an online screening survey.
- Complete a home-and-clinic-based sleep, body weight, cardiovascular, and ecological health assessment.
- Study incentives include \$200.00 US compensation for 100% completion of the home-based portion of the study; free access to health screening documentation for completion of the labbased portion of the study.

Purpose of the research study: The overarching aim of this proposal is to acquire a more comprehensive understanding of the relationship between adiposity, sleep, and cardiometabolic factors by investigating whether normal weight subjects differ from overweight and obese subjects on these outcomes.

What you will do in the study: For the study, subjects must be 18 years of age and older and in general good health. Subjects may come from a variety of backgrounds and must be able to complete clinic-based assessment at the University of Tuscaloosa main campus. All subjects will complete an internet-based screening survey. Eligible subjects will complete a two-phase study. Phase 1 will include the collection of the following data in a laboratory environment: adiposity indices (body mass index [BMI], air displacement plethysmography, anthropometrics); and cardiometabolic measures (blood pressure; pulse wave velocity and analysis, a blood draw for biomarkers including atherogenic lipoproteins and glucose. Phase 2 will include collection of the following sleep and socioecological measures: 7 sleep diary entries, 7 nights of activity monitor entries, 7 survey sets, and a one-night home sleep test (two nights may be required if results are invalid).

Time required: The study will require about 8.5 hours of your time. Screening survey: 30 minutes; clinic-based assessment: 2 hours; home-based assessment: 6 hours. The screening survey can be completed in one sitting. The home-based assessment will include 7 sleep diary entries, 7 nights of activity monitor entries, 7 survey sets, and a one-night home sleep test. The clinic-based assessment will take approximately 2 hours to complete.

Risks:

- Screening survey. There are minimal risks associated with completion of the online screening survey. The primary risk pertains to confidentiality, rather than safety risks.
- Air-Displacement Plethysmography (aka BODPOD). There is minimal risk with air-displacement plethysmography. Mild discomfort due to the small dimension of the chamber is possible.
- Pulse wave velocity/analysis. There is minimal risk associated with the device as it is applied externally.
- Home sleep testing. There is minimal risk associated with home sleep recording. Mild discomfort from wearing the device is possible.
- Blood pressure. There is minimal risk associated with blood pressure measurement. Discomfort from the cuff and bruising is possible.
- Sleep diary and actigraphy. There is minimal risk associated with completing sleep diaries and actigraphy.
- Anthropometrics. There is minimal risk associated with collection of anthropometric data.

- Cardiometabolic biomarkers. There is minimal risk associated with the fingerstick to collect a
 drop of blood. Infection, bruising, fainting, and a small amount of bleeding is possible. As the
 subject will be in a fasted state, there are some health risks associated, including dizziness,
 decreased alertness, and symptoms associated with low blood sugar.
- Survey Sets. There are minimal risks associated with completion of the online survey sets. The primarily risk pertains to confidentiality, rather than safety risks.

Benefits: Subjects may gain satisfaction knowing they contributed to a scientific study which may someday result in better diagnostic and treatment options for obesity and sleep. They will receive a health screening related to their body composition and sleep.

Confidentiality: Every effort will be made to ensure participant privacy. Whenever feasible, identifiers will be removed from study-related information. Data obtained for the proposed study will be used for this research project only. Review of informed consent documents for Phase 1 and 2 of the study will occur face-to-face with subjects. In-lab data will be collected in the Kinesiology Lab. All paper records will be kept in locked filing cabinets located within the Principal Investigator's locked office (doubly locked) and will only be accessible to personnel involved in the study. All interactions, including phone calls and e-mails to and from subjects will comply with HIPPA regulations. E-mails to and from participants may be kept in archives but may only be sent to and from e-mail addresses in the ua.edu domain, where all correspondences are encrypted.

Voluntary participation: Your participation in the study is completely voluntary.

Right to withdraw from the study: You have the right to withdraw from the study at any time without penalty.

How to withdraw from the study: If you want to withdraw from the study, please tell the researcher and leave the room. There is no penalty for withdrawing. You will still receive compensation for the completed parts of the study (please see compensation section). If you would like to withdraw after your materials have been submitted, please contact Dr. Adam Knowlden.

Compensation: For the in-lab component of the study participants will receive no-cost access to documentation associated with the data collected during their lab visit. For the in-home component, payment will be prorated as follows: (1) 7 nights of 100% complete sleep diaries, \$50; (2) 7 nights of 100% complete activity monitor entries, \$50; (3) 7, 100% complete survey sets, \$50; (4) valid and complete home sleep test, \$50. All subjects which complete 100% of the home-based portion of the study will be paid \$200.00 US for their participation.

Using data beyond this study: The researcher would like to make the information collected in this study available to other researchers after the study is completed. Your information will be stored, used, and shared for future research studies, including but not limited to secondary analyses and meta-analyses. Researchers of future studies will not ask your permission for each new study. However, the information you provide will be combined with the information provided by others to create a large data set. Your name and other information that could potentially identify you will not be connected to the information shared with other researchers nor will they attempt to identify you.

| If you have questions about the study or need to report a study related issue please contact, contact: Name of Principal Investigator: Adam Knowlden, Ph.D. Title: Associate Professor |
|---|
| Department Name: Health Science |
| Telephone: 205-348-1625 |
| Email address: aknowlden@ches.ua.edu |
| Faculty Advisor's Name: John Higginbotham, Ph.D. Department Name: Community Health Science Telephone: 205-348-7259 Email address: jhigginb@ua.edu |
| If you have questions about your rights as a participant in a research study, would like to make suggestions or file complaints and concerns about the research study, please contact: Ms. Tanta Myles, the University of Alabama Research Compliance Officer at (205)-348-8461 or toll-free at 1-877-820-3066. You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://ovpred.ua.edu/research-compliance/prco/ . You may email the Office for Research Compliance at rscompliance@research.ua.edu . |
| Agreement: |
| \square I agree to participate in the research study described above. |
| \square I do not agree to participate in the research study described above. |
| \square I agree to video (audio, photograph) in the research study described above. |
| \square I do not agree to video (audio, photograph) in the research study described above. |
| Signature of Research Participant Date |
| Signature of Research Farticipant Date |
| |
| Print Name of Research Participant |
| |

Date

Signature of Investigator or other Person Obtaining Consent

Print Name of Investigator or other Person Obtaining Consent



HOME SLEEP APNEA TEST CONSENT AND RELEASE FORM

The Provider identified in the signature block below ("Provider", "we", "our" or "us") has received directly, or indirectly through one of our affiliates, a physician order for a home sleep apnea test ("HSAT"), for the undersigned individual ("Patient", "you" or "your"). The HSAT includes the diagnostic devices necessary to conduct such HSAT (the "Device"). We understand that your doctor has explained the HSAT to you, including its risks and benefits. We are the HSAT provider you have chosen. Under your doctor's order, we are providing you with the Device. This HSAT consent and release form (the "Consent Form") is intended to provide information about the HSAT and its attendant risks so that you may make an informed decision in providing your consent to the HSAT. Please sign this Consent Form only after you fully understand your rights and responsibilities, and all of your questions have been answered.

YOUR RESPONSIBILITIES

<u>HSAT</u>. If you have any questions or concerns related to the HSAT or Device, you must call us <u>immediately</u> at **855-478-8663**. Our support staff is available 24 hours a day 7 days a week to answer your questions about the HSAT or Device. Our support team can also offer live video support if deemed necessary.

<u>Use of the Device</u>. Pursuant to your doctor's order we are providing the Device to you and the right to use such Device is personal to you and may not transfer or assign your right to use the Device to any other individual or third party. You are the only person authorized to use this HSAT Device which is necessary to conduct the HSAT. Instructions for proper use will be provided at the time the device is delivered to you.

<u>No Guarantees</u>. By signing this Consent Form you acknowledge and agree that the practice of medicine and the administration of this HSAT is not an exact science and that no guarantees or promises are or will be made to you regarding the results of this or any other HSAT or the performance, accuracy or condition of the Device.

YOUR RIGHTS

<u>Privacy Practices</u>. We are giving you a copy of our Notice of Privacy Practices ("NPP"), which explains how we may use and disclose your health information.

<u>Acknowledgement</u>: By signing below you acknowledge and agree that: (1) you are under the supervision of your physician; (2) your physician has prescribed HSAT and you have talked about this with her/him; (3) you will not permit any other person to use the Device or participate in an HSAT; (4) we do not diagnose, write prescriptions, or act as your physician; (5) you have been given our NPP; and (6) you have read, understood and you acknowledge and agree to the terms and conditions of this Consent Form.

Research and Compliance: A research database is a tool that is used in regards to research trials and can include information about diseases. We may share your information with Associated Professional Sleep Societies, LLC's vendors related to registration, membership and 3rd party analytics services. This information can also be used for quality improvement and compliance initiatives within our organization. We will add your information into this database. By signing below you acknowledge and agree that your study data can be kept in our research database.

YOU DO NOT HAVE TO SIGN THIS CONSENT FORM.

IF YOU DO NOT SIGN, WE WILL BE UNABLE TO PROVIDE THE DEVICE NECESSARY TO CONDUCT THE HSAT.

| Printed Name of Patient: | | |
|--------------------------|---|--|
| Date of Birth: | | |
| | | |
| Signature of Patient: | | |
| 0 | | |
| | Date: | |
| | Time: | |
| Printed Name of Witness: | | |
| | | |
| Signature of Witness: | | |
| | | |
| | | |
| | Time: | |
| | | |
| Patient Phone Number: | | |
| I have received face | -to-face instruction on how to use this device (check). | |
| | | |
| | Please | |
| | initial: | |
| | Device | |
| | Number | |

SLUMBRx Study – Planning Your Visit (for details, visit: http://aknowlden.people.ua.edu/day-1.html):

- 1. Please use your Participant ID (found in document header) for all passwords.
- 2. Google acquired FitBit. Please register with Google if you do not have a Gmail e-mail account.
- 3. <u>Download</u> the FitBit app on your smart phone from <u>Google Play</u> or the <u>App Store</u> <u>before</u> your visit. Please "accept" all permissions required by the App (e.g., location, Bluetooth, notifications).
- 4. <u>Download</u> the WatchPAT ONE app on your smart phone from <u>Google Play</u> or the <u>App Store</u> <u>before</u> your visit. **Please "accept" all permissions required by the app (e.g., location, Bluetooth).**
- 5. Bring your fully charged mobile phone and know your mobile phone provider (e.g., Verizon).
- 6. <u>Recommended</u>: please bring a <u>laptop or tablet</u> with you for your Lab visit and we will show you how to use your FitBit and the study website on your device.
- 7. Arrive Fasted. Please do not eat on the day of your visit.
- 8. Avoid Caffeine 12 hours prior to your visit and Tobacco 2 hours prior to your visit.
- 9. Avoid New Forms of Strenuous Exercise and Alcohol 24 hours before your visit.
- 10. *Sip Water* on the day of your visit. Being well hydrated is necessary for the BODPOD. However, please only drink water and no other types of beverages.
- 11. Bring a list of any medications.

How to Dress for Your Visit:

- ✓ Privacy. The BODPOD machine is in a private room where you will be able to change your clothing.
- ✓ We will attempt to gender-match you for the body composition portion of this study; however, this is not always possible.
- ✓ Wear or bring **loose-fitting** shorts and a **loose-fitting**, **short-sleeved shirt** to change into.

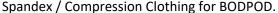
During the BODPOD, Men Must Wear:

- ✓ Form-fitting single layer/tight-fitting Lycra ©/spandex swimsuit like Speedo ©.
- ✓ Compression bike-style shorts (with NO padding) similar to Under Armour © type shorts.

During the BODPOD, Women Must Wear:

- ✓ Form-fitting single layer swimsuit in either one or two-piece. Must be of Lycra ©/Spandex © style similar to Speedo ©.
- ✓ Compression bike-style shorts (with NO padding) or volleyball-style shorts and sports bra with no padding or wires.

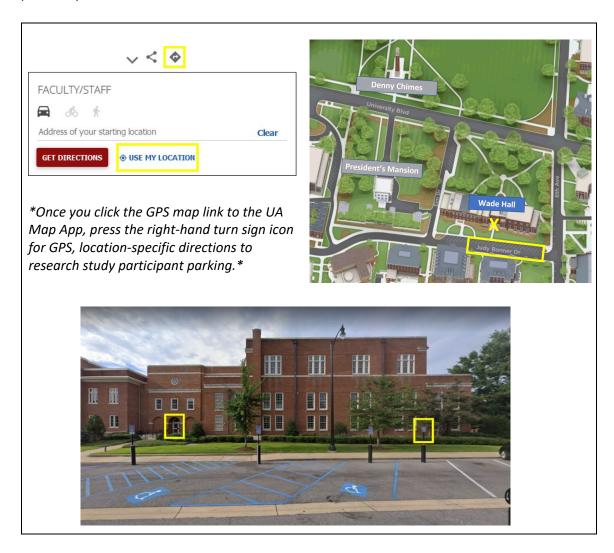






Exercise Science Lab Location & Parking:

- ✓ The first part of SLUMBRx will take place at the **Exercise Science Laboratory** at the University of Alabama, located on the second floor of Wade Hall.
- ✓ Exercise Science Laboratory Physical Address: The University of Alabama, Wade Hall, 620 Judy Bonner Drive, Tuscaloosa, AL, 35401.
- ✓ GOOGLE MAP TO WADE HALL
- ✓ The Exercise Science Lab designated parking for research study participants as well as the entrance to Wade Hall is located at 620 Judy Bonner Drive.
- ✓ GOOGLE MAP TO PARKING
- ✓ The designated parking spots reserved for research study participants are next to the handicapped parking spots (highlighted in yellow in the picture of Wade Hall as it will appear from Judy Bonner Drive, below).
- ✓ Once you park, please meet the SLUMBRx team near the rear entrance to Wade Hall that faces Judy Bonner Drive (highlighted in yellow in the picture of Wade Hall, below).
- ✓ When you arrive, a member of the SLUMBRx team will give you a parking pass that you can place on your vehicle dashboard.





SLUMBRx Quick Start Guide

Day 1: Onboarding Portion of Study

- > Take-Home Materials
 - ✓ Folder with "How To" guides for HypKnowledge Web-App, FitBit, Thigh Activity Monitor, and Overnight Home Sleep Test.
 - ✓ WatchPAT One, Overnight Home Sleep Test Kit.
 - ✓ Ziplock bag with FitBit charger, extra adhesive, and study materials.

Day 2: Start of One-Week Home Portion of Study

- Daily Text Messages
 - ✓ Click link in text messages every day.
- > Vital to wear FitBit and Thigh Activity Monitor all day and night.
 - ✓ If your FitBit needs re-charged, do not charge overnight.
 - ✓ Check for flashing green light from Thigh Activity Monitor.
- Every morning of SLUMBRx Study:
 - ✓ Use <u>HypKnowledge</u> account to:
 - o Fill out online HypKnowledge <u>Sleep Diary</u> (*sleep diary entries must be completed by 6:00 PM for the previous night's sleep to be recorded).
 - Sync FitBit to HypKnowledge; check Other Data tab to ensure data recorded.
 - ✓ Complete Activity Monitor Log.
- Overnight Home Sleep Test (Device Name: WatchPAT One)
 - ✓ Please wait for confirmation from Dr. Knowlden before you complete your Overnight Home Sleep Test; once activated, please complete the test by Day 5 of SLUMBRX.
 - ✓ Most participants only need to do the test one time.
 - ✓ If you are experience any issues with your WatchPAT One, Overnight Home Sleep Test over the duration of the SLUMBRx study, please contact MedBridge 24/7 customer support at: 1-877-249-8331.

- ✓ Please <u>use the adhesive</u> provided to secure the chest sensor in place overnight or you may need to repeat the test; *however, do not cover the top portion of the chest sensor.*
- ✓ Please wear you FitBit on your dominant hand, and the Overnight Home Sleep Test device on your non-dominant hand.

> Activity Monitor Maintenance

- ✓ If you experience any issues with your FitBit over the duration of the SLUMBRx study, please contact FitBit 24/7 customer support: 1-877-623-4997.
- ✓ Extra water-proof adhesive and alcohol swabs have been provided in case the Thigh Activity Monitor comes off or if the adhesive needs replaced.
- ✓ Electronic wipes are provided if your FitBit needs cleaning.
- ✓ FitBit is water-resistant; water lock will turn on automatically if needed; double tap FitBit screen twice, firmly, to turn off water lock.
- ✓ Thigh Activity Monitor adhesive is water-resistant; both can be worn in shower.
- ✓ Do not remove activity monitors on midnight of Day 9; leave on until you awake on Day 9.

Survey Sets

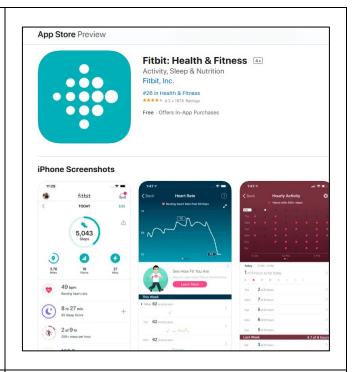
- ❖ <u>Privacy protocol:</u> All PI can see is your password and the "SUBMIT YOUR SURVEY" to ensure completion. All Co-PI can see is a spreadsheet with all participant's answers. All answers are scrambled. In this way, your survey answers cannot be connected to you.
 - ✓ Total of 5 Survey Sets
 - 1. Survey Set 1: Societal Health (30-60 minutes; complete one time).
 - 2. Survey Set 2: Social Health (30-60 minutes; complete one time).
 - 3. Survey Set 3: Personal Well-Being (30-60 minutes; complete one time).
 - 4. Survey Set 4: Personal Health Behaviors (30-60 minutes; complete one time).
 - 5. Survey Set 5: Sleep Behaviors (30-60 minutes; complete one time).
 - 6. As well as a one-time sleep disorders survey on HypKnowledge: <u>Sleep Disorders</u> <u>Survey</u> (10-20 minutes; complete one time).
 - 7. And an activity monitor log you will complete <u>each day</u>: <u>FitBit and Thigh Activity</u> Monitor Log (2-3 minutes).
 - ✓ Use your SLUMBRx password to access all surveys (see document header).
 - All can be completed from your Smart Phone, PC more efficient!
 - Can complete one Survey Set per day -- or all at once.

Meet with Dr. Knowlden at Russell Hall

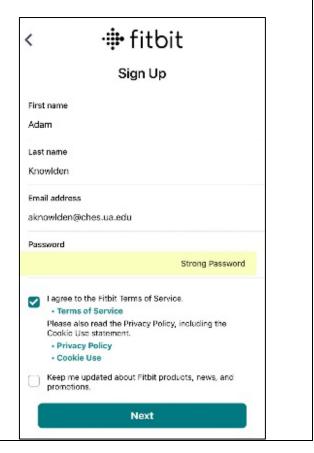
- ✓ Parking pass for BCM parking lot affixed to take home folder.
- ✓ Return FitBit, Thigh Activity Monitor, all unused materials.
- ✓ Review data to ensure it is complete.
- ✓ Please bring a copy of your work schedule for the week with the hours you worked so that we can cross-check your activity monitor logs.
- ✓ Receive a \$200 Visa gift card!
- ✓ Receive a copy of your health reports (\$500 value).

Setting Up Inspire 2 FitBit for SLUMBRx Study – User Guide

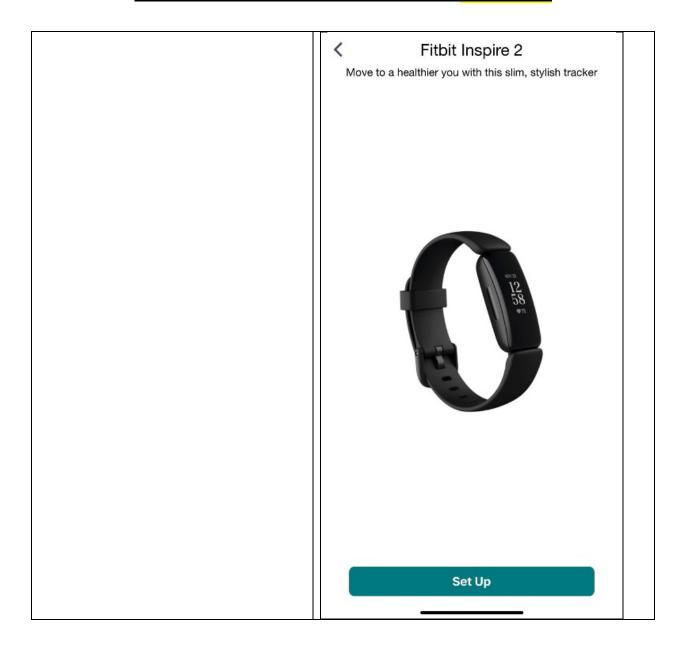
- Please download the FitBit App to your phone using either Google Play (Android) or the App Store (Apple).
- Ensure your phone is fully charged before attempting to set up your FitBit.
- If you are experiencing issues with your FitBit, please contact FitBit 24/7 customer support: (877) 623-4997
- You are welcome to call FitBit when it is convenient for you, or you may meet with Dr. Knowlden and call together.



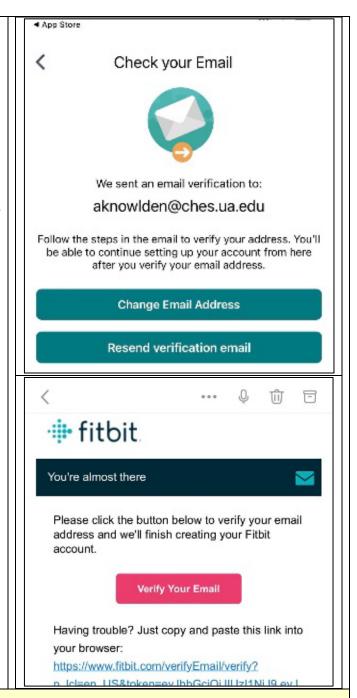
- Open the FitBit App and begin the set up process.
- Please use the e-mail address you registered for the SLUMBRx study.
- If you are setting up a new FitBit account, please be sure to write down the e-mail address and password you use to sign-up with FitBit as you will need this information to sync your FitBit to HypKnowldege, and in the event you need to contact FitBit customer support.
 - FitBit now also provides the ability to link your FitBit account to your Google account.
 - You may link your FitBit account to your Google account at your discretion as it will not affect the study.



When you move through the FitBit set up, please select the **Inspire 2** model. ■ App Store What are you setting up? Sense Versa 3 Charge 5 Inspire 2 Ace 3 - for kids! Charge 4 > Just the app Track steps with my phone >



- Please sign up for FitBit using the email address you provided when you applied to be a participant of the SLUMBRx study.
- Please contact Dr. Knowlden as soon as possible if you would like to use a different email address other than the email address you submitted as part of your application to participate in SLUMBRx.
- Otherwise, we will use the email address you provided to set up your account with HypKnowledge; the Web-App you will sync your FitBit to for each day you participate in SLUMBRx.

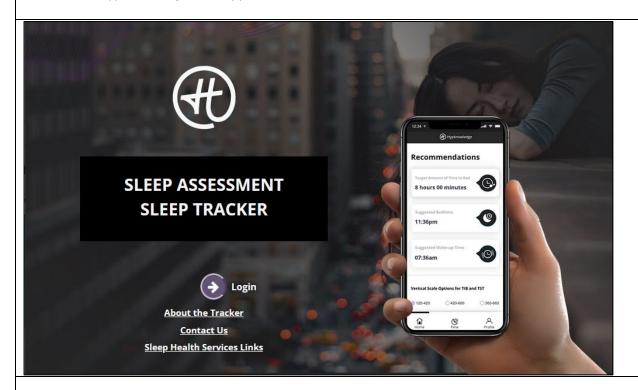


- ✓ That's it! Once you have completed the initial set up of your FitBit, we will help you set up your FitBit during your visit.
- ✓ Please be sure to save your FitBit login information with you on the day of your visit. You will also need to login to your FitBit account the first time you use HypKnowledge.

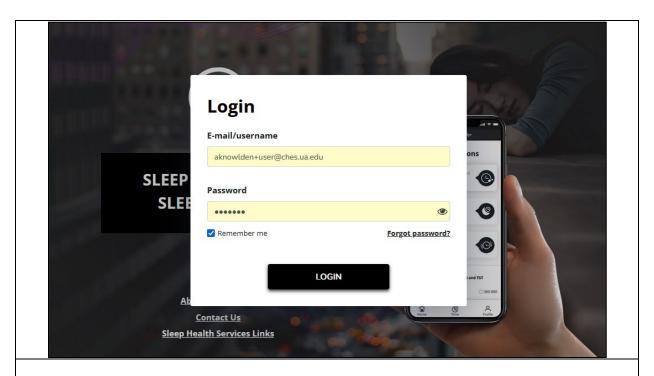
<u>Setting up HypKnowledge for the SLUMBRx Study – User Guide</u>

- HypKnowledge is a Web-app specifically designed to organize your FitBit health data. It plays a
 crucial role in the SLUMBRx study, and we genuinely appreciate your commitment to completing
 the required daily tasks for this study.
- If you wish to use a different email address than the one you provided during your application for SLUMBRx, please contact Dr. Knowlden. Otherwise, we will use the email address you provided to set up your HypKnowledge account, which is the web app you will sync your FitBit to every day of your participation in SLUMBRx.
- Please keep your Inspire 2 FitBit on throughout the entire duration of the SLUMBRx study, as the HypKnowledge Web-app relies on its continuous usage.
- Your FitBit is water resistant, allowing you to wear it even during showers.
- As the primary focus of our study is the collection of health information, we kindly request that
 you promptly reattach your FitBit if you need to remove it for any reason. This ensures continuity
 and accuracy in the gathered data.
- Please ensure that your FitBit is worn each night during your participation in SLUMBRx so that it can accurately record your sleeping patterns.
- It is important not to alter your sleep habits due to wearing the FitBit, as we are interested in your natural sleep patterns. Your sleep health information will be kept confidential and secure, with your name separated from the data.
- Your FitBit will be fully charged upon your initial visit, and the charge should last for the entire
 week of the study. However, a charger has been provided in case you need to recharge your
 FitBit.
- To ensure accurate data collection for the SLUMBRx study, please avoid recharging your FitBit overnight or during nap times. Our primary focus is on gathering your sleep health information.
- For optimal charging and activity tracking, we recommend recharging your FitBit during sedentary periods designated for work-related activities. This minimizes the risk of falling asleep while it charges and ensures accurate recording of your daily steps.
- Once you have finished charging your FitBit, please put it back on immediately. If you encounter
 any issues with your FitBit or it fails to hold a charge, please contact Dr. Adam Knowlden at any
 time at: 205-650-9026 (cell).
- If you notice that your FitBit is losing its charge rapidly, please make sure that you are accepting
 and downloading updates regularly. Neglecting to update your FitBit can result in a significant
 drain on the battery life.

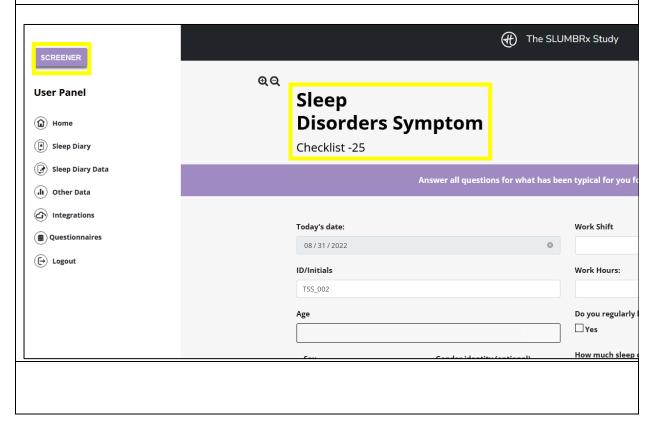
- We will create a HypKnowledge account for you using the email address you provided during your SLUMBRx enrollment. Your password will be provided to you during your visit, and we kindly ask that you refrain from changing it.
- Each day of your participation in SLUMBRx, please log in to the HypKnowledge Web-app using a personal computer, laptop, or tablet, using the email and password provided during your visit.
 Please note, the phone app for HypKnowledge is not fully developed. Please access HypKnowledge via the Web, instead of through the phone app.
- Visit the HypKnowledge Web-app site.

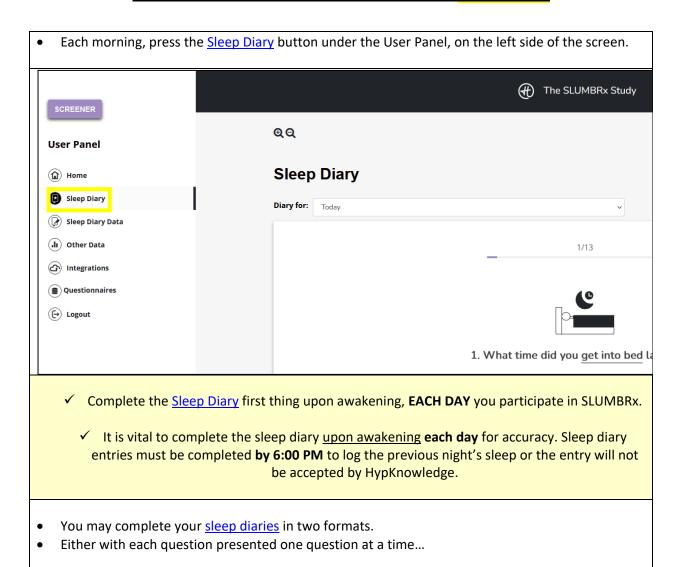


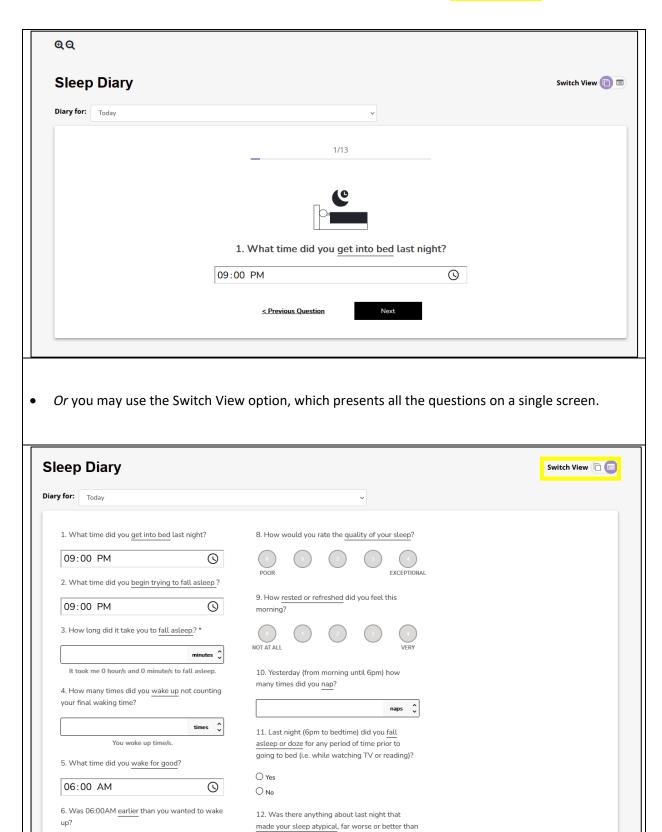
- Login to the HypKnowledge Web-App using the e-mail you provided with your SLUMBRx study application, and the password provided to you during your visit to the Exercise Science Lab.
- Before you login, you can select the "Remember Me" box so that you do not need to enter your login information each time you visit the site.



- Please complete the *Sleep Disorders Symptom Checklist-25*. You only need to complete this screener **one** time.
- To access the *Sleep Disorders Symptom Checklist-25*, please press the purple "Screener" button on the left side of the screen.





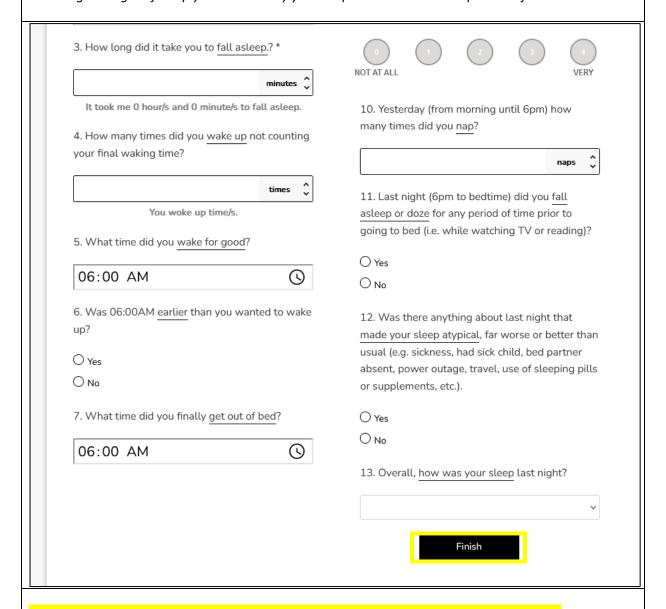


usual (e.g. sickness, had sick child, bed partner

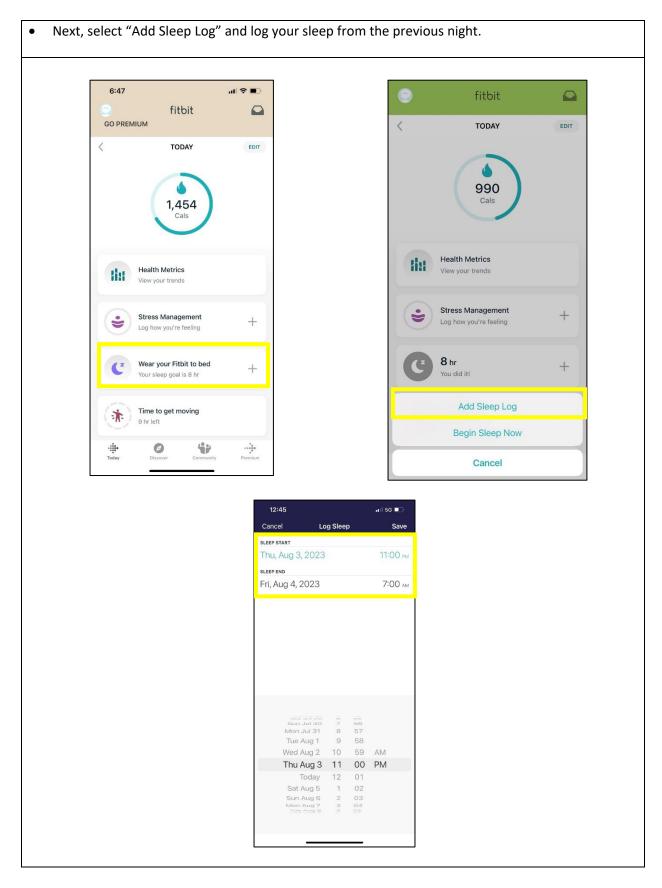
absent, power outage, travel, use of sleeping pills

O Yes

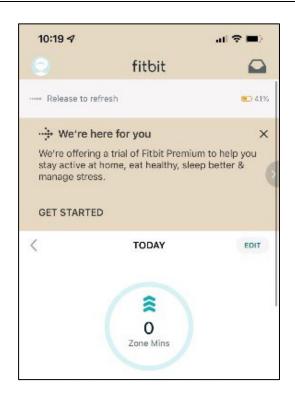
- Once you finish your daily sleep diary, please press the "FINISH" button.
- Sleep diary entries must be completed **by 6:00 PM** for the previous night's sleep or the entry will not be accepted by HypKnowledge. *If you miss an entry, please contact Dr. Knowlden.*
- Before you begin the home-based portion of SLUMBRx, please practice entering a sleep diary entry using the night of sleep you had the day you completed the lab-based portion of SLUMBRx.

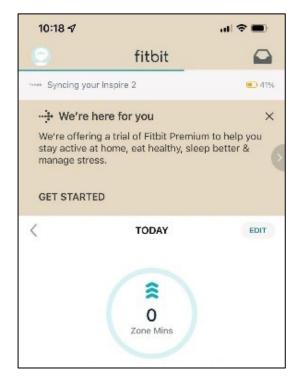


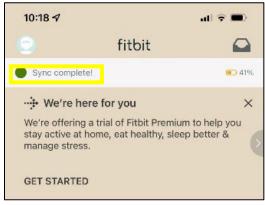
- Next, we will begin the process of syncing your FitBit to the HypKnowledge Web-App.
- To practice the daily FitBit to Hypknowledge sync, we will manually enter a sleep log from your previous night's sleep in the FitBit app.
- This one-time manual sleep log will allow you to practice syncing your FitBit to HypKnowledge.
 Going forward, your FitBit will automatically record your sleep, so you will not need to enter a sleep log manually into your FitBit app after this trial run.
- To enter a manual sleep log into the FitBit app, begin by opening the FitBit app on your phone.
- Press the "+" on the "Wear Your FitBit to Bed" icon.



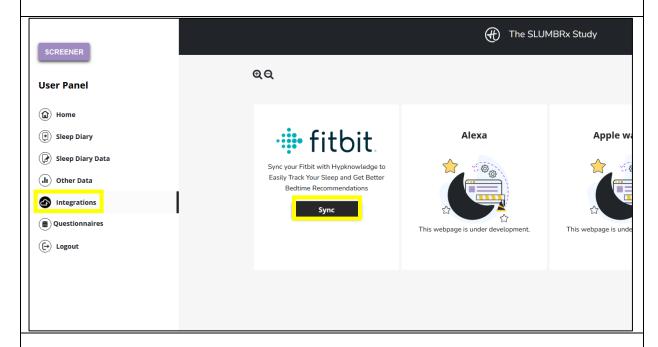
- Once you have entered a sleep log on your FitBit, go to the User Panel on the <u>HypKnowledge</u> Web-App.
- Press the <u>Integrations</u> button icon.
- First sync your FitBit from your FitBit phone app.
 - o To do so, open the FitBit app on your phone.
 - Next, pull your screen down using the touch screen feature of your phone, and release your finger.
- Your FitBit will then sync to the FitBit app on your phone.



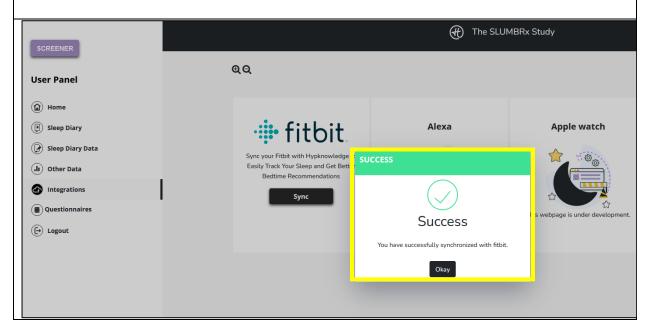




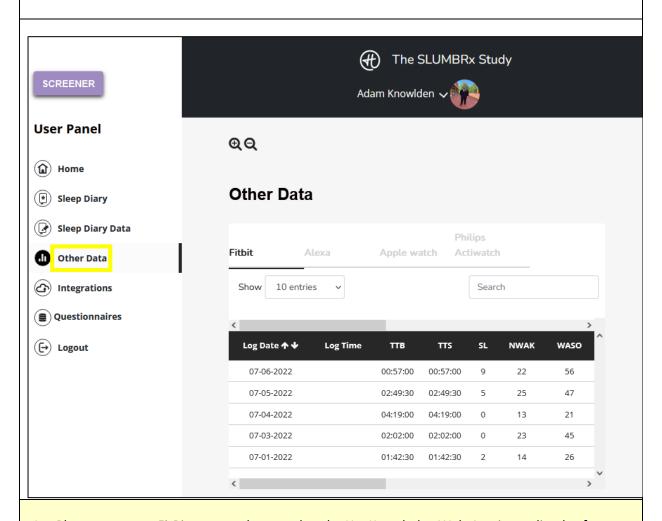
• Then press the Sync button under the FitBit icon in the HypKnowledge Web-App



- This will sync your FitBit to the HypKnowledge Web-App
 - The <u>first time</u> you sync your FitBit with HypKnowledge you will need to enter your FitBit login information.
 - Upon doing so, <u>if you are prompted</u>, select which data to sync (e.g., activity and exercise, profile, heart rate, Fitbit devices and settings, and sleep), please allow HypKnowledge to sync to all available options.



- ✓ Press the Other Data button under the User Panel to double check your FitBit synced with the HypKnowledge Web-App.
- ✓ You should see an entry for the night of sleep you manually logged.
- ✓ Going forward, please do not manually enter your sleep information for your FitBit.
- ✓ This first entry is only done to ensure your FitBit is syncing to HypKnowledge correctly.
- ✓ For the remainder of SLUMBRx, you will not need to enter a manual sleep log. Your sleep will record automatically. You can check that your sleep is being recorded by pressing the "Wear Your FitBit to Bed" icon.
- ✓ Please sync your FitBit to the HypKnowledge Web-App **each day** after you complete your sleep diary. If you go to the <u>Other Data</u> tab and you do not see your sleep data syncing to HypKnowledge, please contact Dr. Knowlden.

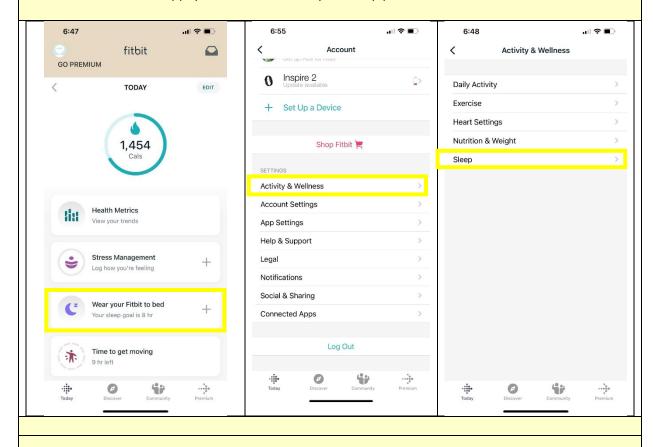


- Please sync your FitBit to your phone and to the HypKnowledge Web-App immediately after you complete your sleep diary, EACH DAY you participate in SLUMBRx.
- 2. It is important to sync your FitBit to HypKnowledge each day, right after you complete your daily sleep diary, for accuracy.

FitBit / HypKnowledge Sync Trouble Shooting

FitBit 24/7 customer support: (877) 623-4997

- 1. You may need to sync your FitBit on the FitBit phone app (e.g., pulling down on your phone screen from the FitBit app home page) to get your FitBit to sync to HypKnowledge.
- 2. If you are not seeing your FitBit data under the "Other Data" tab, please be sure that your FitBit is recording your sleep.
- If it is recording your sleep, you will see the "Wear your FitBit to Bed" icon on your profile page on the FitBit phone app. If you do not see this option, please go to Profile > Settings > Activity & Wellness > Sleep
- If you do not see an option to select "Sleep", please contact Dr. Knowlden.
- If your FitBit is recording your sleep, when you press "Wear your FitBit to Bed" on the main screen in the FitBit app, you will see data for your sleep present.



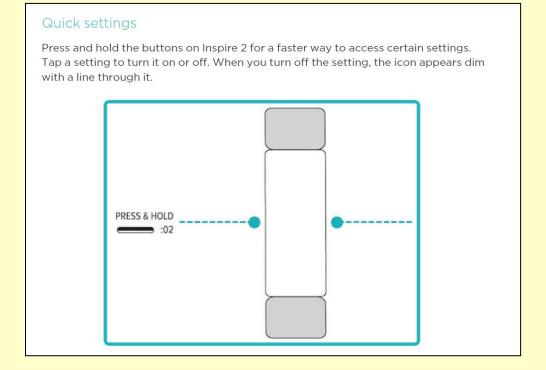
3. Please accept all notification and blue tooth requests from the FitBit app. If notified by the app, please install any updates available for your FitBit. Failure to install pending updates can cause the battery to drain unusually fast. To check battery level ->

From the clock face, swipe up. The battery level is at the top of the screen.

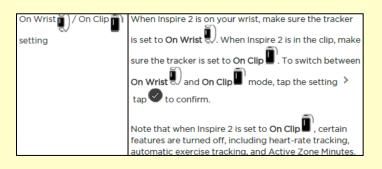
10:34

Wed
31 Feb

- 4. Your FitBit is water resistant but will automatically turn on its Water Lock if it detects water. The water lock can prevent your FitBit from syncing to HypKnowledge. Firmly double tap the FitBit screen to <u>turn off</u> the water lock.
- 5. On occasion, check your FitBit is monitoring your heart rate. To see your heartrate, Swipe up from the clock face. If you do not see your heart rate, which is needed to track your sleep, check that your FitBit is not set to "On Clip". If it is, switch it to "On Wrist." To check, go into Quick Settings:



Then make sure your FitBit is set to On Wrist and NOT On Clip



SLUMBRx Study: Daily Tasks Checklist



-CLICK LINK IN TEXT MESSAGES EVERY DAY-

| Date | Day | Task | Complete? |
|------|----------|--|-----------|
| | 1 | Study On-Boarding | |
| | | Visit to Exercise Science Lab | |
| | <u>2</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | Survey Set 1 | |
| | 2 | Overnight Home Sleep Test Sleep Biograf (court accordate by Cooperat) | |
| | <u>3</u> | Sleep Diary (must complete by 6:00 PM) Sync FitBit | |
| | | Sync FitBit Activity Monitor Log | |
| | | Survey Set 2 | |
| | | Overnight Home Sleep Test (if not yet done) | |
| | <u>4</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | Survey Set 3 | |
| | | Overnight Home Sleep Test (must be done by Day 5) | |
| | | | |

| Date | Day | Task | Complete? |
|------|----------|---|-----------|
| | <u>5</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | • Survey Set 4 | |
| | | Overnight Home Sleep Test (last day to complete) | |
| | <u>6</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | Survey Set 5 | |
| | | Contact Dr. Knowlden ASAP if Overnight Home Sleep Test not yet done | |
| | <u>7</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | <u>8</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | Sleep Disorders Symptom Screener | |
| | <u>9</u> | Sleep Diary (must complete by 6:00 PM) | |
| | | Sync FitBit | |
| | | Activity Monitor Log | |
| | | Meet Dr. Knowlden | |

Quick Tips and Trouble Shooting

Overnight Home Sleep Test

- ✓ Please use the <u>adhesive</u> provided to secure the chest sensor in place overnight. Most participants that do not use the tape must repeat the Overnight Home Sleep Test due to the chest sensor coming off.
- ✓ Please call MedBridge 24-hour customer support line at 877-249-8331 if you have any questions or issues with your Overnight Home Sleep Test.

FitBit Activity Monitor

- ✓ Please <u>install updates</u> that become available for the FitBit during the study; failure to install available updates drains the battery unusually fast.
- ✓ If your <u>FitBit</u> needs re-charged, please <u>do not re-charge it</u>: (1) overnight; (2) if you lay down for a nap; or, (3) if you think you might fall asleep when sitting or lying down.
- ✓ We recommend <u>re-charging your FitBit when you are sedentary for work-related purposes</u>. This will help make sure you don't fall asleep while it is re-charging, but you also will not be very active during this time and miss counted steps (the FitBit also tracks your total daily steps).
- ✓ Check that your FitBit is monitoring your heart rate by swiping up from the clock face. If it is not recording your heart rate, the FitBit may be set to "On Clip" instead of "On Wrist". To check, squeeze the side of your FitBit for 2 seconds and scroll down until you see either "On Wrist" or "On Clip". If "On Clip" change to "On Wrist."

• HypKnowledge Web-App

- ✓ If you are having trouble syncing your FitBit to HypKnowledge, first try syncing the FitBit to your FitBit phone App by "pulling" the screen on your phone down.
- ✓ If the Water Lock is activated on your FitBit, it may also prevent your data from syncing to HypKnowledge. To turn off the Water Lock, firmly double tap the middle of the screen with your finger.

• Thigh Activity Monitor

- ✓ On occasion, please check to ensure the green light is flashing at the bottom of the activity monitor (flashes every 6 seconds). If not, please contact Dr. Knowlden.
- ✓ If the adhesive from the bandage is bothering your skin, please contact Dr. Adam Knowlden.

How do I wear the activity monitor?

- The Activity Monitor is attached directly onto the skin and positioned on the front of the right thigh, about 1/3 of the way between hip and knee with the stick man standing up (see picture). If the activity monitor comes off during the assessment period, please try your best to attach the monitor in the same part of your leg where it was placed by the research team.
- Please wear the monitor every day for 7 full days, only removing the monitor on the date of your return visit.
- You can remove the monitor the morning of your return visit
 or wait and remove the monitor during your return visit. If you
 remove the monitor the morning of your return visit, please place the monitor in the plastic
 bag provided by the research
 team.
- Please wear the activity monitor continuously (24 hours per day) for 7 full days. This may include both working and non-working days.
- The activity monitor can be worn during sleep and is water resistant (up to 1 meter), so you can wear it while showering and bathing.
- If you swim for exercise or recreation, please inform the research team at your initial visit. They will provide further instruction.
- The adhesive patch that sticks the activity monitor to your skin may last up to 7 days. If you experience irritation, you may want to change the adhesive patch with the extra adhesive provided by the research team. You can also cut the adhesive patch in half to reduce irritation.
- **Note:** The activity monitor will emit a green flash every 6 seconds. This is an indication that it is working and recording data.

- Remove the activity monitor from your thigh (note that this may cause some slight discomfort) and peel the adhesive patch off the monitor. The monitor is covered in a waterproof sleeve — please make sure that this protective covering remains on the monitor when you do this.
- With one of the alcohol prep pads provided to you, thoroughly wipe down the monitor and the area of your leg where the activity monitor was attached.
- Position the activity monitor in the same spot as previously on your thigh, ensuring that the stick figure on the front of the activity monitor is standing up (head facing upwards).
- Peel the backing off an adhesive patch and place it over the activity monitor. Press the patch onto your skin, peel back the top layer of the patch and smooth out the air bubbles and wrinkles as much as possible to ensure that the activity monitor is firmly secured to your thigh.
- If you require assistance re-attaching your activity monitor, or if you experience any skin irritation while wearing it, please contact Dr. Adam Knowlden at aknowlden@ches.ua.edu or (205) 348-1625.



OVERNIGHT HOME SLEEP TEST 24/7 CUSTOMER SUPPORT:

877-249-8331



- ✓ The WatchPAT One is the name of the Overnight Home Sleep Test device
 you will use for the SLUMBRx study. You will only need to do the Overnight
 Home Sleep Test one time over the duration of the SLUMBRx study.
 - ✓ Index fingernail of non-dominant hand (used for WatchPAT ONE finger sensor), should be short and without fingernail polish when you complete your test.
- 1. Download the WatchPAT ONE App on your smart phone from <u>Google Play</u> or the <u>App Store</u>. Please "accept" all permissions required by the App (e.g., location, Bluetooth).
- 2. Wait for confirmation from Dr. Knowlden that your Overnight Home Sleep Test is activated, **BEFORE** you complete your Overnight Home Sleep Test.
- 3. Please note, your Overnight Home Sleep Test must be completed by Day 5 of the SLUMBRx study. We recommend you complete your test as soon as your schedule permits (e.g., the weekend you are in SLUMBRx) to avoid device deactivation.

<u>IMPORTANT</u>: DO NOT TURN THE DEVICE ON UNTIL YOU ARE READY TO BEGIN YOUR SLEEP TEST.

- 4. When ready for bed: Follow the step-by-step instructions in the WatchPAT One app to activate your Overnight Home Sleep Test. For additional device directions, including video instruction, visit the WatchPAT ONE video on YouTube.
- 5. <u>Keep your FitBit on during the Overnight Home Sleep Test;</u> however, please attach your FitBit to your dominant hand and your WatchPAT ONE to your non-dominant hand.
- 6. <u>Use the adhesive</u> provided to secure the chest sensor in place overnight. Do not cover the top portion of the chest sensor.
- 7. Please note, you will be prompted to enter a PIN when starting the test. The PIN assigned to you is the last 4 digits of your phone number (XXX) XXX-XXXX
- 8. Once your test is completed, please contact Dr. Knowlden to let him know. Once Dr. Knowlden confirms your data was received, you may dispose of the WatchPAT One device.
 - ✓ If you experience any issues setting up your Overnight Home Sleep Test, please contact MedBridge 24/7 customer support at: 877-249-8331