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 lab-based 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; clinicbased 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 <u>http://ovpred.ua.edu/research-compliance/prco/</u>. You may email the Office for Research Compliance at <u>rscompliance@research.ua.edu</u>.

Agreement:

□ I agree to participate in the research study described above.

 \Box I do not agree to participate in the research study described above.

 \Box I agree to video (audio, photograph) in the research study described above.

 \Box I do not agree to video (audio, photograph) in the research study described above.

Signature of Research Participant

Print Name of Research Participant

Signature of Investigator or other Person Obtaining Consent

Print Name of Investigator or other Person Obtaining Consent

Date

Date



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.

<u>Research and Compliance:</u> 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:		
Date of Birth.		
Signature of Patient:		
	Date:	
	Time:	
Printed Name of Witness		
Thirtee Name of Writess.		
Signature of Witness:		
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	Time:	
Patient Phone Number:		
I have received face	-to-face instruction on how to use this device (check).	
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	initial:	
	Device	
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<u>SLUMBRx Study – Planning Your Visit (for details, visit: http://aknowlden.people.ua.edu/day-1.html):</u>

- 1. Please use your Participant ID (found in document header) for all passwords you are requested to use during the study.
- 2. <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. Use the e-mail you registered with for the SLUMBRx study and use your SLUMBRx study password as your FitBit App password. Please "accept" all permissions required by the App (e.g., location, Bluetooth, notifications).
- 3. <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).
- 4. Bring your *fully charged* mobile phone and know your mobile phone provider (e.g., Verizon).
- 5. Arrive Fasted. Please do not eat on the day of your visit.
- 6. Avoid Caffeine 12 hours prior to your visit and Tobacco 2 hours prior to your visit.
- 7. Avoid Strenuous Exercise and Alcohol 24 hours before your visit.
- 8. *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.
- 9. 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.



Spandex / Compression Clothing for BODPOD.



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.
- ✓ GPS 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.
- ✓ GPS MAP TO PARKING
- ✓ The designated parking spot reserved for research study participants is next to the handicapped parking spot (highlighted in yellow in the picture of Wade Hall as it will appear from Judy Bonner Drive, below).
- ✓ Once you park, please meet Dr. Knowlden 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.

FACULTY/STAFF	:		
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Address of your sta	rting location	Clear	

Once you click the GPS map link to the UA Map App, press the right-hand turn sign icon for GPS, location-specific directions to research study participant parking.







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 <u>link</u> in text messages every day.

> Vital to wear FitBit and Thigh Activity Monitor all day and night.

- ✓ If your <u>FitBit</u> needs re-charged, <u>do not</u> charge overnight.
- ✓ Check for flashing green light from <u>Thigh Activity Monitor.</u>

> Every morning of SLUMBRx Study:

- ✓ Use <u>HypKnowledge</u> account to:
 - 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).
 - <u>Sync FitBi</u>t to HypKnowledge; check <u>Other Data</u> tab to ensure data recorded.
- ✓ <u>Complete Activity Monitor Log.</u>

Overnight Home Sleep Test (Device Name: <u>WatchPAT One</u>)

- 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 <u>MedBridge</u> 24/7 customer support at: <u>1-877-249-8331</u>.

- 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 <u>FitBit 24/7 customer support</u>: <u>1-877-623-4997</u>.
- ✓ 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

- ✓ Total of 5 Survey Sets <u>Survey Set 1: Societal Health</u> (30-60 minutes; complete one time). <u>Survey Set 2: Social Health</u> (30-60 minutes; complete one time). <u>Survey Set 3: Personal Well-Being</u> (30-60 minutes; complete one time). <u>Survey Set 4: Personal Health Behaviors</u> (30-60 minutes; complete one time). <u>Survey Set 5: Sleep Behaviors</u> (30-60 minutes; complete one time).
- ✓ As well as a one-time sleep disorders survey on HypKnowledge: <u>Sleep Disorders</u> <u>Survey</u> (10-20 minutes; complete one time).
- ✓ And an activity monitor log you will complete <u>each day</u>: <u>FitBit and Thigh Activity</u> <u>Monitor Log</u> (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 for completing surveys.
 - Can complete one Survey Set per day -- or all at once.

Follow-Up Meeting

- > Meet with Dr. Knowlden at Russell Hall
 - ✓ Parking pass affixed to take home folder.
 - ✓ Return FitBit, Thigh Activity Monitor, 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



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Setting up HypKnowledge for the SLUMBRx Study – User Guide

- 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 <u>HypKnowledge</u> 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.

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Or you may use the Switch Sleep Diary ary for: Today 1. What time did you get into bed last night? 09:00 PM 2. What time did you begin trying to fall asleep 09:00 PM 3. How long did it take you to fall asleep?* 1. took me 0 hour/s and 0 minute/s to fall asleep. 4. How many times did you wake up not countin your final waking time? 1. took me di you wake for good? 06:00 AM 6. Was 06:00AM earlier than you wanted to wal up?	8. How would you rate the quality of your sleep? 9. How rested or refreshed did you feel this morning? 9. How rested or refreshed did you feel this morning? 10. Yesterday (from morning until 6pm) how many times did you nap? 11. Last night (6pm to bedtime) did you fall asleep or doze for any period of time prior to going to bed (i.e. while watching TV or reading)? 12. Was there anything about last night that made your sleep atypical, far worse or better than usual (e.g. skiness had side child bed partner	s on a single screen.

- 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.

It took me 0 hour/s and 0 minute/s to fall asleep.	10. Yesterday (from morning until 6pm) how
4. How many times did you <u>wake up</u> not counting your final waking time?	many times did you <u>nap</u> ?
times 🗘	11. Last night (6pm to bedtime) did you fall
You woke up time/s.	asleep or doze for any period of time prior to
5. What time did you wake for good?	going to bed (i.e. while watching TV or reading)?
06:00 AM	○ Yes ○ No
6. Was 06:00AM <u>earlier</u> than you wanted to wake up?	12. Was there anything about last night that made your sleep atypical, far worse or better than
⊖ Yes	usual (e.g. sickness, had sick child, bed partner
⊖ No	or supplements, etc.).
7. What time did you finally get out of bed?	○ Yes
06:00 AM	O No
	13. Overall, how was your sleep last night?
	~
	Finish
ext, we will begin the process of syncing you o practice the daily FitBit to Hypknowledge sy	reitbit to the Hypknowledge Web-App. /nc, we will manually enter a sleep log from y
revious night's sleep in the FitBit app.	
his one-time manual sleep log will allow you t	o practice syncing your FitBit to HypKnowledg



Questions? Contact Dr. Adam Knowlden: <u>aknowlden@ches.ua.edu</u>

- 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.
 - 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.

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• Then press the Sync button under the FitBit icon in the <u>HypKnowledge</u> Web-App					
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 This will sync your FitBit to the <u>Hy</u> The <u>first time</u> you sync you login information (please password). Upon doing so, <u>if you are p</u>profile, heart rate, Fitbit d sync to all available option 	pKnowledge Web-App ur FitBit with HypKnowle use the e-mail you signe prompted, select which a levices and settings, and ns.	edge you will need to en d up with and your SLUI data to sync (e.g., activit sleep), please allow Hyp	ter your FitBit MBRx y and exercise, Knowledge to		
SCREENER User Panel	٩	H The SLUMBRX	Study		
 Home Sleep Diary Sleep Diary Data Other Data Other Data Integrations Questionnaires Logout 	Success Sync your Fitbit with Hypknowledge Easily Track Your Sleep and Get Batt Bedtime Recommendations Sync You	Alexa s S Success have successfully synchronized with fitbit.	Apple watch		

- ✓ Press the <u>Other Data</u> 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.

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 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.

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- 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:



SLUMBRx Study: Daily Tasks Checklist



-CLICK LINK IN TEXT MESSAGES EVERY DAY-

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

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

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 <u>24-hour customer support</u> line at <u>877-249-8331</u> 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</u> <u>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.

• <u>Thigh Activity Monitor</u>

- ✓ 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.



- ✓ 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 <u>one</u> <u>time</u> over the duration of the SLUMBRx study.
- ✓ Index fingernail of non-dominant hand (used for WatchPAT ONE finger sensor), should be short and <u>without</u> 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.
- 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. <u>When ready for bed:</u> 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 <u>WatchPAT ONE video</u> 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: <u>877-249-8331</u>

Thigh Activity Monitor Instructions

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.

How do I change the adhesive patch?

- 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 <u>aknowlden@ches.ua.edu</u> or (205) 348-1625.