INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**BetterNight Services / "ASSESSING THE UTILITY OF A REMOTE PATIENT MONITORING PLATFORM FOR IMPROVING CPAP ADHERENCE FOR OBSTRUCTIVE SLEEP APNEA"**
Principal Investigator: (Study Doctor)	**Dominic Munafo, MD**
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BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you have obstructive sleep apnea (OSA) and your doctor has prescribed CPAP (continuous positive airway pressure) or APAP (automatic positive airway pressure) therapy. This research study is comparing the MonitAir remote patient monitoring (RPM) program with BetterNight's standard-of-care (SOC) program in subjects with OSA receiving continuous positive airway pressure (CPAP) therapy for the first time. This study will also compare adherence rates and subject satisfaction of the two programs. BetterNight Services is sponsoring this research study.

OSA is the most common form of sleep-disordered breathing (SDB) and is characterized by repetitive complete or partial collapse of the upper airway during sleep. First-line therapy for OSA is continuous positive airway pressure (CPAP), which improves symptoms including excessive daytime sleepiness, fatigue, memory impairment, and depressed mood.

About 200 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?
Your participation in this study will last approximately 90 days.

You will be randomly assigned by chance (like the flip of a coin) to take part in MonitAir RPM program or the BetterNight's program.

If you are assigned to the BetterNight program, the PAP (positive airway pressure)device provided by your doctor comes with on-going monitoring software. When the device is

shipped to you BetterNight staff will enroll the device for monitoring through their electronic medical record system, Brightree. Once your device has been set up and confirmed to be transmitting, study data sleep coaches will be able to track your progress in their system, Clarity. Once your CPAP starts transmitting data, your participation in the program will begin.

If you do not want to be part of the Clarity monitoring program, this will be documented.

Once confirmed that you have received the CPAP device you will be sent a link to the BetterNight portal. You will be provided with a video on how to set up your device and invited to schedule a 30 minute remote appointment if needed. While participating in the program you will be able to schedule a remote coaching session at any time through the BetterNight portal.

Data that is transmitted will allow study coaches to obtain adherence reports that can be provided to you or your doctor.

Device adherence will be assessed through the Clarity system on days 10, 20, 45, and 60. If you are not adhering to device usage you will be contacted by a study coach for follow up.

Day 80 is the last check for the 90 day adherence period. You will be given recommendations regarding continuing the continuation of treatment.

If you are assigned to the MonitAir RPM program, your will have a ResMed, Respironics, or React device that is eligible for RPM enrollment. A study coach will reach out within 72 hours.

MonitAir data will be reviewed by a study coach weekly and you will receive a text message. Weekly review will occur on days 7, 14, 21, 28, 35, 42, 49, 56, 63, 70, 77, 84, and 90.

At least once per month you will have an audio or video visit with a study coach. If initial contact is made within the 72 hours that will qualify as the first months visit.

A study coach may reach out to you as needed based on MonitAir data review and you are encouraged to call the coach as needed at any time.

EXPECTATIONS
If you participate in this study, you will be expected to complete the visits with study coaches.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS
All subjects will be initiating CPAP or APAP therapy as prescribed by their doctor. The only difference between the MonitAir RPM and BetterNight's programs is how the data is monitored.

All subjects will be monitored for typical CPAP/APAP associated side effects adverse events including but not limited to:

- Dry nasal passages
- Dry eyes
- Rhinorrhea (runny nose)
- Facial soreness
- Epistaxis (nosebleed)
- Respiratory infection

There may be other risks that are unknown.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
You will not receive any monetary compensation for your participation in this study.

CONFIDENTIALITY
Records of your participation in this study will be held in confidence except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS
There will be no charge to you for your participation in this study. The study-related procedures will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00075191.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of BetterNight Services.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the Sonu works and is safe.
- To compare the Sonu to the standard of care.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date