RESEARCH SUBJECT CONSENT FORM

TITLE:	Evaluation of an Incentive-based Intervention to Improve 90-day Adherence in PAP-Naïve Patients: Project Dahlia
PROTOCOL NO.:	SLP-18-08-01 WIRB® Protocol #20190087
SPONSOR:	ResMed
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you, if needed.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to test whether an app on a smartphone (called Restful made by Wellth) can help people get used to and keep using their CPAP therapy. You are being asked to consider participating in the study because you are new to CPAP therapy. If you choose to participate you will be evaluated to determine if you are eligible (a good candidate) for the study.

Restful is a smartphone-based patient engagement tool that utilizes concepts from behavioral economics to help patients improve their adherence to therapy. The intervention includes a financial incentive and a social incentive.

About 300 subjects will take part in this research.

How long will I be in this research?

The total duration of your participation in this study will be 6 months (180 days). Study visits may be done in person, on the phone, or by email.

What happens to me if I agree to take part in this research?

Before any study-related procedures are performed, you will be asked to read and sign this consent document. If you choose to participate and you are eligible for the study, you will be randomly (by chance, like the flip of a coin) assigned to one of two groups: Group A or Group B. You have a 66% chance (2 in 3) of being assigned to Group A and a 33% chance (1 in 3) of being assigned to Group B.

If you are selected for **Group A**, you will be asked to complete some questionnaires and continue to use your CPAP device at home. Your mode of therapy and treatment pressure will not be altered in this study. The study will continue for 6 months after you are enrolled. You will be asked to complete another set of questionnaires after 3 months has passed. Your daily CPAP usage data will be collected from your device through 6 months after your enrollment in the study. If you use the myAir online support program and app during the study, your usage of the app will be collected through 6 months after your enrollment in the study.

If you are selected for **Group B**, you will be asked to complete some questionnaires, and you will be contacted by a representative of Wellth to help you download and get registered for Restful. You will also continue to use your CPAP device at home. Your mode of therapy and treatment pressure will not be altered in this study. The study will continue for 6 months after you are enrolled. You will be asked to complete another set of questionnaires after 3 months has passed. Your access to the Restful will be stopped after 3 months. Your daily CPAP usage data will be collected from your device through 6 months after your enrollment in the study. If you use the myAir online support program and app during the study, your usage of the app will be collected through 6 months after your enrollment in the study.

Study Entry
If you choose to participate, you will complete an entry visit. At the entry visit, the following information will be collected:

- Demographic information
- Questionnaires related to your quality of life and social attitudes

If you are assigned to Group B, you will be contacted by Wellth to setup the Restful app. You will be asked if you would like to nominate someone for the social support part of the app. This can be your spouse, a friend, a sister or brother—someone you trust. You are not required to nominate someone, but if you do, they will be contacted by Wellth and asked if they would like to participate.

During the Study

For both Group A and Group B, you will use your CPAP device at home as usual. The study staff will monitor your usage and may contact you according to their normal practice.

If you are in Group B, you will also receive occasional outreach such as phone calls or text messages from the Restful program.

Follow-up Contact

At 90 days (3 months) after you started your therapy, you will be asked to complete another set of questionnaires. Restful will be turned off for Group B.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing the questionnaires in a timely manner.

Could being in this research hurt me?

This study is considered to be of low risk to you. You will use your CPAP therapy as prescribed. The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

Will it cost me money to take part in this research?

The sponsor will provide Restful at no cost to you.

You will not need to pay for any of the visits, tests, or procedures which are done just for this study. However, you and/or your health plan will need to pay for any tests and procedures that you would normally have as part of your regular medical care.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include improving your adherence to CPAP therapy. Information learned from the study may help other people improve their adherence to CPAP therapy in the future.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical records will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor (such as Wellth)
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study investigator immediately. The study investigator will provide guidance on medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the FDA or the sponsor
- You are unable to use CPAP therapy
- You are unable to complete the study procedures

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can provide you with the end of study questionnaires for completion.

Will I be paid for taking part in this research?

There are no payments for any screening evaluations performed to assess your eligibility.

However, if you are enrolled into the study, you will receive $25 for completing 2 questionnaires, one at the start of the study and one at the end of the study. You will only receive $25 if you complete both questionnaires.

Additionally, participants randomized to Group B may receive another payment of $75. This payment depends on your adherence to CPAP therapy and will be paid at the 3-month study contact. The number of hours you use therapy is determined from the data transmitted by your CPAP device.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

HIPAA Authorization Agreement
Permission to Review, Use, and Release Information about You

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

- Your name.
- Address.
- Phone number.
- Email address.
- 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 research team may share health data about you with authorized users. Authorized users may include:

- Representatives of ResMed Corp
- Representatives of Wellth
- Representatives of WIRB (a Research Ethics Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other US governmental agencies
- Governmental agencies of other countries
- Other authorized users

The sponsor and those working for the sponsor may use the health data sent to them:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law.

Your permission to use and share health data about you [will not end OR will expire [Date].]

You may take back your permission to use and share health data about you at any time by writing to the study doctor. 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 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 this form.

_____ ___ / ___ / ___
Signature of Adult Research Subject Date

_____
Printed Name of Research Subject