

**Evaluation of an Incentive-based Intervention to
Improve 90-day Adherence in PAP-Naïve Patients:
Project Dahlia**

Investigational Plan

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Sponsor: **ResMed Corp**
9001 Spectrum Center Blvd
San Diego, CA 92123
(800) 424-0737

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This protocol has been written in accordance with current applicable guidelines (IDE for USA) as well as all other relevant additional references, medical and legal.

The information herein is confidential and the property of ResMed Corp. It is to be used in confidence for the conduct of the clinical trial according to written agreement.

Version History

Version	Date	Notes
1.0	10Jan2019	Original Version
2.0	08Jul2019	Removed inclusion criteria for patients to have used their device less than an average of 3.5 hours of usage in the first 3 days of therapy.

Protocol Summary

Study Design:	<p>This is a prospective, randomized, open-label study to evaluate effectiveness of applying financial and social incentives via a smartphone-based app in helping participants achieve adherence to therapy. Randomization will consist of an allocation ratio of 2:1 (control:treatment)</p> <p>This study will be conducted on patients with obstructive sleep apnea (OSA) who have been prescribed ResMed flow generator for positive airway pressure (PAP).</p> <p>Participants will be randomized to one of two groups: control or intervention with Wellth app, "Restful". The study comprises up to 2 participant contacts by phone, and 3 data collection timepoints. The first contact involves consenting and enrolling the participant, providing instructions based on the arm they are randomized to, and collecting baseline data including questionnaires. Those randomized to the intervention group will have a second contact, which involves onboarding to Restful. A second administration of the questionnaires will occur at +90 days from baseline.</p>
Intervention:	<p>Restful by Wellth. The intervention is use of the Restful app, which provides a small daily financial reward for achieving therapy usage goals and social support. The app will also send a daily reminder to participants to use their therapy. There is no clinical treatment intervention, as all patients included in this trial will be receiving PAP therapy per standard of care.</p>
Objectives:	<p>Evaluate whether a digitally delivered monetary and social reward scheme can increase 90-day adherence and/or increase average minutes of therapy usage over time. Therapy usage will be monitored using cloud-based technology in which data from each PAP device is automatically transmitted to a secure, HIPAA-compliant system (AirView).</p>
Enrollment:	Up to 300 participants
Clinical Site(s):	1 - 2 sites
Patient Population:	The intended population for the study are patients with a new diagnosis of OSA who have been prescribed a ResMed flow generator compatible with AirView. Participants will be recruited from the site's database.
Endpoint:	Adherence to therapy (average hours per day) at 90-days

Duration of study: Each participant is expected to participate in the study for at least 90 days following enrollment. Enrollment completion is expected within 16 weeks of enrollment initiation. Participants' usage data will also be collected at 180 days following enrollment.

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1 INTRODUCTION

Obstructive Sleep Apnea (OSA) is a condition characterized by the partial or complete collapse of the upper airway during sleep. OSA comprises a continuous spectrum of severity ranging from simple snoring and upper airway resistance through mild to severe symptomatic obstructive hypopnea and apnea. The prevalence of sleep disordered breathing in the adult population is 24% males and 9% for females¹. The prevalence of symptomatic OSA in the adult population has been estimated to be 4% in males and 2% in females¹. These patients demonstrate behavioral and neuropsychological consequences to varying degrees, including excessive daytime sleepiness, intellectual deterioration and depression². More serious consequences include arterial systemic hypertension, arterial pulmonary hypertension and heart disease³.

The treatment of choice for OSA is Positive Airway Pressure (PAP). PAP acts as a positive airway splint, delivering a fixed positive airway pressure to the upper airway via a tube and mask. Humidification is used during PAP therapy to improve comfort of the delivered air and alleviate nasal dryness/congestion.

Although PAP therapy is the gold standard treatment for OSA, adherence to treatment is often poor. CMS guidelines define adherence as 4 or more hours per night of therapy use on 70% of nights during a consecutive 30-day window within the first 90 days of setup⁴. Anywhere from 30 to 85% of patients will be non-adherent according to this definition of adherence, which can be explained, in part, by factors such as socioeconomic status, age, gender, severity of presenting symptoms, health values/beliefs, and social support⁵. Importantly, patients who immediately adopt therapy, within the first 3 days, are significantly more likely to be adherent at 30 days⁶, and patients' usage at 1 month is significantly predictive of adherence at 1 year⁷. Without sustained, long-term therapy adherence, patients are at risk of negative health outcomes including but not limited to cardiovascular disease, stroke, diabetes, and depression. This study tests whether a combined financial plus social incentive can help users new become adherent to PAP therapy.

Financial incentive schemes have demonstrated effectiveness in a wide range of behavior change efforts including physical activity⁸, smoking cessation⁹, glucose monitoring¹⁰, weight loss¹¹, and medication adherence¹². The primary mechanisms of action explaining the observed behavior change are loss aversion and timely reinforcement. Humans are strongly influenced by loss aversion, also known as the endowment effect, whereby the threat of losing something that has been endowed is a stronger motivator than the potential reward of gaining something not currently possessed. Timely reinforcement is also key, given that in order for learning to occur, the behavioral action and the subsequent reinforcement for doing said action must be closely coupled in time - otherwise it is difficult to associate the behavior with the reward.

Additionally, there is an abundance of evidence that social support is a critical component to successful health behavior change¹³; however, the specific test of social support

provision in this project is novel. Social currency (e.g., pictures, video) will be delivered to the participant at intervals (e.g., after a participant hits a streak of therapy use), as well as a weekly summary report of therapy use. Testing the social component is especially intriguing as this is a long-term cost-effective and scalable solution.

2 OBJECTIVES

Evaluate whether a digitally delivered monetary and social reward scheme can increase therapy usage and 90-day adherence. Adherence will be monitored using cloud-based technology in which data from each PAP device is automatically transmitted to a secure, HIPAA-compliant system (AirView).

3 METHODS AND MATERIALS

3.1 POPULATION/PARTICIPANT SELECTION

The intended population for the study are patients with a new diagnosis of OSA who have been prescribed a ResMed flow generator compatible with AirView. Participants will be recruited from the site's database.

Enrollment period for all participants is projected to be 16 weeks after IRB approval and enrollment commencement.

3.2 STUDY DESIGN

This is a prospective, randomized, two-arm, open-label study to evaluate effectiveness of applying financial and social incentives via a smartphone-based app in helping participants achieve adherence to therapy. Randomization will include an allocation ratio of 2:1 (control:treatment).

Two 'site to participant' contacts are required during this study. These contacts can either occur at the clinical site or remotely (e.g., by telephone). During the initial contact, their interest in the study and eligibility will be confirmed, then they will be consented, asked to complete the Baseline Questionnaire, and their demographic information will be collected on case report forms (CRFs).

Participants randomized to the intervention (Group B) will be provided with information and assistance in downloading Restful to their smartphone and registering with Wellth.

At the final contact (90 days), the participant will be asked to complete an End of Study Questionnaire and the investigative staff will collect PAP therapy data for the trial period and record it on CRFs. Participants in Group B will have access to the Restful app discontinued. This completes the participant's active participation in the study.

Daily usage data from AirView will be collected and transmitted electronically from usage initiation to 90 days, and then through 180 days.

Study data will be captured on CRFs. See **Appendix A** for the **Baseline and End of Study Questionnaires**. See **Appendix B** for **Participant Instructions** related to the study procedures and the Restful app.

3.3 NUMBER OF PARTICIPANTS

Up to 200 participants will be enrolled in the control arm and up to 100 participants will be enrolled in the treatment arm for a total of up to 300 participants enrolled in the study.

3.4 INCLUSION CRITERIA

All Participants enrolled into the study must meet the following criteria for entry:

- Adult participants (≥ 18 years of age)
- New diagnosis of OSA
- Prescribed CPAP or APAP for treatment of OSA
- Prescribed a ResMed flow generator compatible with AirView
- Owns a smart phone and is willing to download an app on their phone
- Willing and able to give informed consent
- Can read and comprehend written and spoken English

3.5 EXCLUSION CRITERIA

The participant will be excluded from entry if any of the following criteria apply:

- Have used PAP therapy in the past
- Have been prescribed bi-level or adaptive servo-ventilation therapy
- Are participating in another app-based research study
- Cannot participate for the full duration of the study (at least 90 days)
- Participants who have a medical history or concurrent illness that the investigator considers sufficiently serious to interfere with the conduct, completion, or results of this study, or constitutes an unacceptable risk to the participant for the duration of the study

3.6 SAMPLE SIZE

N= 300

A minimum total sample size of 270 patients, with 2:1 randomization (180 in Control group, 90 in Test group) is required to yield an 80% probability of detecting a difference of 0.8 hours in mean usage (160% of the minimally clinically significant difference) when the standard deviation is 2.5 and 2.0 in the Control and Test groups, respectively. The required sample size was calculated in the Two Sample T-Tests Assuming Unequal Variances Procedure using NCSS Power Analysis Statistical Software, Version 16 (PASS 16¹⁴) based on a one-sided, two sample t-test, using a significance level of 0.025.

Assuming a potential 10% drop-out rate due to study withdrawal or lost-to-follow-up, the final sample size will be 300 patients (270/0.9), equating to 200 in the Control group and 100 in the Test Group. The 2:1 randomization ratio was chosen because it is more cost-effective to enroll subjects in the control group.

3.7 STUDY ENDPOINTS

Primary Endpoint: mean PAP usage at 90 days collected from participants' flow generators

Secondary Endpoints:

- Percentage of participants that meet the Medicare compliance standard (at least 4 hours per day on at least 70% of the days in a consecutive 30-day period any time in the first 90 days of therapy)
- Change in ESS and FOSQ-10 questionnaire scores
- Baseline scores of perceived disease severity, claustrophobia, coping skills, and health literacy as moderators of the intervention's effectiveness

3.8 ANALYSIS POPULATIONS

Randomized Population: all participants enrolled and randomized to treatment groups.

Intent-to-Treat (ITT) Population: all participants randomized to control or intervention group, regardless of the actual intervention received.

Evaluable Population: all ITT subjects who complete the 90-day study period and complete the end-of-study questionnaire.

3.9 DATA ANALYSIS

Baseline demographic and psychosocial factors will be summarized for each randomized group for ITT and Evaluable Populations. For continuous variables, such as age and PAP usage, the mean, standard deviation, median, and range will be presented. For categorical variables, such as gender, the number and proportion of participants in each category will be presented. Baseline demographics and psychosocial factors for the control and intervention groups will be compared with t-tests and Fisher's exact tests, as appropriate.

The primary analysis compares mean PAP usage at 90 days in the control and intervention groups using a two-way ANOVA on the ITT population. Randomization group and myAir usage (Yes/No) will be included as factors in the model. The interaction of the two factors will be considered, but will only be retained in the model if it is significant at the 5% level. Missing usage hours during a day will be imputed as 0 usage. A secondary analysis of mean PAP usage will be conducted using the Evaluable Population. A sensitivity analysis of the missing data assumption will be conducted by considering missing data as missing. In this analysis, participants with no usage data will be assumed to have a mean usage of 0 hours; other participants' mean usage will be calculated as the mean usage across nights for which there is data.

A subgroup analysis of the primary endpoint will be generated for patients who are identified as strugglers. A struggler is defined as a patient who uses their device for less than or equal to 3.5 hours/night during the first 3 days of usage. Mean PAP usage at 90 days will be compared in the control and intervention groups using a two-way ANOVA on the struggler population as described above. Descriptive statistics will also be presented for mean PAP usage, comparing strugglers and non-strugglers in control and intervention groups.

Adherence will be calculated for the ITT population from daily usage data using the Medicare definition for adherence (a patient is adherent if they use the device for more than 4 hours per night for 70% of the nights during the first 90 days of usage). Percent adherence will be compared between control and intervention groups using a logistic regression model on the ITT population. Randomization group, myAir usage, and the interaction of these two factors will be included in the model. Missing usage hours during a day will be imputed as 0 usage.

Mean change in ESS and FOSQ questionnaire scales will be compared between control and intervention groups using a mixed-effects linear model on the ITT population and a two-sample t-test on the Evaluable population. In the mixed-effects model, the response variable will be the mean questionnaire score and the model will include randomized group, visit, and a randomized group by visit interaction as fixed effects and subject as a random effect.

Baseline perceived disease severity, claustrophobia, coping skills, and health literacy will be tested as moderators of the intervention's effectiveness. Baseline scores will be regressed on the primary outcome (usage), and then in a mixed-effects model, the response variable will be usage and the model will include baseline score, randomized group, and a randomized group by baseline score interaction as fixed effects and subject as a random effect.

An exploratory analysis will examine how engagement with the study is associated with PAP usage. Engagement will be measured as app usage (number of touches). A linear regression model with PAP usage as the dependent variable and engagement as the independent variable will be fit to all ITT subjects (engagement is zero for all control subjects). An exploratory analysis will also test whether the intervention has a direct or indirect effect on the following psychosocial factors: the pros and cons of change, self-efficacy, and social support. Finally, an exploratory analysis will test whether nomination of, and the extent of engagement with, a social support person moderates the intervention effectiveness.

4 STUDY SCHEDULE

Informed consent will be obtained prior to the initiation of any protocol related activities.

4.1 SCREENING FOR ELIGIBLE PARTICIPANTS:

Patients who have been newly diagnosed with SDB and prescribed PAP for their treatment will be evaluated for eligibility, and if all entry criteria are met, they may be invited to participate in the study. This may be accomplished by phone or in person.

4.2 INITIAL (ENROLLMENT) CONTACT

1. Provide patient with access to informed consent document.
2. When consent has been obtained, collect device information (device ECN, device settings, mask type), demographic, and baseline data into the electronic data capture (EDC) system.
3. Randomize participant in EDC.
 - a. Participants randomized to the Control group (Group A) will complete a set of baseline questionnaires.
 - b. Participants randomized to the Treatment group (Group B) will complete a set of baseline questionnaires and provided with instructions to download Restful to their smartphone.
 - c. Monitor both groups' PAP device usage per your standard of care.

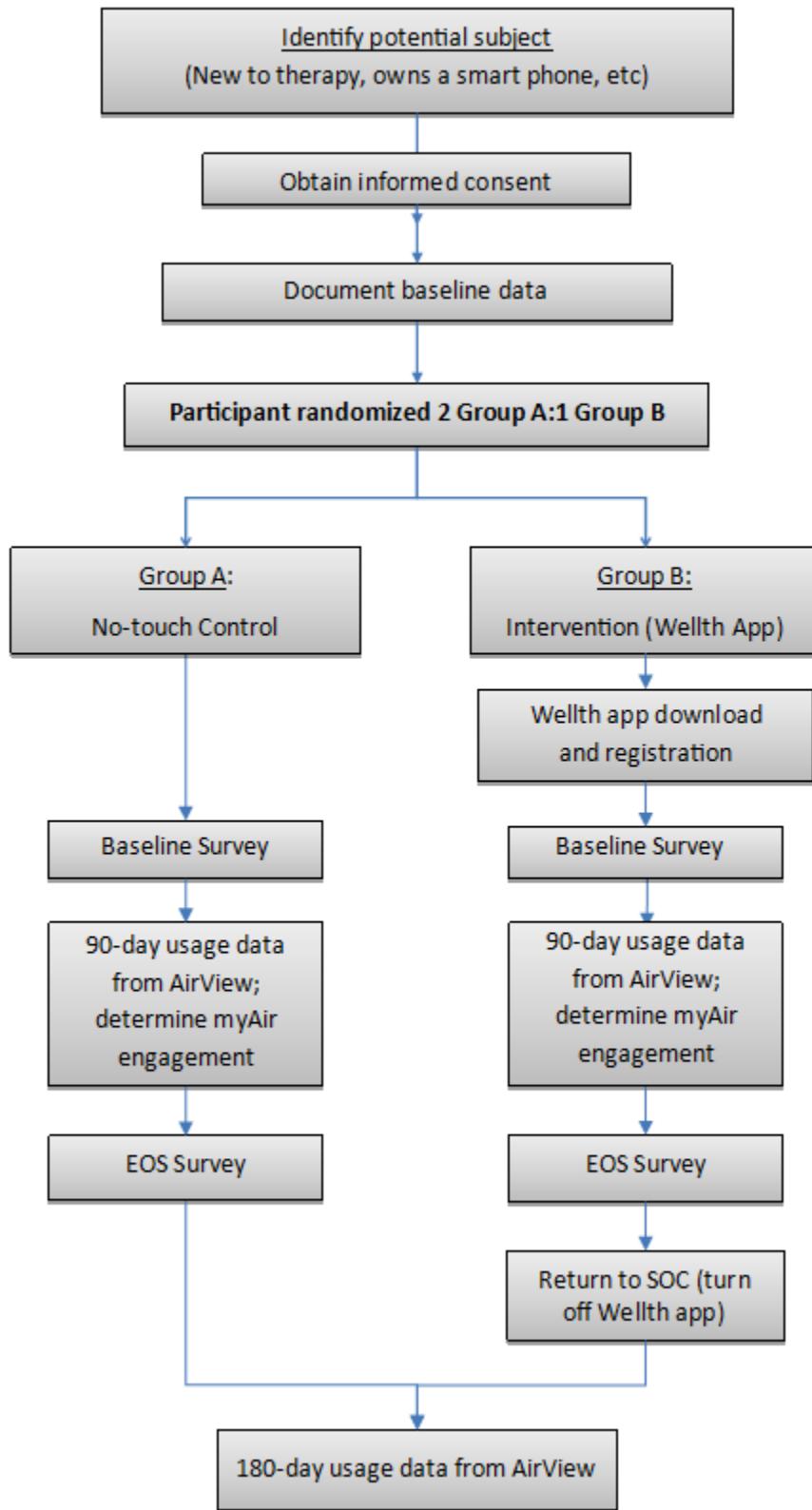
4.3 90-DAY STUDY CONTACT

1. Both Group A and Group B will be asked to complete a set of end of study questionnaires. Restful will be 'turned off' for Group B participants.
2. Continue to monitor participants' PAP device usage per your standard of care.
3. Distribute compensation for study participation.

4.4 REPORT OF DEVICE USAGE DATA

1. A report of PAP usage data (including average hours used per day, leak, pressure, and AHI) will be generated by the ResMed Data Analytics group at 90 days and 180 days and provided to the statistician for analysis.
2. A user-level analytics report of myAir engagement (including participants who registered for myAir and number of times they engaged with the app during the study) will be generated by the ResMed Data Analytics group at 90 days and 180 days and provided to the statistician for analysis.
3. A user-level analytics report of Restful engagement (including participants who registered for Restful and number of times they engaged with the app during the study) will be generated by Wellth at 90 days and 180 days and provided to the statistician for analysis.

4.5 STUDY FLOW



4.6 INFORMED CONSENT

IRB approved informed consent (21 CFR Part 50) will be obtained by the Investigator or delegated investigative staff. The Investigator or delegated staff will be responsible for confirming that each patient understands the nature, purpose, and risks associated with participating in this study.

The investigative site will have the option of remotely consenting patients. Patients will be securely emailed a patient-specific link to access and create a login with the EDC system (Medrio). This website will contain the informed consent form, HIPAA, instructions on how to have any questions answered, and a knowledge assessment. The same login will also be used later in the study to complete participant questionnaires.

Patients will be given sufficient time (either remotely or in clinic) to consider the study's implications, ask any questions, and get these questions answered before deciding whether to participate. If consented remotely, patients will be clearly provided with information on how to contact an appropriate investigative staff member for questions about the study. Patients will not be able to authorize consent until they have confirmed that they have no further questions about the study. A copy of the consent form will be emailed or given to each participant for their records so they are able to access the consent form at any time throughout the course of the study.

Participant consent for this protocol will be obtained prior to the initiation of any study procedures.

5 INTERVENTION

5.1 WELLTH APP (RESTFUL)

The intervention is the use of Restful, the Wellth self-management application. There is no clinical treatment intervention, as all participants will be receiving PAP therapy per standard of care.

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:

Financial incentive:

The incentive is \$75, and is distributed as follows: Participants unlock \$5 after completing the app introduction/onboarding, and then \$10 for successful nights on days 1, 2, 3, 5, 8, 13, and 21. Successful nights are nights where therapy is used for ≥ 4 hours. Once money is "unlocked," the reward is always visible to the participant. However, participants only receive the financial reward if they unlock all \$75 by the end of the program. In between

“pay days,” participants receive positive reinforcement messages and visual cues but no financial reward is unlocked.

Recognizing that participants are likely to struggle initially, and that there are 9 days in which participants can afford to have non-adherent nights (i.e., $30 - 21 = 9$), the participants will be granted 9 hearts in the app. These hearts represent the “misses” available to them, and they will lose a heart each non-adherent night. The program will deliver a tailored intervention message of support or encouragement after every 2 lost hearts (e.g., remind participants how close they were to a successful night).

If the participant does not meet adherence in the first 5 weeks and/or they have lost 9 hearts, then they will get a second chance. The intervention will “reboot.” Participants will not be made aware of this opportunity at the outset.

Social incentive:

The social incentive will have two components: social currency and social support messages. Participants will have the opportunity to nominate a social support person during the Wellth onboarding process. This person will be contacted directly by Wellth via text message and provided with information that will explain their role in supporting the participant. The support person will be asked to provide social currency (described below) that they think will be meaningful to the participant, as well as some supportive messages. Over the course of the 90-day trial, Wellth will reach out to the support person to solicit additional currency and messages. If the support person is generally non-responsive, or if the participant does not nominate a social support person, then the participant will receive Wellth-designed content for the social currency and social support components.

- Social currency: Pictures and/or videos that are meaningful to the participant. Delivered to the participant when they hit a therapy usage streak of 3 days in a row ≥ 4 hours.
- Social support messages: Encouraging messages that are meaningful to the participant. Delivered to the participant at seemingly random intervals throughout the 90 days (i.e., via a rules-based delivery algorithm).

5.2 AIRVIEW

AirView is the HIPAA compliant web-based system that is routinely used for telemonitoring. The PAP device contains built in wireless connectivity which transmits data via a mobile network to a secure data center. Data is transmitted at the completion of each period of use (e.g. after each night of use). Data can then be accessed, via a login code, by the respiratory/sleep team to assess items such as device efficacy (residual AHI), mask leak, and usage hours.

AirView is compliant with HIPAA, EU 95/46/EC, and national privacy laws. Data are encrypted and all database accesses are logged and can be re-traced.

5.3 MYAIR

In addition to AirView, a patient-focused version of the data is available through the myAir app. The myAir app can be accessed via the participant's smartphone or computer and allows the participant to monitor their own treatment data. myAir also provides tips to the participant on things like coping with therapy, managing mask leaks, and adjusting comfort settings. These tips are personalized based on each individual's data. The myAir app is not mandatory in this trial, but participants' usage of myAir will be documented in both Group A and Group B.

5.4 CONTROL GROUP

The control group will be monitored and managed per the site's standard of care with the exception of completion of questionnaires at baseline and again at 90 days after enrollment.

6 DATA HANDLING AND RECORD KEEPING

6.1 CONFIDENTIALITY

Information about study participants will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed participant authorization informing the participant of the following:

- What protected health information (PHI) will be collected from participants in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research participant to revoke their authorization for use of their PHI
- All the institutes involved in the study to keep the medical information confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

6.2 SOURCE DOCUMENTS

Source data is all information, original records of clinical compliance records, observations, or other activities necessary for the reconstruction and evaluation of the study. Source data are contained in source documents. Examples of these original documents and data records include: participants' records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, participant files, and records.

6.3 CASE REPORT FORMS

Participant data will be collected through use of a CRF and Participant Questionnaires (**Appendix A**). Objective usage data will be collected directly from AirView.

The clinical site will provide study data to the Sponsor by recording data in the Medrio EDC System (21 CFR Part 11 compliant).

6.4 RECORDS RETENTION

Records to be kept at the site. Records retention includes electronic as well as hard copy records for 5 (five) years after the final analysis is complete.

7 MONITORING

The site will utilize internal monitoring procedures to review the flow of the study and make sure that all procedures are being performed in a timely manner and the project meets the timelines.

8 ADVERSE EVENT REPORTING

For the purpose of this protocol, an adverse event is any deviation from baseline health in a participant that can be attributed to the device, disease, or study procedures required by this protocol.

A serious adverse event (SAE) is any event that is fatal or immediately life-threatening AND that requires a participant to be hospitalized or hospitalization is unduly prolonged because of potential disability or danger to life or because an intervention has been necessitated. This includes events that cause fetal distress, fetal death, congenital anomaly or malignancy or any permanently disabling event.

For the purposes of this protocol, 'serious' is defined as any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are non-life-threatening and that are temporary and reasonably reversible.

As noted above, changes in a participant's health should be documented in the participant's record and an assessment should be made regarding association with the study device or procedure. If it is determined that the event can be attributed to the device or procedure required by the protocol, the investigator should obtain and document all the information required to document the event, including cause, treatment, and resolution. All adverse events must be followed until resolution or until a stable clinical endpoint is reached. If the event can be attributed to the device or study procedure, all required treatments and outcomes of the adverse event must be recorded on the CRFs.

Unanticipated adverse device effects are defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.

Under the requirements of the FDA's IDE Regulations, an investigator must submit to the manufacturer (or its designee) and to the reviewing Institutional Review Board any unanticipated adverse device effect occurring during the study as soon as possible, but in no event later than ten (10) working days after the investigator first learns of the effect.

9 EXPECTED ADVERSE DEVICE EFFECTS

This study is considered to be of very low risk to the participant.

10 NON SIGNIFICANT RISK DETERMINATION

This study is considered non-significant risk (NSR) based on standard of care procedures being employed and a review of the Code of Federal Regulations for significant risk devices. As required by FDA, the IRB will review this study and determine if it concurs with the NSR designation.

11 RISK MITIGATION

This study is considered to be of very low risk to the patient due to the non-invasive nature of the procedures.

12 REFERENCES

¹ Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle-aged adults. NEJM. 1993. 328 (17); 1230-1234.

² Kingman P, Redline S. Recognition of obstructive sleep apnoea. Am J Respir Crit Care Med. 1996. Vol 154; 279-289.

³ Young T, Peppard P, Gottlieb D. Epidemiology of obstructive sleep apnoea – A population health perspective. Am J Respir Crit Care Med. 2002; Vol 165; 1217-1239.

⁴ Medicare Learning Network. 2016. *Positive Airway Pressure (PAP) Devices: Complying with Documentation & Coverage Requirements*. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Centers for Medicare & Medicaid Services. Accessed 20Nov18. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf>

⁵ Shapiro GK, Shapiro CM. Factors that influence CPAP adherence: An Overview. Sleep Breath. 2010 Dec;14(4):323-35

⁶ Budhiraja R, Parthasarathy S, Drake CL, et al. Early CPAP use identifies subsequent adherence to CPAP therapy. Sleep. 2007 Mar;30(3):320-4.

⁷ Chai-Coetzer CL, Luo YM, Antic NA, et al. Predictors of long-term adherence to continuous positive airway pressure therapy in patients with obstructive sleep apnea and cardiovascular disease in the SAVE study. Sleep. 2013 Dec 1;36(12):1929-37

⁸ Van der Swaluw K, Lambooij MS, Mathijssen JJP, et al. Commitment Lotteries Promote Physical Activity Among Overweight Adults—A Cluster Randomized Trial. Ann Behav Med. 2018 52:342-351

⁹ Halpern SD, Harhay MO, Saulsgiver K, et al. A Pragmatic Trial of E-Cigarettes, Incentives, and Drugs for Smoking Cessation. N Engl J Med. 2018;378:2302-10

¹⁰ Wong CA, Miller VA, Murphy K, et al. Effect of Financial Incentives on Glucose Monitoring Adherence and Glycemic Control Among Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA Pediatr. 2017. Dec 1;171(12):1176-1183.

¹¹ Volpp KG, John LK, Troxel AB, et al. Financial Incentive-Based Approaches for Weight Loss. JAMA. 2008 Dec 10;300(22):2631-7

¹² Asch DA, Troxel AB, Stewart WF, et al. Effect of Financial Incentives to Physicians, Patients, or Both on Lipid Levels: A Randomized Clinical Trial. JAMA. 2015 Nov 10;314(18):1926-35

¹³ Berkman LF, Glass T, Brissette I, et al. From social integration to health: Durkheim in the new millennium. Soc Sci Med. 2000 Sep;51(6):843-57.

¹⁴ PASS 16 Power Analysis and Sample Size Software (2018). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.

APPENDIX A: PARTICIPANT QUESTIONNAIRES

Note: Study is using electronic case report forms and patient reported outcomes. The attached PDF is an outline of all participant questionnaires available in EDC.

APPENDIX B: TAKE HOME INSTRUCTIONS

GROUP A

Instructions for Research Study

Thank you for participating in our **confidential** research study. The purpose of this study is to test whether a smartphone app can help people get used to and keep using their CPAP therapy. We value your comments and suggestions.

Throughout this study please keep this list of instructions handy.

- You will continue to use your CPAP therapy as prescribed.
- You will be asked to complete 2 questionnaires as part of this research study. If you experience any problems with completing these questionnaires online, please contact your provider.
- If you experience any problems with your therapy, using myAir, or your CPAP equipment, please contact your provider.
- If you are unable to complete the study for any reason, please contact your provider immediately.

Your participation in this evaluation is voluntary and it is your right to stop the evaluation at any stage.

All aspects of the evaluation, including your identity, will be strictly confidential. While the study may be used for device improvement, education, regulatory and marketing activities, you will never be specifically identified.

Provider contact if you have any concerns or questions:

Provider name

Provider address

Provider phone number

GROUP B**Instructions for Research Study**

Thank you for participating in our **confidential** research study. The purpose of this study is to test whether the Wellth app (Restful) can help people get used to and keep using their CPAP therapy. We value your comments and suggestions.

Throughout this study please keep this list of instructions handy.

- You will continue to use your CPAP therapy as prescribed.
- You will be asked to complete 2 questionnaires as part of this research study. If you experience any problems with completing these questionnaires online, please contact your provider.
- If you use your CPAP device for at least 4 hours a night for 21 nights within a 30-day period, you will receive a \$75 payment at the end of the study.
- If you experience any problems with your therapy, using myAir, or your CPAP equipment, please contact your provider.
- If you experience any problems with using Restful, please contact a Wellth representative.
- If you are unable to complete the study for any reason, please contact your provider immediately.

Your participation in this evaluation is voluntary and it is your right to stop the evaluation at any stage.

All aspects of the evaluation, including your identity, will be strictly confidential. Wellth will receive your contact information (including name, address, and email address) to help you register for Restful and to mail your payment at the end of the study. The results of this study may be used for device improvement, education, regulatory and marketing activities, but you will never be specifically identified.

Provider contact:

Provider name
Provider address
Provider phone number

Wellth contact:

Wellth name
Wellth phone number

APPENDIX C: MYAIR PRIVACY POLICY

myAir™ Privacy Notice

Effective: May 2018

ResMed wants to share with you how we treat personal data we receive about you, including special categories of personal data relating to sleep data and device setting information. We collect personal data about you only with your consent or if you voluntarily submit the information to us.

This Privacy Notice is delivered in accordance with data protection laws. We process and protect your personal data under the principles and safeguards in the legislation applicable to you. This Privacy Notice provides you with information about your rights, and the privacy practices that govern how we process your data.

This Privacy Notice is specific to ResMed's myAir service (Service). Your relationship with us may also be governed by separate privacy notices if you use other ResMed products and services.

Scope

The myAir Privacy Notice applies to your use of the Service, which includes:

- myair.resmed.com,
- myair.resmed.eu, and
- the mobile application known as myAir App, if available in your country.
-

In this Privacy Notice, the terms "you" and "yours" refer to the person using the Service.

In this Privacy Notice, "we," "our," "us" and "ResMed" refer to:

- ResMed Corp., a Minnesota corporation, headquartered at 9001 Spectrum Center Blvd. San Diego, CA 92123 United States (+1 858 836 5000), if your usual place of residence when you download the Service is in North, South or Central America;
- ResMed SAS, a company incorporated in France (company registration number 407775170) whose registered office is at Parc Technologique de Lyon, 292 Allée Jacques Monod, 69791 Saint-Priest CEDEX, France (+33 426 100 200), if your usual place of residence when you download the Service is in France;
- ResMed Deutschland GmbH, whose registered address is at Haferwende 40, 28357 Bremen, Deutschland (+49 421 489 930), if your usual place of residence when you download the Service is in Germany;
- ResMed (UK) Ltd., a company incorporated in England (company registration number 02863553), whose registered address is at London, 8 Wimpole Street, London, W1G 9SP, United Kingdom (+44 0 1235 862 997), if your usual place of residence when you download the Service is anywhere in Europe other than France or Germany; and

- ResMed Holdings Limited, a company incorporated in Australia (company registration number 28 003 765 133), whose registered address is at 1 Elizabeth Macarthur Drive, Bella Vista, NSW 2153, Australia (+61 2 8884 1000), if your usual place of residence when you download the Service is in the Asia-Pacific region or the Middle East.

This Privacy Notice sets out:

1. Why we process your personal data and the legal basis for the processing
2. What personal data we collect about you
3. How we obtain your personal data
4. How we use your personal data
5. How we protect your personal data
6. Who we share your personal data with
7. Where your personal data is currently hosted and processed
8. How long we retain your personal data
9. Your personal data rights
10. Collection and use of anonymous data
11. Your communication preferences
12. Links to other sites
13. Personal data from children
14. Updates to this Privacy Notice
15. Questions and complaints
16. Your right to lodge a complaint with a supervisory authority
17. Data Protection Officers (EU only)

1. Why we process your personal data and the legal basis for processing

We process your personal data only if you consent to this processing for purposes of providing you the Service outlined within this Privacy Notice.

Under certain laws we are required to state the legal basis for processing your personal data and any special categories of personal data. We process your personal data on the legal basis that processing is required to meet the Service contract and for our legitimate interests to improve our product and services. We rely on your consent to process any health data that is classified as a special category of personal data or used for marketing purposes. You can withdraw your consent at any time by changing your preferences on the Service or by contacting us directly.

2. What personal data we collect about you

We may collect the following personal data about you:

- First and last name
- Date of birth and gender
- Email address and location of residence
- Phone number
- Products and services you use for treatment
- Where you took your sleep test and when therapy started
- Sleep and settings data from your device(s)
- Your baseline Apnea Hypopnea Index (AHI)

Through certain technologies employed by our websites and mobile applications, we also collect other information about you in accordance with our Cookie Notice. For more details about this type of data collection, please refer to our Cookie Notice.

Special categories of personal data

Other than the data described in this Privacy Notice, we will not intentionally collect or maintain, and do not want you to provide, any information regarding your race or ethnic origin, political opinions, religious or philosophical beliefs or other sensitive information.

3. How we obtain your personal data

- When you submit your personal data as part of the registration to create an account for the Service or engage in any transactions with us through the Service.
- When you submit your device serial number as part of the online registration process, you consent to the ongoing transmission of your device data to the Service.
- With your consent, we may collect information about you on your behalf from your healthcare or home medical equipment provider.
- We may also collect demographic information about you from a vetted third party that works with leading national compilers of consumer and business data from public sources, such as telephone directories and consumer surveys.

4. How we use your personal data

- We use your first name, last name, email address and phone number to communicate with you via unencrypted email and text messages (SMS messages), as part of the Service, to send you therapy coaching messages, including but not limited to communications regarding your use of the Service.
- We use the products you use for treatment (your device and your mask), together with data transmitted from your device (sleep and device settings), to provide you your nightly sleep therapy score and key metrics of your nightly therapy sessions.
- We use your date of birth to ensure we do not collect data from children under the age of 13 or otherwise considered a minor under the laws of your country of residence.
- We use your first name, last name, email address, and the products you use for treatment, to respond to your requests for information or materials, and to create, develop and maintain our relationship with you.
- Depending on your communication preferences, we may use your first name, last name, email address, phone number, location of residence and the products you use for treatment to communicate with you via unencrypted email and text messages to send you newsletters, press releases or content relating to products, programs, services, or general information we believe may be of interest to you.
- We may use your first name, last name, and email address to cross-reference information about you with other ResMed services for purposes of benefiting you (e.g. to provide you with the contact information of your current or last identified healthcare or home medical equipment provider) and to help us

better understand the sleep apnea population (currently applicable to the United States only).

- Subject to local laws, we may use your demographic data to improve the Service. Depending on your communication preferences, we may also use your demographic data to provide relevant, timely marketing messages.
- We may use aggregated, pseudonymous data transmitted from your device (sleep and device settings), such as sleep test location, therapy start date, baseline AHI, the number of apnea events per hour, year of birth, gender and location of residence to conduct statistical analyses, surveys and market research to enhance existing or develop new products and services.

5. How we protect your personal data

- We use a number of different security and privacy controls to protect your data and to comply with applicable data protection laws. For example, we use encryption to protect your personal data, both when it is in transit as you use the Service and when it is at rest in the servers we use. Despite the security measures we employ, you should be aware that it is impossible to guarantee absolute security of information sent through the internet.
- If we confirm that your personal data has been subjected to a data breach, we will follow applicable data breach notification laws.
- We will make reasonable efforts to ensure that the personal data collected is the minimum necessary to fulfill the purposes described in this Privacy Notice.
- We will retain your personal data only for as long as you keep your account with the Service. Your personal data is deleted as soon as your account is deleted.

6. Who we share your personal data with

- We do not sell or rent your personal data. We only share your personal data in accordance to this Privacy Notice, with your consent, and only to the extent permitted by applicable law.
- We may share your personal data with any affiliate or subsidiary of ResMed, and any company owned or controlled by ResMed.
- We may share your personal data if some or all of the business of ResMed is transferred to another entity by way of merger, sale of its assets or otherwise.
- We may share your personal data in limited circumstances and in a controlled and secured manner, with third-party data processors and service providers we engage to provide certain aspects of the Service on our behalf. These data processors and service providers are contractually required to keep your personal data confidential and to use your personal data for the sole purpose of performing the services we asked them to provide. They may not use your personal data for any other purpose. These third-party data processors and service providers include:
 - Data hosting providers
 - Online ad management providers
- We may share your personal data if we are required to do so by law.

- We may assist healthcare or home medical equipment providers that use our AirView™ service to identify which of their monitored devices have not been registered with the Service.

7. Where your personal data is currently hosted and processed

- + North, South and Central America, and the Asia-Pacific region
- + Europe and the Middle East

8. How long we retain your personal data

We will retain your personal data:

- up to the point where you withdraw consent, which you have the right to do at any time; or
- if there is a legal reason for retention.

9. Your personal data rights

Subject to local laws and when applicable, you can request that we:

- provide a copy of personal data we have about you on file
- delete your personal data from our systems
 - We delete personal data associated with your Service account when you decide to close your Service account.
 - If we have a legal obligation to retain any of your personal data, we will inform you of this obligation.
- send you a copy of the personal data you knowingly and actively provided us (including any data we may generate by your activity)
 - We will transmit a copy of this data to another data controller upon your request.
- restrict how we process your personal data if:
 - the accuracy of the data is being disputed;
 - processing is unlawful and you oppose its deletion;
 - the data is no longer needed by ResMed but needed for your personal legal reasons.

You may have a right to object the processing of your personal data when we process your data for marketing.

The Service includes a feature that allows you to perform some of these data requests on your own. For example, you can update or correct your personal data yourself when you visit your user profile through the Service.

For those personal data requests that you cannot perform, please email us at privacy@resmed.eu if you are in Europe or privacy@resmed.com if you are anywhere else. Your rights are not absolute and we will assess them on your request.

When you send us your request, we may need to verify your identity prior to disclosing your personal data or taking any action on it.

10. Collection and use of anonymous data

- We may collect anonymous statistical information from your use of the device and the Service. For example, the number of visitors that visit a specific web page on the Service, how long they stay on that page, which hyperlinks, if any, they click on, and what features are used on the Service.
- When applicable, we may collect this type of information through the use of cookies and other tracking technologies, which we discuss in detail in our Cookie Notice. We may disclose aggregate data to third parties, but this aggregate data will in no way personally identify you or any other users of the Service.
- To help us understand how users interact with our mobile apps, we use a third-party service provider. The provider does not collect or access personal data (or the handset identifier on an iOS™ device or the advertiser ID on an Android™ device) and does not link such data to your usage data of our mobile apps. Currently, you can opt-out at any time after you download one of our mobile apps. Otherwise, you consent to, and accept, the collection of anonymized information by our third-party provider.

11. Your communication preferences

- You may consent or withdraw your consent to our use of your personal data for marketing at any time by changing your preferences on the Service, or by following the instructions to unsubscribe included in each marketing-related email sent to you.
- If you have signed up to receive text messages (SMS messages) and no longer wish to receive such messages, you may withdraw your consent. This may include replying "STOP" to the received text message (SMS message), or changing your preferences on the Service.
- If you withdraw your consent to receive marketing information, we will use reasonable efforts to remove your personal data from our marketing database within five business days after receipt of your withdrawal of consent.
- Communicating promotional information that may be of interest to you is not essential for your use of the Service. You control whether to receive marketing information or text messages (SMS messages) from us.
- If you do choose not to receive marketing emails from us, we may still send you important administrative and transactional messages (i.e. service notifications) from the Service.

12. Links to other sites

For your convenience, the Service may from time to time include links to third-party websites whose personal data practices may be different to ours. We encourage you to review the privacy notices for these websites, as we have no control over information submitted to, or collected by, these third parties. Use of third-party websites may be subject to a third party's terms and conditions and is at your own risk. We are not responsible for these websites.

13. Personal data from children

We do not knowingly collect personal data from children. The content of our Service is not intended for, or directed to, children. If you are under 13 years of age or otherwise

considered a minor under the laws of your country of residence, please do not use or access our Service at any time or in any manner. If a parent or legal guardian becomes aware that their child has provided us with personal data without appropriate consent, please contact us by sending an email to privacy@resmed.eu in Europe or privacy@resmed.com if you are anywhere else. If we confirm that a user is a minor and has provided us with their personal data, we will delete their information from our databases.

14. Updates to this Privacy Notice

We may update this Privacy Notice from time to time. We encourage you to review this Privacy Notice regularly. Each Privacy Notice includes the date on which it was last updated. If we change this Privacy Notice, we will notify you as appropriate. If we make a material change, we will ask you to review and reaccept the Privacy Notice. Your continued use of the Service confirms your acceptance of our Privacy Notice, as amended. If you do not agree to our amended Privacy Notice, you may choose to discontinue using the Service.

15. Questions and complaints

If you have questions or concerns about this Privacy Notice, or if you want to make a complaint about a possible breach of local privacy laws, please contact one of the following offices:

Europe:

Privacy Office
ResMed Deutschland GmbH
Haferwende 40
28357 Bremen
Deutschland
Tel. +49 421 489 930
privacy@resmed.eu

Outside Europe:

ResMed Corp.
9001 Spectrum Center Blvd.
San Diego, CA 92123
United States
Tel: 1 800 424 0737
privacy@resmed.com

16. Your right to lodge a complaint with a supervisory authority

If you are unsatisfied with our response to your personal data question or request, you have the right to complain to a supervisory authority in the location where you live or work, or where the alleged infringement of your personal data rights took place.

If you ask us, we will try to provide you with information about relevant complaint options that may be applicable to your circumstances.

17. Data Protection Officers (EU only)

German Data Protection Officers
ResMed Deutschland GmbH
Haferwende 40
28357 Bremen
Deutschland
Tel. 0421 48993 0
datenschutz@resmed.de
ResMed Healthcare
ResMed GmbH & Co. KG
Fraunhoferstr. 16
82152 Martinsried
Deutschland
Tel. 089 9901 00
datenschutz@resmed.de
French Data Protection Officer
ResMed SAS
Bureau du délégué à la protection des données
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint-Priest CEDEX
France
Tel. +33 426 100 200
privacy.france@resmed.eu
EMEA Data Protection Officer
ResMed Germany Inc.
Data Protection Office
Fraunhoferstr. 16
82152 Martinsried
Deutschland
privacy.germany@resmed.eu

If you are a resident of California, California Civil Code Section 1798.83 permits you to request information regarding the disclosure of your personal data to a third party for the third party's direct marketing purposes. This right is granted to California residents only for their activities within the State of California. To make such a request, please send an email to privacy@resmed.com.

If you would like a list of all the data processors with whom we share personal data for direct marketing, please send us an email to privacy@resmed.eu in Europe or privacy@resmed.com outside Europe. Please allow 30 days for a response.

2281440/1 2018-05

APPENDIX D: WELLTH PRIVACY POLICY

I. INTRODUCTION

Wellth, Inc. (collectively referred to herein as “we,” “us,” “our,” or “Wellth”), respects your privacy and the importance of the information you entrust to us. With this in mind, we provide you this privacy policy (the “Policy”) to help you understand the kinds of information we may gather about you when you use the Platform or any of our Services, how we may use and disclose the information, and how you can control, correct and/or update the information. By accessing or using the Platform or Services, you are accepting the policies and practices described in this Policy. Each time you visit or use the Platform or Services, you agree and expressly consent to our collection, use and disclosure of the information that you provide as described in this Policy. Any capitalized terms not defined herein shall have the meaning as set forth in the Terms of Use.

Please note that this Policy does not apply to your use of third-party sites, services, or applications you may access through the Platform. We encourage you to review the privacy policies of those third parties for more information regarding their privacy practices.

We may make changes to this Policy from time to time. Your continued use of the Platform or Services after we make changes is deemed to be acceptance of those changes, so please check this Policy periodically for updates.

II. CHILDREN UNDER THE AGE OF 18

Our Service is not intended for use by anyone under 18 years of age. No one under age 18 may provide any information to or on the Service. And no one providing information on behalf of another person may provide such information for anyone under the age of 13. We do not knowingly collect personal information from children under 18 or about children under 13. If you are under 18, do not use or provide any information on this Service or on or through any of its features. If we learn we have collected or received personal information from a child under 18 without verification of parental consent or about a child under 13, we will delete that information. If you believe we might have any information from a child under 18 or about a child under 13, please contact us at help@wellthapp.com.

III. INFORMATION WE MAY COLLECT

When you use the Platform or Services, we may collect information about you or your use of the Platform or Services. Some of the Services require us to learn more about you so that we can best meet your needs. When you access the Services, we may ask you to voluntarily provide us certain information that personally identifies you or could be used to personally identify you (“Personal Information”). Personal Information includes (but is not limited to) the following categories of information:

- (1) contact data (such as your e-mail address and phone number);
- (2) demographic data (such as your gender, your date of birth and your zip code);

(3) medical data (your Healthcare Entities, your dates of medical visits, your medical history, and other medical and health information you choose to share with us); and (4) other identifying information that you voluntarily choose to provide to us, including without limitation unique identifiers such as passwords, and Personal Information in emails or letters that you send to us

We may also collect additional information, which may be Personal Information, as otherwise described to you at the point of collection or pursuant to your consent. You may still access and use some of the Platform if you choose not to provide us with any Personal Information, but features of the Services that require your Personal Information will not be accessible to you.

Other information we may collect includes (but is not limited to):

- information regarding your mobile devices, including their locations, your mobile devices on which you have installed the Mobile App, and other information related to your use of the Services;
- information that is about you but individually does not identify you;
- information about your wireless or mobile internet connection, the equipment you use to access our Services and usage details;
- information about your uses of services within the Platform, including Partners you visit, and any of your Healthcare Entities;
- information about your device, such as the type and model, manufacturer, operating system (e.g. iOS or Android), carrier name, IP address, mobile browser (e.g. Chrome, Safari), and identifiers assigned to your device, such as its iOS Identifier for Advertising (IDFA), Android Advertising ID, or unique device identifier (a number uniquely allocated to your device by your device manufacturer);
- log information, including the apps or websites visited, the time and your time zone, network connection type (e.g., WiFi, cellular), and cookie information;
- the geo-location of your device (using GPS or other geo-location data), when location services have been enabled for the Mobile App or browser accessing our Platform or Services;

INFORMATION WE COLLECT DIRECTLY

We collect this information directly from you when you provide it to us, or as we process your transactions, for example:

- information that you provide by filling in forms on our Platform or Services, including information provided at the time of registering to use our Service, setting up your Account, receiving care from a Healthcare Entity, redeeming Wellthpoints, or requesting further services relating to the Platform or your use of the Services;
- records and copies of your correspondence (including email addresses), if you contact us;
- your responses to surveys that we might ask you to complete for research purposes; and
- your use histories within the Platform, including the Healthcare Entity where you have received healthcare or wellness service and the date of each interaction.

INFORMATION WE COLLECT THROUGH AUTOMATIC DATA COLLECTION TECHNOLOGIES

As you interact with our Platform or Services, we may use automatic data collection technologies to collect certain information about your equipment, browsing actions and patterns, including:

- details of your use of our Service, including traffic data, location data, logs and other communication data and the resources that you access and use on the Platform or Service; and
- information about your device and Internet connection.
- The information we collect automatically is statistical data and does not include personal information. It helps us to improve our Platform or Service and to deliver a better and more personalized service, including by enabling us to:
 - estimate our audience size and usage patterns;
 - store information about your preferences, allowing us to customize our Service according to your individual interests; and
 - recognize you each time you use the Service.

We may use third-party analytics services to provide us with analytic data collection and reporting. We will not provide any personally identifiable information to such third parties.

IV. HIPAA AND PHI

Under a federal law called the Health Insurance Portability and Accountability Act (“HIPAA”), some demographic, health and/or health-related information that we collect as part of providing the Services may be considered “protected health information” or “PHI.” Specifically, when we receive identifiable information about you from or on behalf of your Healthcare Entities, this information is considered PHI.

HIPAA provides specific protections for the privacy and security of PHI and restricts how PHI is used and disclosed. Wellth may only use and disclose your PHI in the ways permitted by your Healthcare Entity(s). In addition, you may be asked to sign the Wellth authorization form (the “Wellth Authorization”). Your decision to sign the Wellth Authorization is entirely voluntary. If you choose to sign the Wellth Authorization, you agree that Wellth may use and disclose your PHI in the same way it uses and discloses your Personal Information that is not PHI. These uses and disclosures are described in this Privacy Policy.

To the extent any provision in the Wellth Authorization is inconsistent with this Privacy Policy or other provisions of the Agreement, then the provision in the Wellth Authorization only controls with respect to your PHI. If you do not sign the Wellth Authorization, then your Personal Information that is not PHI is governed by this Privacy Policy and your Personal Information that is PHI is used and disclosed only as permitted by your Healthcare Entity(s).

V. USE OF INFORMATION

We use the information we collect to provide and improve our Platform and our Services. For example, we use such information to process your electronic signatures and account for electronic delivery of documents, and to optimize and improve our technologies and delivery of our Services. We use information that we collect about you or that you provide to us, including any Personal Information or PHI:

- to present our Services and its contents to you;

- to provide you with information, products or services that you request from us;
- to fulfill any other purpose for which you provide it;
- to carry out our obligations and enforce our rights arising from any agreements entered into between you and us, including for billing and collection;
- to notify you about changes to our Services or any products or services we offer or provide through it;
- to communicate with Healthcare Entities and Partners regarding the Wellthpoints you have earned;
- to communicate with Partners and facilitate the redemption of Wellthpoints;
- to allow you to participate in interactive features on our Platform or Services;
- to show you ads for Wellth or our advertising partners that are more relevant to your interests. These interest-based ads may be presented to you while you are browsing our site or third-party sites not owned by Wellth. We belong to ad networks that may use your browsing history across participating websites to show you interest-based advertisements on those websites. Currently, our Site does not recognize if your browser sends a “do not track” signal or similar mechanism to indicate you do not wish to be tracked or receive interest-based ads. To learn more about interest-based advertisements and your opt-out rights and options, visit the Digital Advertising Alliance and the Network Advertising Initiative websites (www.aboutads.info and www.networkadvertising.org). Please note that if you choose to opt out, you will continue to see ads on our Site, but they will not be based on how you browse and shop;
- in any other way we may describe when you provide the information;
- for any other purpose with your consent.

This policy is not intended to place any limits on what we do with data that is aggregated and/or de-identified so it is no longer associated with any particular Patient User of the Platform or Services. For example, we may use Patient User data to generate, among other things, statistics about Patient Users, common health concerns, or the demographic distribution of Patient Users.

VI. SHARING OF INFORMATION

We may share or transfer information about you as follows or as otherwise described in this Privacy Policy:

- With your Healthcare Entities in connection with providing the Services;
- With Partners, and other service providers who need access to such information to carry out aspects of the Services on our behalf (including but not limited to hosting, billing, fulfillment, data storage, security, Website analytics, ad serving, mobile communications) and/or who make certain services, features or functionality available to our users;
- In response to a request for information if we believe disclosure is in accordance with any applicable law, regulation, or legal process, or as otherwise required by any applicable law, rule, or regulation;
- If we believe your actions are inconsistent with the spirit or language of our user agreements or policies, or to protect the rights, property, and safety of you, us, or others;
- In connection with, or during negotiations of, any merger, sale of our assets, financing, or acquisition of all or a portion of our business to another company (should one of

these events occur, we will make reasonable efforts to notify you before your information becomes subject to different privacy and security policies and practices); - With your consent or at your direction, including if we notify you through the Platform that certain information you provide will be shared in a particular manner and you provide this information.

We may also use or share aggregated or de-identified information, which cannot reasonably be used to identify you.

VII. ANALYTICS SERVICES

We may allow others to provide analytics services in connection with the Services. These entities may use cookies, web beacons, and other technologies to collect information about your use of the Platform or Services, including your IP address, web browser, pages viewed, time spent on pages, links clicked, and conversion information. We and others may use this information to, among other things, analyze and track data, determine the popularity of certain content, personalize the User experience, and better understand your activity. Cookies may store unique identifiers, user preferences and other information. You can reset your browser to refuse all cookies or to indicate when a cookie is being sent. However, some Platform features or Services may not function properly without cookies. We use cookies to improve the quality of our service, including for storing user preferences, tracking user trends and providing relevant advertising to you. Also, we use Google Analytics, a web analytics service provided by Google, Inc. ("Google") to collect certain information relating to your use of the Platform. Google Analytics uses "cookies", which are text files placed on your computer, to help the Platform analyze how Users use and interact with the Platform. You can find out more about how Google uses data when you visit our Platform by visiting "How Google uses data when you use our partners' sites or apps", (located at www.google.com/policies/privacy/partners/).

VIII. SECURITY

We work hard to protect your information and take appropriate, industry standard physical, electronic, and other security measures to help safeguard personal information from loss, unauthorized access, alteration, or disclosure. Our security practices include: encrypting many of our services using SSL; two-step verification for account access; and frequent review of information collection, storage and processing practices, including physical security measures, to guard against unauthorized access to systems. Although we make good faith efforts to store Personal Information and PHI in a secure operating environment that is not open to the public, we do not and cannot guarantee the security of your Personal Information and PHI. Any transmission of personal information is at your own risk. We are not responsible for circumvention of any privacy settings or security measures contained on the Service. The safety and security of your information also depends on you. Where we have given you (or where you have chosen) a password for access to certain parts of our Service, you are responsible for keeping this password confidential. We ask you not to share your password with anyone. Please note that e-mails and other communications you send to us through our "Contact Us" form are not encrypted, and we strongly advise you not to communicate any confidential information through these means.

IX. OTHER WEBSITES

This Privacy Policy applies only to information we collect at and through our Platform. The Platform or Services may contain links to or embedded content from third-party websites. A link to or embedded content from a non-Wellth site does not mean that we endorse that site, the quality or accuracy of information presented on the non-Wellth site or the persons or entities associated with the non-Wellth site. If you decide to visit a third-party site, you are subject to the privacy policy of the third-party site as applicable and we are not responsible for the policies and practices of the third-party site. We encourage you to ask questions before you disclose your information to others.

X. ACCESS TO YOUR INFORMATION AND CHOICES

You can access and update certain information we have relating to your Account through the profile settings on the Mobile App. If you have questions about Personal Information we have about you or need to update your information, you can Contact Us, or email our support team at help@wellthapp.com. You can opt-out of receiving marketing and promotional e-mails from us by using the opt-out or unsubscribe feature contained in the e-mails. You can close your online account by going to the Settings tab in the Wellth app. If you close your account, we will no longer use your online account information or share it with third parties. We may, however, retain a copy of the information for archival purposes, and to avoid identity theft or fraud.

XII. CALIFORNIA PRIVACY RIGHTS

California Civil Code Section 1798.83 permits Patient Users of the Platform that are California residents to request certain information regarding our disclosure of personal information to third parties for their direct marketing purposes. To make such a request, please send an email to help@wellthapp.com.

XIII. QUESTIONS AND HOW TO CONTACT US

If you have any questions, concerns, complaints or suggestions regarding our Privacy Policy or otherwise need to contact us, please Contact Us or contact us by US postal mail at the following address:

Wellth, Inc.
ATTN: Wellth Privacy Officer
12130 Millennium Drive, Fl 3
Los Angeles, CA 90094
