

STUDY INFORMATION AND CONSENT TO RESEARCH

TITLE: Journey PRO

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SPONSOR: Celgene Corporation

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This consent form tells about the Journey PRO research study. It explains what we will ask you to do to participate in the study. Please read this form carefully. If you have questions, there is a list of people you can contact at the end of this form. If you decide to join the study, we will email you a copy of this form to for you to keep.

What is Journey PRO?

Journey PRO is a research study. This study will look at how chronic anemia (low red blood cell counts that persist over time) impacts health-related quality of life. You must be age 18 or older and have an iPhone model 5 or newer with iOS 8 or later to join. We encourage people with chronic anemia as a result of beta thalassemia, myelodysplastic syndrome (MDS), or myelofibrosis and people who do not have chronic anemia to join Journey PRO.

We will study quality of life by measuring health and overall well-being. If you join, we will ask you to download the experimental Journey PRO app, where we will ask you to answer questions about your quality of life. We will give some participants an Apple Watch. The Apple Watch will measure your daily activity (for example, number of steps taken in a day, number of stairs climbed, etc.) and your heart rate, which are signs of your health and well-being. We will look for patterns in the data. In this way, we hope to learn more about how chronic anemia impacts quality of life for people.

Please note: Journey PRO is not a medical treatment. It is a research study. If you have questions about your health, please see your doctor.

We would like at least 300 people to join Journey PRO.

How long will Journey PRO last?

The Journey PRO research study will be open for six months. If you join, we ask that you participate for about three months in a row during that time.

How much time will it take me to participate?

We will ask you to do about 5 minutes of daily study activities. Once a week, we will also ask you to do a set of study activities that should take about 40 minutes. If you decide to join the Journey PRO study, you can withdraw (quit) at any time.

What will you ask me to do?

1. Download the Journey PRO app. We will ask you to download the Journey PRO app and use it to complete the study activities. You can continue to use the app for as long as you like, even after the study is finished. However, we will collect your data only for as long as the study lasts.
2. Answer a health survey. After you download the app, you will be asked to answer some questions about your health. This should take about 20 minutes. You will only be asked to do this one time.
3. Do check-ins. Check-ins are a set of 3-9 questions. These questions should take about 5 minutes to complete. You can choose to complete a check-in once a day, once every two days, or twice a week. You can skip or postpone any question you do not want to answer.
4. Do challenges. Challenges have three parts: a health survey, brain tests, and a walking activity. We will ask you to complete a challenge at least once a week. You can skip or postpone any question or activity you do not want to answer/do.
 - a. Health survey. The health survey has about 30 questions. It will take about 25 minutes to complete.
 - b. Brain tests. The brain tests measure your short-term memory, reaction time, and attention. Each of them takes about 3 minutes to complete.
 - c. Walking activity. We will ask you to walk as far as you can in 6 minutes. This measures fitness. It is not necessary to run or exercise heavily to complete this activity.
 - d. Heart rate. We will ask you to measure the number of times your heart beats in a minute using your iPhone or Apple Watch. We will provide instructions on how to do this.
 - e. Record health events. We will ask you to enter when you have blood taken and to record results related to your anemia, like hemoglobin levels. We will ask you to tell us if and when you have a transfusion and information about it, like the

number of units of blood you receive. You can enter your doctor's appointments and prescription drug changes.

There is also a journal page where you can put notes. These notes are for you only. We will not collect them or look at them. Your notes are not part of the study.

5. Wear a fitness tracker (optional). If you have an Apple Watch fitness tracker, we will ask you to connect it to the Journey PRO app. In this way, we will know more about your activity level.

If you do not have an Apple Watch fitness tracker, we may ask if you would be willing to wear one for this study. This is optional. You can say no and still participate in Journey PRO. If you say yes, we may send you an Apple Watch. To activate it, you will need to create an Apple Watch account and link your Watch to your iPhone. We will ask that you wear the Apple Watch every day you participate in the study. It will record information like the number of steps you take and your heart rate.

What are the risks of taking part in Journey PRO?

The main risk of taking part in the Journey PRO research study is to your privacy. If there is a data breach, someone could get access to the information we have about you. Your information could be misused. We believe the chance of this is very small, but it is not zero.

We will gather information from you through the Journey PRO app. We may also gather information from you through an Apple Watch. There is a risk to your privacy whenever you use an app or fitness tracker like an Apple Watch. In general, there is no additional risk to your privacy if you use these technologies as part of the Journey PRO research study. However, we will be collecting several different types of information from you, so if there is a data breach, there may be additional risk to your privacy because of the amount of information the study database contains about you.

If we give you an Apple Watch to use, you will be asked to agree to the Apple Watch *Terms of Service* and *Privacy Policy*. Please review both of these policies carefully. We do not have control over these policies; they are set and updated by Apple.

What will you do to protect my privacy?

Your privacy is very important to us. We will take great care to protect it.

- Your study data will be encrypted on your phone. Unauthorized people will not be able to access your study data on your phone easily.
- We will separate your study data from the account information that identifies you. Your account information will not be stored with your study data
- Your study data will not be labeled with your name or other information that directly identifies you. We will label it with a random code. There will be a master list linking the codes to names, but we will keep it separate and secure.

- All information we have about you will be stored on protected computers. We will limit and keep track of who sees the information.
- We will tell you if there is a data breach.
- Apple Health Kit is the only app on your phone that we will access. We will not access your contacts, photos, texts, email, or browsing history.

What else should I consider before joining?

- Participating in Journey PRO may generate a wide range of emotions. Seeing patterns in your quality of life may affect your mood.
- Data collected in this study could count against your phone's data plan. You can configure the app to use only wifi to limit the impact data collection has on your data plan.
- Other people may glimpse the study notifications or reminders on your phone and realize you are in this study. This might make you feel self-conscious.
- Taking part in Journey PRO may have risks that we don't know about yet. We will tell you if we learn anything that might change your decision to take part.

Are there any benefits to joining?

Journey PRO is not a medical treatment. It is a research study. You will not get direct medical benefit from taking part in it. You will be helping scientists make discoveries that may help others in the future with similar diseases.

You may indirectly benefit from taking part. For example, you will be able to see all of your study data. This information may be interesting to you. You may learn about your health and well-being. If you choose, you can share your Journey PRO information with your health care team.

We may give you an Apple Watch to use in the study. You can keep it after the study ends and use it for as long as you like.

What are my options if I do not take part?

This is not a treatment study, your alternative is not to take part.

Are there any costs or payments?

There are no direct costs to you or your insurance. There may be an indirect cost to participating: the data we collect from you through the app may count against your phone's data plan.

There are no direct payments. We may give you an Apple Watch to use as part of the study. If we give you one, you can keep it.

Your information will be used by scientists to make discoveries. If any of their research leads to new tests, drugs, or other commercial products, you will not get any profits. These inventions will be the property of the scientists who develop them.

Will you ever give out my name or other information that identifies me?

We will never sell, rent, or lease your contact information.

However, we will give out information as required by law or regulation. For example, there are regulations that make sure scientific research is safe and ethical. These regulations specify that officials from the U.S. government, such as the U.S. Food and Drug Administration (FDA), must be able to review our work.

Research records which identify you and the consent form electronically signed by you may also be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies,
- Western Institutional Review Board® (WIRB®).

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

If you get an Apple Watch and wear it as part of this study, Apple will have information that identifies you. They will have the information from the Watch. They will use this information as they describe in their *Terms of Service* and *Privacy Policy*. Please review these policies carefully.

What if I get injured?

We will not pay for medical care if you are injured as a result of taking part in the Journey PRO research study.

If you are injured as a direct result of this study, call us at the phone number on page 1 and we will help you find medical care for your injury. If you have insurance, it may be billed for this treatment. You may be responsible for any co-payments or deductibles. If you do not have health insurance, you may be responsible for the cost of your care.

Do I have to take part in Journey PRO?

Taking part in Journey PRO is completely voluntary. You can choose to join or not. No matter what you decide, now or in the future, it will not affect your medical care.

- You should not feel obligated to join Journey PRO.
- Your questions should be answered clearly and to your satisfaction.
- You have a right to download or transfer a copy of all of your study data.
- By agreeing to participate you do not waive any of your legal rights.

What if I change my mind?

Even if you decide to take part in Journey PRO, you can change your mind at any time. If you decide you want to withdraw ("quit"), you need to tell us. You can tell us through the app, or use the contact information at the end of this form to call or write to us. There is no cost to withdraw.

If you withdraw, we are still required by law to keep your name and basic contact information in the study records. We will keep this information in a separate, secure place. It will not be used for research of any kind.

How long will you collect and use my study data for?

If you withdraw from this study, we will stop collecting your study data right away. If you withdraw, we will not use your study data for any future research.

If you do not withdraw, we will stop collecting your data at the end of the study period. We will use your study data for research long into the future unless there are limits imposed by law.

Who is doing this research?

Sage Bionetworks, a non-profit research organization, and its partners are conducting the Journey PRO research study. The Journey PRO research study is being funded by Celgene Corporation (www.celgene.com).

Who can answer my questions?

If you have questions, concerns, or complaints about:	Please contact:
The Journey PRO research study, or a research-related issue	<p>Name: Lara Mangravite, PhD Address: 1100 Fairview Ave. North Seattle, Washington 98109-4433 Phone: (206) 667-2103 or toll-free (844) 822-4708</p> <p>Name: Larsson Omberg, PhD Phone: (206) 671-1561</p>
Your rights as a research participant, or if you have concerns or complaints about the study	<p>Western Institutional Review Board® (WIRB®) Address: 1019 39th Avenue SE, Suite 120 Puyallup, WA 98374-2115 Telephone: (360) 252-2500 or toll-free (800) 562-4789 Email: Help@wirb.com</p> <p>WIRB is a group of people who perform independent review of research.</p> <p>WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.</p>

STATEMENT BY PERSON AGREEING TO TAKE PART IN JOURNEY PRO RESEARCH STUDY

Please check the box below if you agree to take part:

- ☐ **I have read this consent form. I understand the information in this form. All of my questions have been answered. I freely and willingly choose to take part.**

Type/sign your full name _____

Date _____