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NCT04094844

Health Information Technology System ("Roadmap 2.0") in the Context of Hematopoietic Cell Transplantation

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: ROADMAP 2.0 INTERVENTION

Company or agency sponsoring the study: National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator:

Sung Won Choi, M.D., M.S. Pediatrics – Hematology/Oncology

1.1 Key Study Information

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child.' All of the information in this form is important. Take the time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for caregiver health and well-being. This research will test the efficacy of Roadmap 2.0, a mobile health app, on caregiver health-related quality of life in a randomized controlled clinical trial. Your health-related information will be collected for this research study.

This study involves a process called randomization. This means that Roadmap 2.0 that you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on change (like the flip of a coin), to compare different treatments (Roadmap 2.0 vs no app). If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include discomfort from answering personal questions about health history, reactions to wearing a wearable sensor, and battery life of your mobile device. You have the choice to not answer those questions. There are no physical risks to participation in this study. There is also a minimal risk of a breach of data confidentiality. More detailed information will be provided later in this document.

You may not receive any personal benefits from being in this study. You will have access to the Roadmap 2.0 app, which may or may not be helpful. It is possible that your care team will be more aware of your needs as a caretaker because of your participation in this study. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 18-weeks (or 5-months).

You can decide not to be in this study. This study is for research and product development purposes only. There is no alternative treatment to this study. The only alternative is to not participate in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: In recent years, mobile health-mediated technology is rapidly spreading into consumer markets and provides unique opportunities to engage individuals on tracking and managing their health. Utilization of mobile applications (apps) in health care research and administration can streamline health care delivery (e.g., wellness exercises, health care information) and data collection. Wearable sensors (e.g., smart watches) can be utilized to measure a variety of physiological and contextual data, such as the number of steps taken, stand hours, heart rate, sleep, and other activity data.

The purpose of this research study is to use a mobile health app (Roadmap 2.0 and Social Rhythms) and a wearable sensor (from mobile devices and wearables), along with health information and surveys, to understand the relationship between sensor data and different health outcomes (health-related quality of life [HRQOL]). This study is not to provide any treatment, but rather to investigate the use of a mobile health technology-mediated intervention (Roadmap 2.0) in caregivers and patients and to collect information for research. The study aims to see the benefits of a positive psychology intervention delivered via mobile application.

You have the option of participating in the study. This research study is being conducted by the University of Michigan (“Study Team”). With appropriate permissions, your information may also be shared with Other Researchers (“Other Researchers”), here, around the world, and with other companies.

In this study participants will be given either the Roadmap 2.0 app with positive activity components and a Fitbit, or Roadmap 2.0 without positive activity components and a Fitbit. By randomly assigning participants to either the arm with positive activities, or the arm without, we can test the difference in our primary outcome, or caregiver health-related quality of life [HRQOL].

When this document is signed, it gives us your permission to obtain and use your protected health information as described in this consent/assent and authorization.

Additional information regarding data sharing is explained in the below sections.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adult caregivers (age ≥ 18) are comfortable understanding, reading, writing, and speaking in English while using your mobile phone or tablet and sensor device, agree to participate as caregiver-patient dyads, and sign informed consents/assents. Patients (age ≥ 5 years) agree (assent) to allowing caregivers to receive information about their medical health. Patients (age ≥ 10 years) also agree (assent) that caregivers can share information about the patient on Roadmap 2.0. Participants (caregiver-patient pairs) agree to answering survey questions and provide certain health data to the Study Team.

3.2 How many people are expected to take part in this study?

We will enroll 300 caregiver-patient dyads (600 total study participants).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will be provided with an Apple iPad containing the Roadmap 1.0 application to use while you are inpatient, and a wearable sensor to use the Roadmap 2.0 app. In addition to the provided device, your own phone or tablet (e.g., Android, iPhone) will be used to collect data. You, your family and/or your child/loved one (patient) are free to use these tools as much as you would like on your own time. Your care team will collect the Apple iPad when you are discharged and ready to go home.

Participating in the study:

- Participation criteria: The Study Team will ask you questions to verify that you meet the study participation criteria.

If you are eligible to participate, you should understand that:

- Study Device and Apps. Roadmap 1.0 will be used inpatient. While this device is in use you and your caregiver will have access to your patient-specific information displayed in Roadmap 1.0 on the imaged iPads. You must setup and maintain the study devices (mobile phone or tablet) and app (Roadmap 2.0 and Social Rhythms) in the required manner. The Study Team will help you with the setup.

- Circadian Rhythm Report. You will be provided a circadian rhythm report through the Social Rhythms app that is based on your circadian rhythm. This report will mention items such as what time your body begins to prepare for sleep and what time you should reduce lighting to not interfere with your sleep.
- Sensor Data. You give the Roadmap Study Team permission to collect raw sensor data streams from your wearable, wrist-worn sensor and mobile phone during your study participation. Once the Fitbit app has been downloaded, you will be instructed on how to sync to a Fitbit, and how to connect your Fitbit to the Roadmap 2.0 app. Roadmap 2.0 in conjunction with the Fitbit application, will be passively collecting your sensor data. Both caregivers and patients, in both arms of the study, will be provided with a Fitbit.
- Health Surveys. You will be asked to complete surveys about your health, quality-of-life, and well-being upon consenting (e.g., baseline). You will also be asked to complete additional surveys over the course of the study regarding topics, including but not limited to quality-of-life, pain, mood, activity, sleep, well-being (i.e., around days 30 and 120 from the initial baseline survey).
- Interviews. You may be asked to complete interviews via the Zoom or other digital platform or in-person. These interviews will take about 10-15 minutes and cover topics related to your transplant or caregiving experience as well as your opinions and feelings towards the apps and study.
- Health Records. You give the Roadmap Study Team your permission to collect your protected health information and link it to use of Roadmap 1.0, 2.0 and the wearable sensor data. Your permission to let this Study Team do this expires after 1-year post-HCT.
- Re-contact. With your permission, researchers may contact you again to; i) ask for more information; ii) to tell you something they have found out about your information; iii) to offer you the opportunity to participate in future studies. You will always have the right to say no when you are approached in the future. The Study Team may also contact you if you have not completed the required study tasks.
- Qualitative Interview. Researchers may contact you to conduct qualitative interviews which may occur at day discharge (+/- 7 days), Day +30 (+/- 14 days), Day +60 (+/-14 days), Day +90 (+/- 14 days), and Day +120 (+/-30 days). Qualitative interviews will occur based on study team and participant choice and may include all, some, or none of the interviews for a participant. Study subjects may be asked for permission to audio-record the qualitative interviews. These will be conducted in person, via telephone, or through video conferencing platforms, such as Zoom. These interviews may be conducted before or after clinic appointments. Participants can choose to opt in or out of these interviews.

You should understand that:

- This is a research study. It is not part of your health care and will not directly help you.
- It is designed to help us learn about health and well-being for the benefit of caregivers.
- Participating in this study is completely up to you.
- If you decide not to participate in this study, it will not affect your health care treatment or payment, enrollment in your health plan, or your eligibility for health care benefits.
- You will not receive payments from scientific discoveries made using the information you provide.

- You are responsible for any information that you post about yourself or the patient you are caring for in the Roadmap 2.0 app.

If you decide to participate in this study, data in categories such as the following will be collected from or about you ("Study Data"):

- Positive Activity Data: your data entries of these exercises. For example, "Gratitude Journaling" or "Random Acts of Kindness" – any information posted in the Roadmap 2.0 app.
- Survey data, such as information on weight, medical history, lifestyle, pain.
- Physiological data, such as accelerometer, activity (e.g., steps), heart rate, and sleep.
- Electronic health record data, such as visit history, demographics, test results, procedures, diagnosis, prescriptions, and fulfillment history, billing related information and date of event. Information related to sensitive conditions, such as mental health records, alcohol and substance abuse, and HIV or AIDS could be included.
- Study software diagnostics, protocol adherence metrics and metrics for interactions such as a concern, adverse event, or other reportable matter arising in the study.
- Contact information, such as name, phone number, physical address and email address and identifiers, such as medical records number, date of birth and social security number (this is needed.
- Demographic information, such as your age, gender, race, ethnicity, geography-based metrics (for example environmental, economic, education-level, population health information).
- Signed informed consent/authorization.
- Device identifiers.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

Allowing us to do future research on your medical information will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?

You will be asked to complete the following tasks each **day**:

- Wear the wearable sensor every day, except for when showering or charging the device. Capturing sleep and activity data are very important in this study.
- Enter your mood on a scale of 1-10 once daily in Roadmap 2.0.
- If randomized to Roadmap 2.0, participate in any of the positive activity exercises

You will also be asked to complete the following tasks at **various time points**:

- Survey questionnaires: baseline and around days 30 and 120 from the initial baseline survey (approximately 30-minutes)
- Semi-structured interviews: baseline, discharge, and around days 30 and 120 from the initial baseline interview (approximately 30-minutes)
- Syncing data to the Social Rhythms app can be completed at baseline (+/- 14 days), around day 30 (+/- 14 days), and around day 120 (+/- 14 days). At baseline, Social Rhythms will collect data starting 1 week prior to consenting.
- Qualitative interviews may occur at some, all, or none of the following timepoints (discharge, day 30, day 60, day 90, and day 120).

Each of the interviews you participate in should take less than an hour. These interviews will start at baseline, occur during hospitalization (i.e., right before discharge), at around day 30, and at around day 120 from the initial baseline interview when you return for a clinical visit. Permission will be asked to audio-record the qualitative interviews. These will be conducted through video conferencing platforms, such as Zoom or phone. Survey questionnaires will take about half an hour to complete (baseline and days 30 and 120), totaling approximately one and a half hours during your participation in the study.

4.3 When will my participation in the study be over?

Although you are free to discontinue your participation at any point, participation in this component of the study concludes after the last interview and survey, around 120 days post-transplant. The study team will have access to the electronic medical records for 1-year post-HCT.

4.4 What will happen with my information used in this study?

Your biospecimens and collected information may be shared with the National Institutes of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- You may experience discomfort or anxiety from answering personal questions about health history, from viewing blood pressure values that appear to be above normal ranges, or from abnormal testing results. We encourage you to contact your physician if you have these concerns.
- Risk from the wearable sensor: A small number of people will experience reactions to certain materials. This can be due to allergies, environmental factors, extended exposure to irritants like soap or sweat, and other causes. If you experience redness, swelling, itchiness, or any other irritation, you may want to consult your physician before you put your wearable sensor back on.
- Data collection during the study may affect the battery life of your mobile phone and may use your mobile phone's data plan.
- The Study Team and the Sponsor will make every reasonable effort to keep your data safe and protect the confidentiality of your data, including storing study data in a secure system; however, total confidentiality cannot be guaranteed. There is always a risk that you could be identified by your health information. It is possible that there could be unauthorized access to or a breach of the systems where your data is stored.

Sharing: The Study Team will follow all regulatory standards before releasing information. However, as the study involves use of various apps related to Roadmap 2.0, Social Rhythms, and/or wearable sensor, the privacy policies could be similar or different.

As part of this study, you will be asked to use a wearable sensor. While participating in this study, you must set permissions to enable sharing information from the wearable sensor to the Study Team. Any information you provide to the Study Team for the purpose of the study is called "Study Data" and the current consent document explains how this will be protected by the study team.

As part of this study, you will be asked to download the Roadmap 2.0 app and Social Rhythms app from App Store. There could be other risks, which are yet unknown. However, we will contact you if there is a change in risk profile of this study that we think would make you reconsider your decision to be in the study.

Although there are no physical risks to participation in this study, participants may feel increased emotional distress as a result of reporting their experiences as a patient or caregiver. This distress is not expected to exceed what you may be experiencing in your daily life at this time. There is also a minimal risk of a breach of confidentiality.

The researchers will try to minimize these risks by providing a safe environment for you to express your concerns and devising appropriate interventions for you, if needed.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your Confidentiality and Privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

There is no expectation that participation in this research will result in any physical illness or injury.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You may be randomized to have access to Roadmap 2.0's positive activity exercises, which may or may not be helpful during the caregiving process. It is possible that your care team will be more aware of your needs as a caretaker because of your participation in this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this research study is completely voluntary and the alternative is to not participate, in which case there will be no penalty. You may ask the researchers or your doctors about other options you may have.

If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you discontinue participation.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices

- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

The total length of the study is approximately 18-weeks or 5-months. Once enrolled in the study, you will be asked to complete various tasks and you'll be compensated if those tasks are completed.

You will be compensated for each completed survey questionnaire ($25 per time-point), or up to $75 for completing all three time-points (baseline and days 30 and 120). The Day 30 survey must be completed withing 14 days of your day 30 post-baseline. The day 120 survey must be completed within 30 days of your day 120 post-baseline. You will be compensated $20 for participating in a post-trial interview around Day 120. Although we hope you wear the sensor all day long, you will get to keep the wearable sensor for completing all of the recommended tasks to the best of your ability.

8.3 Who could profit or financially benefit from the study results?

In this study, we are using an App, developed by the investigators on this study. If it works the way we hope, there's a chance other researcher will want to use it. If it is sold to them, the inventors and U-M could benefit.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Research records will be kept in password-protected research files that do not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Your responses to questionnaires and interview notes are for research use only and will not become a part of your permanent medical record. The design of Roadmap 2.0 and Social Rhythms includes extensive security to maintain the privacy of any health information.

Whenever possible, your health information will be stored with a code instead of identifiers (such as name, date of birth, medical record number). However, the more information about you that is combined together, the more likely it is you could be identified.

Other Researchers will only have access to Coded Study Data.

All information used by this project will be protected so that it can only be accessed by authorized people. The Study Team will do its best to ensure that the Study Data is kept private and secure. Your Study Data will be stored and transmitted using secure systems. Still, absolute confidentiality cannot be guaranteed.

No published scientific reports or presentations will identify you directly.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease and/or other communicable disease status
- Genetic counseling/genetic testing records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)

- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

You can contact the Roadmap 2.0 study staff by emailing ROADMAPstudy@med.umich.edu for any of the following reasons:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Sung Won Choi, M.D., M.S.
Mailing Address: 1500 E. Medical Center Drive, D4118 MPB, Ann Arbor, MI 48109-5718
Telephone: 734-615-5707

University of Michigan Study Coordinator Team
Mailing Address: 1500 E. Medical Center Drive, D4206 MPB, Ann Arbor, MI 48109-5718
Email: Choi-Lab-Coordinators@med.umich.edu
Telephone: 734-936-2263

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800

Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. COPY OF CONSENT FORM

11.1 What documents will be given to me?

By tapping accept in the next section it means that you understand all of the following :

- You will receive a paper copy of this consent form if you request one.
- A blank version of this consent form can also be found on the roadmap.study website, as well as within the Roadmap app itself in the info section

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

This study involves audio recording. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to let the study team keep my data for future research and allow for audio recordings.

_____ No, I do not agree to let the study team keep my data for future research and allow for audio recordings.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Legally Authorized Representative or Parent Permission

Subject Name:

_____

Parent/Legally Authorized Representative:

Printed Legal Name:

_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____