UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: A Randomized Trial of the SYNC App

Company or agency sponsoring the study: National Institutes of Health and Arcascope Inc.

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 may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. 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 family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. 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 child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's light exposure and behavior can have an impact as a treatment for cancer-related fatigue. This research will test the efficacy of Sync, a mobile health app, on user fatigue, sleep, anxiety, depression, and overall mood in a randomized controlled clinical trial. Sync was developed by Arcascope Inc., a University of Michigan startup company partially owned by researchers involved in this study at the University of Michigan and Arcascope Inc. Your health-related information will be collected for this research study and shared with Arcascope Inc.

This study involves a process called randomization. This means that the app you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups,

based on chance (like the flip of a coin), to compare different treatments (Sync app with intervention vs no intervention). 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 Sync app, which may or may not be helpful. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 12 weeks (or 3 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: Fatigue is extremely common among cancer patients and survivors, and it can negatively impact quality of life, mood, and overall health and well-being. Fatigue can be difficult to treat, and there is currently no gold-standard treatment for fatigue. In this study, we are investigating whether light exposure and behavioral changes may improve circadian rhythms and reduce cancer-related fatigue. Using a mobile application, wearable sensor, and personalized behavioral recommendations, we hope this study may help reduce fatigue among cancer patients and survivors.

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?

Adults (age $\geq$ 18) who are comfortable understanding, reading, writing, and speaking in English can agree to participate in this study. To participate, you must own an iPhone 6s or later (with iOS 14 or later or willing to update to iOS 14+) and be willing to complete surveys on it. Alternatively, patients without iPhones must be willing to use a loaner iPhone provided by the study team to use during the study and return at the end of the study. You can use sleep aids, so long as you've been on a stable dose for at least 4 weeks prior to enrollment and agree to stay on that dose during the study. To participate, you'll need to report at least a four on a 10-point scale to the question "How fatigued did you feel in the last four weeks?" We are recruiting patients and survivors from three different cancer types. If you are a breast cancer patient, you need to have been diagnosed with stage 1-3 breast cancer in the last ten years without metastatic disease. If you had chemotherapy or radiation therapy, you must have completed it at least three months prior to enrollment. If you are a prostate cancer patient, you must have been on androgen deprivation therapy (ADT) for at least three months and be anticipated to remain on ADT for the three months of the trial. If you are a patient who has undergone hematopoietic stem cell transplantation (HSCT), commonly known as bone marrow transplantation (BMT), you must be from the University of Michigan Blood and Marrow Transplant Program. You cannot be undergoing chemotherapy at the time of enrollment unless it is post-transplant maintenance chemotherapy. Patients undergoing post-transplant maintenance chemotherapy are permitted to enroll. Additionally, you must have no evidence of disease progression or recurrence. Finally, you must not be a night shift worker.

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

We will enroll 138 participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will be provided with the Sync app, which you will download onto your iPhone. You will also be given an Apple Watch if you don't have one of your own already, and you will pair that Watch with your iPhone. Finally, you will also be provided with glasses that you may be asked to wear at certain times throughout the study.

This study involves a process called randomization. This means that the version of the Sync app and the type of glasses you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments (Sync app with intervention components vs no intervention components). The intervention components in this study are personalized lighting and behavioral recommendations delivered through the app. The intervention group will receive blue-light blocking glasses, while the control group will receive glasses that do not block any light. By randomly assigning participants to the group with intervention components, or the group without, we can test if the intervention helps reduce fatigue.

For some research studies, such as the one you are being asked to join, it is important that you do not know what group you have been assigned to. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

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. You must set-up and maintain the study devices (mobile phone, Watch) and app (Sync) in the required manner. A study team member can assist you in downloading the app and setting up the Watch to work with your phone.

- Sensor Data. You give the Sync team permission to collect raw sensor data streams from your Apple Watch and mobile phone during your study participation. Once the app has been downloaded and the Watch has been paired with your device, data will be collected through the phone.

- Health Surveys. You will be asked to complete surveys about your sleep, fatigue, mood, sleep aid usage, and overall health. You will answer a one question survey about your fatigue every day, and multiple questions about how you're feeling and how the experience with the app is going every week. At the beginning and ending of the study, you will also take a longer survey about your overall health.

- Health Records. You give the Sync Study Team your permission to collect your protected health information and link it to use of Sync and the wearable sensor data. Your permission to let this Study Team do this expires 5 years after study completion.

- 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.

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 cancer patients and survivors.
- 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 share with the Sync 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"):

- Physiological data, such as accelerometer, activity (e.g., steps), heart rate, and sleep, collected from the Apple Watch
- Survey data, such as information on mood, sleep, fatigue, and overall health, and self-reported sleep aid use and alcohol consumption
- 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 record number, date of birth, and social security number.
- 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 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 samples and 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.

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.
- Rate your fatigue on a scale from 1 to 5 once daily in Sync.
- Complete the light exposure and behavioral tasks assigned each day in Sync.

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

- End of week surveys on health and experience with the app (approximately ten minutes)
- Pre- and post-trial surveys on health and experience with the app (approximately 15 minutes)

Weekly questionnaires will take about ten minutes to complete, totaling approximately two hours to complete over the 12-week study. The pre- and post- trial surveys together are expected to take 15 minutes each, for a total of 2.5 hours of survey completion. The post-trial survey must be completed within two weeks after the 12-week intervention period.

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 post-trial survey, 12 weeks after starting.

In addition to the time above, we will collect information from your medical records for another 5 years after you complete the study.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the National Institutes of Health and Arcascope Inc.

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

Your identifiable private information or identifiable biospecimens 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. 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 Sync 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 Sync app from TestFlight. 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. 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 Sync’s interventions, which may or may not be helpful for fatigue.

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.

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 12 weeks or 3 months. Once enrolled in the study, you will be asked to complete various tasks.

You will be compensated for each 4-week period of active participation in the study. Active participation is defined as completing at least 5 daily fatigue surveys per week, on average, during each four-week period. People who already had an Apple Watch will get $25 at the end of the first four weeks of active participation in the study, $25 at the end of the second four weeks of active participation, and $35 at the end of the third four weeks of active participation and after completion of the exit survey. People who didn't already have an Apple Watch will be provided with an Apple Watch that they may keep after the study; they will also be compensated $15 at the end of the first four weeks of active participation, $15 at the end of the second four weeks of active participation, and $25 at the end of the third four weeks of active participation and after completion of the exit survey. Although we hope you wear the sensor all day long, you will get to keep the Apple Watch for completing all of the recommended tasks to the best of your ability. All participants will also receive glasses to use during the study, and they may keep the glasses after the study. Participants who do not own iPhones may receive a loaner iPhone from the study team to use during the study and return at the end of the study.

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

The company whose product is being studied:

In this study, we are using the Sync App, which was developed by the sponsor of this research, Arcascope Inc.

The researchers conducting the study:

Researchers working on this project at the University of Michigan and Arcascope Inc. also have a financial interest in Arcascope Inc. and the technology used in this project. The following researchers – Drs. Danny Forger and Olivia Walch– are affiliated with and have a personal interest in Arcascope Inc.

The University of Michigan:

The University of Michigan has a financial interest in Arcascope Inc. This means that the University of Michigan, these researchers, and Arcascope Inc. might one-day benefit financially from this study.

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 Sync 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.

Records of your participation in this study and your Study Data will be held confidential except if disclosure is required or allowed by law or as described in this informed consent and authorization document.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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

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 5 years after you complete 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 Sync study staff by emailing SYNC-Study@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

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. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)

12. SIGNATURES

Sig-A

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): _____

Sig-B

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.

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

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

Print Legal Name: _____

Signature: _____

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

Sig-C

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): _____