UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: My Fitness Study

Company or agency sponsoring the study:
No Sponsor

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

Principal Investigator: Sung Won Choi, M.D., Department of Pediatrics, University of Michigan

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'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take 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 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.

When this document is signed, it confirms our promises to you and gives us your permission to obtain and use your samples and your protected health information, as described in this consent and authorization.

This study may not offer any benefit to you now but may benefit others in the future by learning about health and disease for the benefit of caregivers and patients receiving cancer, transplant, or cellular therapy. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 120 days.

You can decide not to be in this study. Alternatives to joining this study include the option to join other clinical trials.

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 in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: In recent years, wearable technology has rapidly spread into consumer markets and provides unique opportunities to engage individuals on tracking and managing their health. Utilization of mobile applications (apps) in healthcare research and administration can streamline participant consent, data collection, and distribution of healthcare interventions (e.g., medical information, surveys, reminders, self-care techniques). Wearable sensors can be utilized to measure a variety of physiological and contextual data, such as the number of steps taken, stand hours, heart rate, heart rate recovery, temperature, and other sleep and activity data.

The primary purpose of this research study is to assess the feasibility and acceptability of using wearable sensors (Fitbit Charge 3 and TempTraq patches). We are also interested in using sensor data from mobile devices and wearables, along with surveys, and your health and genetic information, to understand the relationship between sensor data and different health outcomes. This study is not to provide any treatment, but rather to collect information for research and product development purposes.

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?

Family caregivers (age ≥18) of a registered patient at the University of Michigan are being asked to participate in this study. The registered patient is also being asked to participate in the study. The caregivers and patients will be linked together in this study as a pair, if both the patient and caregiver would like to participate, otherwise the patient and caregiver will be separate. Both the patient and the caregiver must possess his/her own smartphone or iPad tablet to participate in the Fitbit portion of the study. You or your child are being asked to take part in a research study, use a mobile device, use a Fitbit Charge 3 and TempTraq temperature patch device with a mobile device, and have expressed a willingness to download and use certain apps, answer survey questions, undergo neuropsychological testing, provide saliva and blood samples for genotyping and analysis and provide certain health data to the Study Team.

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

Approximately 200 subjects will be eligible for this study per year.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you are eligible to participate, you should understand that the following components of the study are for research purposes. You may choose to complete all, some, or none of the components:

- **Sample donation.** You will be asked to provide a blood sample (25 mL, approximately 2 tablespoons) and/or saliva sample for genetic and pathology analysis. These analyses may include DNA, genetics, cytokine protein levels.

Genetic Analysis: Genomic information relates to the structure and function of all of the genetic material in the body. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

- **Health Survey**. You will be asked to complete a survey about your health upon consenting. You will also be asked to complete surveys regarding topics including but not limited to: quality of life, pain, mood, and sleep.

- **Neuropsychological Testing**. You will be asked to complete neuropsychological assessments about your cognitive function.

- **Study Devices and Apps.** You will setup and maintain the study devices (Fitbit Charge 3 and TempTraq patch) and apps (Fitbit app, Roadmap app, TempTraq) in the required manner. The study staff will help you with the setup.

  Health Records. You give the Study Team your permission to collect your protected health information and **any** other past, present, or future sources and link it to your donated blood sample. The study team will have unlimited access to your medical records as well as all blood samples. Your permission to let this Study Team do this has no expiration date.

- **Biorepository:**

  We will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

  Genomic information relates to the structure and function of all of the genetic material in the body.

  We will submit your genomic information to a repository to be used for scientific purposes. A repository contains information from many people. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies.

  Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different.

  We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to

researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally.

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

- **Research and Product Development Uses.** You give your permission to use your samples and health information to study **any** disease or health condition; health and educational research; and product development purposes. 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.
- **Re-contact.** With IRB approval, researchers may contact you again to (1) ask for more samples or information; (2) to tell you something they have found out about your sample; (3) to offer you the opportunity to participate in future studies. You will always have the right to say no when you approached in future. The Study Team may also contact you if you have not completed the required study tasks or to diagnose and correct study hardware or software problems. It is possible, but unlikely, that a follow up visit may be requested to troubleshoot these problems. You always have the right to say no to these requests.
- Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your blood/saliva and 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.

	Baseline	Day 30	Day 120	Day 180	Day 365
Deemed eligible to participate in study	**X**				
Consent to Study	**X**				
Training of wearable sensors; download apps	**X**				
Training of Roadmap 2.0; download app	**X**				
Questionnaires	**X**	**X**	**X**		
Neuropsychological Testing	**X**	**X**	**X**	**X**	**X**
Saliva	**X**				
Blood*	**X**	**X**	**X**		

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

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

We may share your blood/saliva and 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 blood/saliva and medical information with other researchers, we will not be able to get it back. There may be additional risks that the future risk may pose that we are currently not aware of, but we will make all efforts to minimize them by destroying any identifiers that link that data to you.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements. You will not find out the results of future research on your blood/saliva. Allowing us to do future research on your blood/saliva and 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 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.

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?
Each visit is expected to last about 30-minutes and will always be coordinated at the time of a routine clinic visit of the study participant.

4.3 When will my participation in the study be over?
The follow-up on this protocol will continue up to 5 years (i.e., with annual surveys and/or neuropsychological testing), unless the participant withdraws their approval or the investigative and clinical team loses contact with the participant.

4.4 What will happen with my information and/or biospecimens used in this study?
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?

You should understand that the known or expected risks are:

- There are minor physical risks involved with providing your sample. Collection of blood samples may cause pain, bleeding, bruising or infection. It is also possible that you may feel lightheaded or faint. Please tell your study doctor or the study nurse if you do not feel well after having your blood drawn at any time during your study participation.
- You may experience discomfort or anxiety from answering personal questions about health history, from viewing sleep or activity data. We encourage you to contact your physician if you have these concerns, but you do not have to answer any question that may make you feel uncomfortable.
- Risk from wearing the Fitbit Charge 3: 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 Fitbit Charge 3 back on.
- Risks from wearing the TempTraq patches: 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 using another TempTraq patch.
- Data collection during the study may affect the battery life of the Fitbit Charge 3 and your mobile device and may use your mobile device data plan.
- The Study Team 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 blood sample and health information. It is possible that there could be unauthorized access to or a breach of the systems where your data is stored. *See the Privacy and Confidentiality section for important details.*

The researchers will try to minimize these risks by:

- **Sharing:** The Study Team will follow all regulatory standards before releasing samples or information. However, as the study involves use of various apps, the privacy policies could be similar or different.

1. As part of this study you will also be asked to use a third-party study app – Fitbit App and Roadmap App. While participating in the study, you must set permission to share information from the Fitbit App with the Roadmap app. Any information that you provide in the Fitbit or Roadmap App falls under the App's privacy policy. Data shared with the Roadmap app may be shared with Arbormoon, the company that provides the Roadmap app, so you should be sure to review the App's privacy policy and terms to makes sure you are comfortable with its data use and sharing practice before signing this consent. Roadmap Study privacy policy - Your survey data, and all other information entered through your mobile phone or iPad tablet will be coded with a unique non-decodable identifier so that all information you provide will remain confidential.
2. As part of this study, you will be asked to use a Fitbit Charge 3. While participating in this study, you must set permissions to enable sharing information from the Fitbit App 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. Please be sure to review this document to make sure you are comfortable with the proposed data use and sharing practices before signing this consent document.

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?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

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.

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?

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

No, there is no anticipated harm to you if you decide to leave the study before it is finished.

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. In this study that includes blood/saliva samples for this study, research surveys, wearable devices and apps, and neuropsychological testing. 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

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?

Caregivers will receive $25 for each time you complete a neuropsychological assessment for a maximum of $125 (or 5 times of testing). Patients will also receive $25 for each time you complete a neuropsychological assessment for a maximum of $125 (or 5 times of testing). Payments will be received after each completed neuropsychological assessment.

8.3 Who could profit or financially benefit from the study results?
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?
Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

Genetic Information Nondiscrimination Act (GINA) -- If the research involves analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes, insert the following two paragraphs:

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

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.)
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease and/or other communicable disease status
- 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 at the end of the study (up to 5 years), 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?
Please contact the researchers listed below to:

- 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, MD MS
Mailing Address: 1500 E. Medical Center Dr., 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.)*
- Other (specify):

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: _____
(Participants ages 15-17 will sign this box)

Signature: _____

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

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. 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 specimens for future research.

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

Print Legal Name: _____

Signature: _____

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

Sig-D

Consent/Assent to Specific Portions of the Study

This project involves the option to allow you to opt in or out of each aspect of the study. I understand that it is my choice whether or not to opt in to all or some of the aspects of the study. 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 submit blood samples for this study.
_____ **No**, I do not wish to submit blood samples for this study.

_____ **Yes**, I agree to submit saliva samples for this study.
_____ **No**, I do not wish to submit saliva samples for this study.

_____**Yes**, I consent to completing surveys.
_____**No**, I do not consent to completing surveys.

_____**Yes**, I consent to completing neuropsychological assessments (baseline, day 30, day 120)
_____**No**, I do not consent to completing neuropsychological assessments (baseline, day 30, day 120)
_____**Yes**, I consent to completing neuropsychological assessments (day 180 and day 365)
_____**No**, I do not consent to completing neuropsychological assessments (day 180 and day 365)

_____**Yes**, I consent to being provided one or more wearable devices and apps (Activity monitor).
_____**No**, I do not consent to being provided a wearable device or apps (Activity monitor).

_____**Yes**, I consent to being provided one or more wearable devices and apps (Temperature monitor).
_____**No**, I do not consent to being provided a wearable device or apps (Temperature monitor).

Print Legal Name: _____

Sig-E

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: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-G

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): _____