**Central Michigan University**

**Detroit Medical Center – Children’s Hospital of Michigan**

**Research Informed Consent - Medical**

Title of Study: *[insert the full name of the study]*

Principal Investigator (PI):

[*Name*] [*Address*] [*Phone*]

Location(s):

[*Where study will have services rendered*]

Funding Source:

[*Name*]

[*Delete funding source section if there is no funding*]

[*List Institution or Whom*] is being paid to conduct this study.

## When we say “you” in this consent form, we mean you or your child; “we” means the doctors and other staff.

[*Delete if minors are not involved in the research. If minors are involved in the research revise footer to Parent/Participant Initials.]*

**Key Information about this Study** *(Refer to section 2.2 of the CONSENT FORM SOP)*

1. *A statement that the project is research and participation is voluntary*
2. *A summary of the research including purpose, duration, and a list of procedures*
3. *Reasonable foreseeable risks or discomforts*
4. *Reasonable expected benefits*
5. *Alternative procedures or course of treatment (if any)*

# Purpose

You are being asked to be in a research study of [*insert a general statement about the study*] because you [*explain succinctly and simply why the prospective subject is eligible to participate*]. This study is being conducted at Detroit Medical Center - Children’s Hospital of MI (DMC CHM) [*and/or lists all other locations where the PI will be conducting this study*]. The estimated number of study participants to be enrolled at DMC CHM [*and/or the proposed site(s)*] is about [*insert number*] as well as about [*insert number*] throughout [*insert location where study will be conducted; e.g., U.S., Europe, Canada, etc.*]. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, [*provide a brief paragraph or two that describes the purpose of the research study in lay language (6th -8th grade reading level). If a drug/device is involved, state whether or not it is experimental and who will be providing the drug/device*.]

**Disclosure of Financial Support.** Central Michigan University and Children’s Hospital of Michigan are being paid by the Sponsor [insert name of Sponsor] to conduct this research study.

*[Add when applicable]*

**Disclosure of Investigator’s Financial Interest.** Dr [name of PI] has disclosed a financial intererest in [describe the nature of the interest]. CMU and Dr [name of PI] have agreed [describe financial interest management plan].

# Study Procedures

If you agree to take part in this research study, you will be asked to [*explain in simple, nonscientific terms what the participants will be asked to do as part of the research study*. *Medical terminology should be simplified or explained. All abbreviations and acronyms should be defined*. *The following information, as applicable, should also be addressed in paragraph form:*

1. *Describe exactly what tasks the participant will have to do to take part in the research protocol—take medications, return for clinic visits, fill out a diary, refrain from certain activities, etc. [If several visits are identical, procedures/tasks can be collapsed under a general category.]*
2. *Clearly state how long each study visit will last, the frequency of visits, and the total duration of active treatment and follow-up. Give an estimate of how much time is required at each session for required activities such as completion of questionnaires, procedures, interviews, etc.*
3. *Describe what tests will be performed over what period of time. Clearly differentiate what is outside of the standard of care.*
   1. *If blood or other tissue is to be collected, state in lay terms (i.e., teaspoons, inches, pounds, etc.) the amount, frequency, and method of collection as well as how the specimens will be used.*
   2. *State how the participant’s identity will be protected.*
   3. *State if biospecimens may be used for commercial profit, and whether the participant will or will not share in this commercial profit.*
   4. *If biospecimens will be used, state whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*
   5. *State whether clinically relevant research results, including individual research results will be disclosed to participants, and if so, under what conditions.* ***(ex. The results of testing will not be given to you or your doctor. These test results are for research purposes only. We will not understand the meaning of most of the differences in this information until there is more research in the future).***
   6. *Explain the need for any radiation exposure that is specific to the research protocol (i.e., X-rays or scans that would not be done except for participation in this protocol).*
   7. *Identify all aspects of the research that are experimental.*
4. *NOTE: All procedures listed in the protocol should be included in the Study Procedures section.]*

*If photographs will be taken please include the following text: Photographs will be taken of visible disease sites to monitor the progression of the disease, rash or lesion. Every attempt will be made to avoid a full-face photograph. If this is not possible, the photograph will be ‘de-identified’ as much as possible, including a black box over the eyes. There is a risk that a photograph may not protect your identity.*

**Benefits** [*select only one of the following paragraphs and delete the one that does not apply*].

As a participant in this research study, there [*select the appropriate verbiage, may/will*] be no direct benefit for you; however, information from this study may benefit other people [*if applicable, state— with similar health issues*] now or in the future.

The possible benefits to you for taking part in this research study are [*describe any direct benefit to the participant; e.g., information about health status, improvement in their medical condition, or any other personal gain other than financial*]. [*If there is also an indirect benefit to the participant, add: Additionally, information from this study may benefit other people (with similar health issues, add if applicable) now or in the future.*]

**Risks** [*Select only the applicable statements that follow*]

There are no known risks at this time to participation in this study. [*if selected, delete the next paragraph*].

By taking part in this study, you may experience the following risks: [*describe in lay language the risks that are inherent to the study in order of severity and likelihood; when possible, quantify in percentage or likeliness of occurrence—e.g., most likely, likely, less likely. Include a description of the following category of risks, as applicable:*

* *Physical risks (e.g., nausea, vomiting, muscle aches, rashes, discomforts, etc.)*
* *Emotional risks (e.g., feelings of sadness or anxiety)*
* *Social/Economic risks (e.g., possible loss of confidentiality, possible effect to employment status)*
* *Legal risks (e.g., possibility of being arrested)*
* *List risks of other procedures that are involved in this research (e.g., MRI, PET scan, ultrasound, etc.).*

[*If death is a possible or probable result due to drug or device, it should be stated here.]*

[*List all standard of care medications and/or devices* ***explicitly required*** *by the protocol and their inherent side effects. It is preferred that multiple medications and side effects be referred to an* ***appendix****, but they may be incorporated into the body of the consent if preferred by the PI or sponsor.*] [*If applicable, the following statement may be included:* As a part of the study, you will be taking

(*insert medication*) that is part of the normal treatment for your disease or medical condition. Please refer to the appendix for all known side effects.]

[Add paragraph when pregnancy risks are unknown]

Participation in this study involves unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to minimize the risks and to take part in this study, medically acceptable forms of birth control are required by (a) women during the study and for at least 1 month after the study drug has been stopped; and (b) men during the study and for at least 3 months after the study drug has been stopped. Men must wait longer to account for the time needed for sperm to fully mature compared to eggs in women. *[Note to PI: If the amount of time* ***exceeds*** *1 month for women and 3 months for men, then insert the* ***greater*** *specific length of time to continue to use medically acceptable birth control. The time should not be decreased from the template amount]*

In order to participate in this study, you must use at least two forms of medically acceptable birth control. Medically acceptable birth control include the following methods: barrier protection—such as condoms used with contraceptive jelly;, intrauterine devices (IUD);, and abstinence (not having sex). Oral contraceptives may be used but should not be the only means of protection. The use of medically acceptable birth control may not be necessary if the female partner has had permanent hysterectomy (sterilization) with some form of tubal occlusion, or if the male partner has had a vasectomy (so long as the female partner does not get a new partner). No birth control method completely eliminates the risk of pregnancy.

*[Add when applicable]* In addition to the pregnancy testing done prior to the start of the study, additional testing will be done at the following times…[list]

*[Add when applicable]* You should inform the study doctor (PI) immediately if you or your partner intends to become pregnant, or if you or your partner should become pregnant while participating in this research study, so that your choices and options can be explored and discussed.

*[Add when information must be reported to authorities]* The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that: *[include applicable bullet(s]*

* child abuse or elder abuse has possibly occurred;
* you have a reportable communicable disease (such as certain sexually transmitted diseases or HIV);
* you disclose illegal criminal activities, illegal substance abuse or violence.

*[Add when blood samples will be obtained]*

Blood samples will be obtained from your veins. Possible side effects of obtaining blood samples are pain, bruising, bleeding, or infection at the blood draw site. Occasionally nausea, lightheadedness or fainting may occur.

*[Add when photographs will be obtained]*

Photographs will be taken of visible disease sites to monitor the progression of the disease, rash or lesion. Every attempt will be made to avoid a full-face photograph. If this is not possible, the

photograph will hide your identity as much as possible, including a black box over the eyes. There is a risk that a photograph may not protect your identity.

There may also be risks involved with taking part in this study that are not known to researchers at this time.

# Alternatives

[*If the study involves treatment and/or intervention, clearly spell out alternative procedures or course of treatment, if any, that may be appropriate for the participant. The only alternative might be* ***not*** *to participate in the study.*]

# Study Costs

**Step 1: [CHOOSE EITHER NON-INTERVENTION OR INTERVENTION PATH ]**

[FOR NON-INTERVENTION STUDIES ONLY] (ex. Questionnaire studies)

Participation in this study will be of no cost to you.

[FOR INTERVENTION STUDIES ONLY]

You will not be charged for [study drug or device]. [*select one*]

# THEN

[**Step 2: *select only the applicable statement(s) below*]**

* The study sponsor will pay for all costs and charges associated with your participation in this research study. *[If there is a study drug or device used during the study, please include the following statement]* You will not be charged for the study drug or device.

OR

* Your participation in this study could result in increased costs to you and/or your insurance company for additional monitoring and tests.

AND/OR

* You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered “standard of

care” and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x- rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these “standard of care” charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study. [ ***PIs please provide a separate list to the IRB or include the items in the consent. ]***

**Compensation** [*select only the applicable statement. Note: participants are not* ***paid*** *for participation, but are compensated for their time and inconvenience*].

You will not be paid for taking part in this study.

*[Only if there is a compensation involved]* For taking part in this research study, you will be paid for your time and inconvenience [*enter form of payment, amount of payment, and payment schedule*. *(Note: all payments to participants should be prorated for partial participation) The IRS requires that compensation greater than or equal to $600 per year (or cash equivalent) be reported by the Institution providing payment to the Internal Revenue Service (IRS) (*[*http://www.irs.gov/pub/irs-*](http://www.irs.gov/pub/irs-pdf/i1099msc.pdf)[*pdf/i1099msc.pdf*](http://www.irs.gov/pub/irs-pdf/i1099msc.pdf))

*If the participant is not a U.S. citizen and/or not a U.S. tax payer 30% of the compensation will be withheld by CMU before the check is disbursed. You must inform the participant of this regulation in the consent form.*

**Research Involving the Future Use of Biological Specimens** [*Delete this section if not applicable- this only applies to proposals that aim to keep the collected biological specimens for future research outside of the specific aims of the current project- ie. Separate proposal*]

[Include the following information in the following paragraphs where applicable:

1. *A description of planned future use of the specimens. If this is unknown, state so.*
2. *Details of procedures that will be used to protect the confidentiality and privacy of any personal identifiers that will be associated with the source of a tissue sample or cell line.*
3. *Information about the control and ownership of the tissue samples during storage.*
4. *The participant’s right to withdraw his/her consent at any time either by requesting that the tissue be destroyed or that all personal identifiers be removed.*
5. *Information about the length of storage.*
6. *State whether the participant can obtain future access to the stored samples for information that may be of clinical relevance to him/her. Similarly, participants must be told if such*

*information will not be available in the future (e.g., because personal identifiers are to be removed).*

1. *How the PI will handle future third-party access. (ie. Proposal review by a committee to determine feasibility, scientific merit and the plan for management of the samples and data)*
2. *Information about possible secondary use of the stored tissue, or the possible creation of an immortalized cell line based on the specimen.*
3. *When research after the delivery of a fetus, involves the placenta, dead fetus, or macerated fetal materials (such as tissues, cells, or organs) if the information is associated with this material is recorded in a manner that living individuals can be identified (either directly or through identifiers linked to the individual), those individuals are research subjects and all pertinent subparts of the federal regulations 45 CFR 46.206 (a) and (b) are applicable.*]
4. *Use the following paragraphs below to guide your description of the proposal to use the collected data/samples in future research:*

As part of the study, we will collect <*type of data/sample*>. We may wish to use these samples in a future study about <*related conditions or disease- describe*>. The samples will be given a unique code and will not include information that can identify you or your <samples>. Information that can identify you or your blood samples may be kept permanently with the investigator team and in an CMU IRB

<IRB number> in a password protected computer database at CMU. Only the study doctors and those working with them on this study will be able to see information that can identify you. If you leave the study, you can ask to have the data collected about you removed or your

samples destroyed. You can also ask us to remove information that identifies you from the data or samples.

The collected information and/ or samples will be available indefinitely and will be available to other, qualified researchers for study in related diseases. Before a researcher can get any study data or samples, they must get approval from the NIH or sponsor and have the approval of the study principal investigator and they approval committee overseeing this study. Researchers will not be able to link samples or information back to you and only the study doctors and those working for them on this study will be able to re-identify which study specimens or data are yours. If you would like to understand this further or if you have concerns, please talk with the study doctor/staff before you initial below.

# It is important to note that if you do not consent to have your samples or data saved to assist in further studies about the disease/condition, it will not impact your ability to participate and to be followed as part of this current study protocol.

Please indicate whether you will allow your samples to be used for future research by putting your initials next to one of the following choices <*outline initial lines below to denote the options*>:

**I agree to allow my/my child’s blood sample to be studied for any disease, health condition or risk factor in the future.**

**I agree to allow my/my child’s blood sample to be studied only for heart defects, heart disease, or risk factors for them.**

**I do not agree to allow my/my child’s blood sample to be stored for use in future research.**

**Genetic Information Nondiscrimination Act (GINA): (*Only required if study involves genetic work)***

*A Federal law, called the 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 generally will protect you in the following ways:*

* *Health insurance companies and group health plans may not request your genetic information that we get 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 get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

*Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.*

**Special Considerations:** *Delete when not* applicable

*There may be situations where a patient or a research participant is known to possess biologic materials with unique characteristics thought to have potential commercial value. In this case, if specimens are to be collected for research and the investigator expects that the specimens will be commercialized into a marketable product or sent to a commercial sponsor for research or development, the consent form must state this possibility.* You will not receive any financial or proprietary interest in the samples or in any products or processes that may result from research on the samples*.*

# Research Related Injuries

*[Please note the language in this section must match the Clinical Trial Agreement (CTA)/Contract. The Office of Sponsored Programs will assist the PI with the language.]*

*[If the risks to the study are no more than minimal (i.e., protocol may be expedited or exempted), this disclaimer, including the header, may be removed if IRB chair or designee concurs with its elimination.]*

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. No reimbursement, compensation, or free medical care is offered by Central Michigan University.

TENET’s LANGUAGE FOR SUBJECT INJURY- PICK THE FIRST PARAGRAPH OR SECOND PARAGRAPH BELOW DEPENDING ON WHO IS RESPONSIBLE FOR PAYMENT

If a “research related- injury” results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

OR

If a “research related injury” results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.

It is important for you to follow your physician’s instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury- or illness-related costs, such as lost wages. ***You are not waiving any legal rights and are not freeing the sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study.***

You will not lose any of your legal rights as a research subject by signing this consent form.

If you have any questions of if you think that you have suffered a research related injury, please contact the PI right away at [*insert phone number*].

# Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Central Michigan University or *[insert name of central IRB]*, or federal agencies with appropriate regulatory oversight [such as the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR)] may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. [*Delete the following if not applicable:* If photographs, videos, or audiotape recordings of you will be used for research or educational purposes, your identity will be protected or disguised. [*Describe the subject’s right to review and/or edit the tapes, who will have access, and when the tapes will be erased. Describe how personal identities will be shielded or disguised, etc.)*].

*(For clinical trials listed on ClinicalTrials.gov, you must include this statement:)*

***A description of this clinical trial will be available on*** [**http://www.clinicaltrials.gov**](http://www.clinicaltrials.gov/) ***as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.***

# Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. [*Delete the following sentence if not applicable,* If you decide to take part in the study you can later change your mind and withdraw from the study.] You are free to answer only questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Childrens’ Hospital of Michigan or Central Michigan University or their affiliates, or other services you are entitled to receive.

[*Explain if there are consequences of a subject’s decision of early withdrawal from the research and state whether withdrawal must be gradual for reasons of safety, etc.]*

The PI may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

FDA regulations require that data collected on human subjects enrolled in an FDA- regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the study to be scientifically valid.

[*Delete the following statement if not applicable (e.g., one time only study, no identifiers are being kept)*]. While taking part in this study you will be told of any important new findings that may change your willingness to continue to take part in the research.

# Questions

If you have any questions about this study now or in the future, you may contact [*insert name of PI*] or one of [*his/her*] research team members at the following phone number [*insert telephone number*]. If you have questions or concerns about your rights as a research participant, and wish to speak to someone other than the research staff, the Chair of the CMU Institutional Review Board, or IRB Coordinator, can be contacted at (989) 774-6401 or via email at [irb@cmich.edu.](mailto:irb@cmich.edu)

# Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative\* Date

Printed name of participant / Legally authorized representative \* Time

Signature of witness\*\* Date

Printed of witness\*\* Time

Signature of person obtaining consent Date

Printed name of person obtaining consent Time

**\***Remove LAR reference if you don’t intend to consent participants that have or may have LAR.

**\*\***Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

Signature of translator Date

Printed name of translator Time

**Delete if not applicable Continue to HIPAA Authorization on next page**

[*DELETE the following pages if not applicable*]

# HIPAA Authorization

A federal regulation, known as the “Health Insurance Portability and Accountability Act (HIPAA)” gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and [*his/her*] research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and [*his/her*] research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI’s research office and can take place anytime during the study or after the study has ended.

**The PHI that will be “USED”** for this research includes the following: [*Delete elements of PHI that will NOT be* ***used*** *for this research*]: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, fax numbers, social security number, medical record number, health insurance number, account numbers, certificate/license numbers, vehicle and serial numbers, web URLs, internet protocol (IP) addresses, biometric identifiers (voice and fingerprints), full face photographs, and any unique identifying numbers or characteristics or code.

**The PHI that will be “DISCLOSED”** or shared with others for this research includes the following: [*Delete elements of PHI that will NOT be disclosed/or shared with others for this research*]: name (or initials), address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, fax numbers, social security number, medical record number, health insurance number, account numbers, certificate/license numbers, vehicle and serial numbers, web URLs, internet protocol (IP) addresses, biometric identifiers (voice and fingerprints), full face photographs, and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups: [*Delete or add others who will have access to the PHI*]:

* The PI, co-investigators, and key personnel of Children’s Hospital of Michigan or CMU- associated with the research project. Do not delete
* CMU’s Institutional Review Boards (IRB). Do not delete
* Authorized members of Children’s Hospital of Michigan or CMU’s workforce who may need to access your information in the performance of their duties. [*For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.*]
* Other collaborating academic research institutions, which include: [*list all academic centers that have key personnel participating in this research project*].
* The study Sponsor or representative, including companies it hires to provide study related services, which include: [*list the sponsor, its representative(s), and affiliated companies- CRO’s, etc.*].
* Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR.) may review your records Do not delete.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

[*Select only one of the next two paragraphs, delete the other*]:

* During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.
* During your participation in this research project you will not be able to access that part of your medical record involved in the research. This will be done to prevent the knowledge of the research results from affecting the reliability of the project. Your information will be available to the treating physician should an emergency arise that would require for him/her to know this information to best treat you. You will have access to your medical record when the study is ended or earlier, if possible. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the CMU University Pediatricians.

# Authorization to use and disclose PHI

* By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of participant Date

Printed name of participant

* For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

Signature of authorized representative Date

Printed name of authorized representative Relationship to the participant

Signature of person obtaining Authorization Date

Printed name of person obtaining Authorization Time