

CIRB Approved Research Informed Consent Template

INSTRUCTIONS FOR FORM:

- Please follow italicized instructions listed in brackets and highlighted areas
- **Delete all instructions from the consent template when finished.**
- Make sure that formatting is correct and delete all colored fonts and hanging headers.
- Only a size 12 font or larger may be used.
- Consent given to participant/parent must be one sided only.
- **No letterhead or logos** are allowed.

CIRB Approved Research Informed Consent Template

For Studies Using Both Children and Adults, please use Medical or Behavioral Template and define you as “you, your child or ward”

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

Principal Investigator (PI): *[Name]*
[Address]
[Phone]

Sponsor: *[Name]*
[Delete funding source if no funding]

PURPOSE OF THE STUDY

STUDY PROCEDURES

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 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 likelihood 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.)

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- 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]

There may be unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to take part in this study, a medically acceptable form of birth control is required—for both male and female participants. Medically acceptable birth control may include the following methods: barrier protection—such as condoms, intrauterine devices (IUD), abstinence (not having sex), etc. Oral contraceptives may be used but should not be the only means of protection. No birth control method completely eliminates the risk of pregnancy. [Add when applicable, You should inform the study doctor (PI) immediately if you or your partner intends to get 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 (i.e., 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 be 'de-identify' 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 from taking part in this study that are not known to researchers at this time.

ALTERNATIVES

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[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 FOR KARMANOS CANCER INSTITUTE PROTOCOLS

The study sponsor will provide (*list items to be covered by sponsor per funding information*) during your participation in this research study.

You and/or your health plan/insurance company will need to pay for those procedures that are considered routine care for your disease. These include (list items based on protocol) clinic, hospital, and doctors' services, labs, the cost and administration of other medications to treat your disease, and the treatment of side effects. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. You will be responsible for any charges that your insurance does not cover including co-payments, co-insurance and deductibles.

For more information on clinical trials, you can visit the National Cancer Institute's (NCI) web site at <http://www.cancer.gov/aboutnci/organization/clinical-center-fact-sheet>

To learn more information about paying for clinical trials and paying for clinical trials and insurance, you can visit the NCI web site at www.cancer.gov or <https://www.cancer.gov/about-cancer/treatment/clinical-trials/paying>

Another way to get information is to call the NCI at 1-800-4-CANCER (1-800-422-6237) and talk to an Information Specialist, Monday-Friday 8am-8pm EST. You can request free information to be sent to you, such as the Cancer Clinical Trials FactSheet.

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.

For taking part in this research study, you will be compensated for your time and inconvenience. [*Enter form of payments, amount of payment, and payment schedule. (Note: all payments to participants should be prorated for particular participation.) The IRS requires that compensation greater than or equal to \$600 be reported to the IRS – refer to <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 WSU 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.]

[If applicable, include the following information:

- A description of planned future use of the specimens. If this is unknown, state so.
- 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.
- Information about the control and ownership of the tissue samples during storage.
- 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.
- Information about the length of storage.
- 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).
- How the PI will handle future third-party access.
- Information about possible secondary use of the stored tissue, or the possible creation of an immortalized cell line based on the specimen.
- 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.]

GENETIC INFORMATION NONDISCRIMINATION ACT (GINA) [Only required if the 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 new 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 other 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. 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.]

Wayne State University's Compensation for Injury Policy:

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. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University *[or (insert as applicable, the name(s) of the Detroit Medical Center, Karmanos Cancer Institute, University Pediatricians, University Physician Group, sponsor, and any other facility involved with this study)]*. If you think that you have suffered a research related injury, 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 *(List the sponsor, its representative(s), affiliated companies, CRO's, etc., as they are listed in the sponsor template consent)*, the Institutional Review Board (IRB) at Wayne State University, the Detroit Medical Center, the Karmanos Cancer Institute, the National Cancer Institute, or federal agencies with appropriate regulatory oversight (e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.), 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 identify. *[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 participant's right to review and/or edit the tapes, who will have access, and when the tapes will be erased. Describe how personal identifies will be shielded or disguised, etc.]*

[For clinical trials listed on ClinicalTrials.gov, you must include the following statement:]

A description of this clinical trial will be available on <http://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.

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 free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not

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change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

[Explain if there are consequences of a participant'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.

[Delete the following statement if it is 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, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

(**) The witness must be impartial (someone not connected with the research or the study team). Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language.)

If a Translator, this person should be fluent both in English and the language that is understandable to the participant or legal representative. The translator gives an oral presentation to the participant or legal representative that is understandable to the participant that describes the entire content of the English version of Informed Consent.

[If any research activities involve accessing a medical record, electronic or hard copy, in- or out-patient, retrospective or prospective, or involve databases or tissue banks outside of normal health care activities, please refer to the IRB Policy/Procedure, “HIPAA in Research” available on the IRB website. If a HIPAA Authorization is required for this study, add the following language to this consent document and have the participant or legally authorized representative sign the last page.]

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), elements of dates, telephone numbers, email address, 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, address (street address, city, state and zip code), 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 WSU and KCI associated with the research project
- **Do not delete**

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- WSU's Institutional Review Boards (IRB) - **Do not delete**
- Authorized members of WSU's, KCI's, and DMC'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, etc.) 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 any time, 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 WSU School of Medicine Practice Plans.

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.

Printed Name of Participant

Signature of Participant / Legally Authorized Representative (*)

Date

Printed Name of Legally Authorized Representative (*)

(*) *For participants unable to give Authorization the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.). Remove LAR reference if you don't intend to consent participants that have or may have LAR.*

I observed the above (or his/her legally authorized representative, if applicable) sign this authorization form.

Signature of Person Obtaining Authorization

Date

Printed Name of Person Obtaining Authorization

Signature of Translator (**)

Date

Printed Name of Translator (**)

As an impartial third party, I witnessed the authorization process and the participant's signature on this form. I confirm that this entire form was read to the participant named above. The participant voluntarily agreed to be in this study.

Signature of Witness (**)

Date

Printed Name of Witness (**)

(**) The witness must be impartial (someone not connected with the research or the study team). Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated

into foreign language.) If a Translator, this person should be fluent both in English and the language that is understandable to the participant or legal representative. The translator gives an oral presentation to the participant or legal representative that is understandable to the participant that describes the entire content of the English version of Informed Consent.