Permission to Take Part in a Human Research Study & HIPAA Authorization for Release of Health Information for Research Purposes

Key Information for **Title of Study**

Principal Investigator: **Name, Credentials**

Sponsor: **Sponsor *(if research is not sponsored, remove)***

Funding Source: **Funding Source** ***(insert name of funding source (if funded) and different from sponsor)***

“You” refers to the subject.

“We” refers to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***(include organizations affiliated with the research, for example, WMU Homer Stryker M.D. School of Medicine and Ascension Borgess)***

The following is a short summary of this study to help you decide whether or not to be a part of this study. ***[This section must not exceed two pages.]***More detailed information is listed later on in this form.

***What are the purpose, procedure(s), and duration of this study?***

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. ***[Fill in the circumstance or condition that makes subjects eligible for the research. Tell the subject the purpose of the research. Explain the background of the research problem.]***

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ ***[hours/days/months/weeks/years, until a certain event]***.

You will be asked to \_\_\_\_\_\_\_\_\_ ***[include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to come for 3 study visits. You will be given a total of 3 blood samples and fill out questionnaires asking about how you feel.]***

More detailed information about the study procedures can be found under *“What happens if I say yes, I want to be in this research?” on page number \_\_.*

***What are reasons you might choose to volunteer for this study?***

***[State the most important reason(s) {i.e. potential benefit(s)} a person may want to volunteer to participate in this study?]***

***[Include for a study with no direct benefits to participation.*** There are no direct benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]***

***What are reasons you might choose not to volunteer for this study?***

***[State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective.]*** There are some risks you might experience from being in this study. They are ***[describe specific risks, and indicate what the study team will do to minimize those risks.]***. **[OR]** We don’t believe there are any risks from participating in this research.

***Do you have to take part in this study?***

Participation in research is completely voluntary. You can decide to participate or not to participate.

***Are there other treatments for me besides being part of this research study?***

Other treatments for patients with Mutant Melanoma; Parkinson's Disease; Lung Cancer, etc., are:

* + Getting treatment or care without being in a study
	+ Taking part in another study
	+ Getting no treatment
	+ Please talk to your doctor about their potential benefits and risks.

 ***[Include if there are no alternatives other than participating.]*** Your alternative to participating in this research study is to not participate.

**Title of research study: *(insert title of research study here with protocol number, if applicable)***

**Investigator: *(insert name of investigator)***

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***(Fill in the circumstance or condition that makes participants eligible for the research, for example, “…because you have diabetes and you take insulin.”)***

***Some content included in this template applies only to studies that are classified as a clinical trial which is defined as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.”***

***What are some general things to know about research studies?***

* Someone will explain this research study to you.
* You volunteer to be in a research study.
* Whether or not you take part is up to you.
* You can choose not to take part in the research study.
* You can agree to take part now and later change your mind.
* Whatever you decide it will not be held against you.
* Feel free to ask all the questions you want before you decide.

***Whom do I call if I have questions or problems?***

If you have questions, concerns, or complaints, or think the research has hurt you talk to the investigator or members of the research team at ***(Insert contact information for the research team e.g. phone number, email)*** or to report a complaint visit <https://med.wmich.edu/researchcomplaints>.

This research has been reviewed and approved by the WMU Homer Stryker M.D. School of Medicine Institutional Review Board. You may talk to them at (269) 337-4345 or irb@med.wmich.edu for any of the following:

* Your questions, concerns, or complaints are not being answered by the investigator or research team.
* You cannot reach the investigator or research team.
* You want to talk to someone besides the investigator or research team.
* You have questions about your rights as a research participant.
* You want to get information or provide input about this research.

***Why are we doing this research?***

***(Tell the participant the purpose of the research. Explain the background of the research problem. For example, explain to the participant the current therapies for their disease and why they are not satisfactory. For non-therapeutic studies, explain the scientific problem. Describe how this research will attempt to solve the problem.)***

***How long will I be in the research?***

We expect that you will be in this research study for \_\_\_\_\_\_\_\_\_\_\_ ***(Months/weeks/years, until a certain event. Duration of follow-up/data collection only should be included as well)***.

***How many people will be studied?***

We expect about \_\_\_\_\_\_\_\_ people will be in this research. ***If registry indicate approximate prospective/retrospective enrollment.***

***What happens if I say yes, I want to be in this research?***

***(Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:***

* ***A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits***
* ***The drugs or biologics that will be given to the participant***
* ***If a placebo is used consider describing as “substance, such as sugar pill, that does not contain active ingredients such as medicine”***
* ***All devices that will be used***
* ***All hospitalizations, outpatient visits and telephone or written follow-up***
* ***The length and duration of visits and procedures***
* ***If blood will be drawn, indicate the amount (in English units) and frequency***
* ***If the collected data/specimens might be used for future unspecified research***
* ***With whom will the participant interact***
* ***Where the research will be done***
* ***When the research will be done***
* ***List experimental procedures and therapies and identify them as such***
* ***How often procedures will be performed***
* ***What is being performed as part of the research study***
* ***What is being performed as part of standard care***
* ***What procedures are part of regular medical care that will be done even if the participant does not take part in the research***
* ***If the primary physician will be informed of participation in the research study)***

***(For clinical trials describe the chances of being assigned to each treatment group/arm. For example)*** The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ***(equal/one in three/etc.)*** chance of being given each treatment. ***(For double-blinded studies add)*** Neither you nor the study doctor will know which treatment you are getting. ***(For single blinded studies add)*** You will not be told which treatment you are getting, however your study doctor will know. This means you may not have access to research records through your electronic patient portal to view lab results or progress notes that may tell you which treatment you are getting.

***(For clinical trials)***

***(Describe any responsibilities of the participant during study participation. For example)*** If you wish to take part in this study, we expect that you will:

* ***Keep your study appointments. If you cannot keep an appointment, contact your study doctor or research study staff to reschedule as soon as you know that you will miss the appointment.***
* ***Tell your study doctor or research staff about any medications you are taking so they can check how the drug being studied and your medications may interact. If you need to start on any new medications while you are in the study, please check with your study doctor before you do so.***
* ***Tell your study doctor or research study staff about any side effects, doctor visits, or hospitalization that you may have whether or not you think they are related to the study therapy.***

***(For genetic research)***

***(Describe genetic research, including DNA sequencing, how and where the specimens and genetic information will be stored, and who owns the specimens and related genetic information. Here is an example of describing genes and DNA sequencing)***

Like all tissues and cells in your body, these tissues/cells have genes. A "gene" is the basic "instruction book" for how to build a cell. Your genes determine your physical characteristics, such as your height and hair and eye color. Your genes can also help determine whether you have a chance of developing a certain illness or medical condition.

Many diseases can come from changes in a person’s genetic material that cause cells to not work properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know all of the genetic changes that can cause disease.

We would like to study the genetic material from you as part of this research. We will compare the DNA from people with certain diseases to the DNA from people without those diseases to find the differences that exist. By combining this information with information from your medical records, it may be possible to identify the genetic changes that are associated with different diseases. We will perform this same process with other people who have agreed to participate in this research project. This research could lead to more knowledge about why certain people respond differently to treatment. This knowledge could lead to future treatments customized to a patient’s unique genetic make-up.

***What happens if I say no, I do not want to be in this research?***

You may decide not to take part in the research and it will not be held against you. A refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

***(If there are no alternatives other than not participating, this section may be deleted.)*** Instead of being in this research study, your choices may include: ***(List alternative procedures, especially any that may be advantageous to the subject. For clinical trials describe other treatment options that you would normally offer patient. If applicable, include supportive care as an option.)***

***(For clinical trials)*** The important risks and possible benefits of these alternatives are listed below: ***(Describe the important risks and potential benefits of the alternative procedures and courses of treatment.)***

***What happens if I say yes, but I want to stop before my part of the study is complete?***

You can agree to take part in the research now and stop at any time. It will not be held against you.

Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled.

***(If there are adverse consequences to withdrawing from the research, add)*** If you decide to leave the research, the consequences of your decision are ***(Describe the adverse consequences. For example, participants on a drug may experience worsening of their disease or withdrawal problems without substituting another drug or tapering the study drug.)*** If you decide to leave the research, contact the investigator so that the investigator can tell you how to stop safely. ***(Also, describe other procedures for orderly termination by the participant.)***

***(Include the following paragraph for FDA regulated clinical trials)***

If you choose to withdraw from the study early, the data collected from you up until the point you withdraw will remain in the study database per U.S. Food & Drug Administration (FDA) policy. This is so the FDA can have accurate information regarding any possible safety concerns about the drug or device being studied.

***(Include the following paragraph for FDA regulated clinical trials requesting to collect further clinical outcome data if the subject discontinues the interventional portion of the study)***

At the time of withdrawal, the investigator will ask you to consider allowing the investigator to continue to collect follow-up data from your medical record regarding your routine medical care for your condition. If you agree, this data will be handled the same as research data and entered into the study database to evaluate outcomes.

***What are the possible risks and discomforts I may have if I take part in this study?*** (***Describe each of the following risks/discomforts, if appropriate):***

* ***Physical risks (for example, medical side effect)***
* ***Psychological risks/discomforts (for example, embarrassment, fear or guilt)***
* ***Privacy risks (for example, potential loss of confidentiality)***
* ***Legal risks (for example, legal prosecution or being reported for child abuse)***
* ***Social risks (for example, social ostracization or discrimination)***
* ***Economic risks (for example, having to pay money out of pocket for research or medical expenses, losing health insurance, or being unable to obtain a job))***

***(If there are risks to participation in the research, describe them for each relevant procedure (For example, blood drawing, computerized tomography, survey procedure, etc.) and for each investigational article (For example, drug, device or biologic.)***

* ***Drugs ( List any/all potential drug allergies that may be caused by the investigational and other drugs used in the research)***
* ***Devices (If the research involves use of an investigational device with a potential for malfunction, list “ device malfunction as one of the device risk)***

***(Include relevant risks based on animal and in vitro studies.)***

***(Group the risks into those that are expected, occasional, or rare and describe them as such. List all expected and occasional side effects. List all side effects, no matter how rare, that are life altering or potentially life altering, for example visual loss, anaphylaxis, paralysis, and aplastic anemia. Explain the ramifications of the significant risks. For example what will happen to the participant if liver enzyme tests indicate an abnormality.)***

***(For research that involves risks to an embryo, fetus, or nursing infant)*** This drug may harm a pregnancy/unborn child or nursing infant in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You should not become pregnant, nurse a baby, or father a baby while on this research study.

***(For research that requires a blood draw, add)*** You may experience discomfort, pain, swelling and/or bruising where the blood is taken from your vein. Sometimes bleeding can occur at the place where blood is drawn. Fainting and infection can also occur, but they are rare.

***(For research that exposes researcher to blood draw or other bodily fluids, add)*** Under Michigan law, an HIV and hepatitis test may be done on you (or your child) without your consent if a healthcare worker is exposed to your (or your child’s) blood or other bodily fluids. If the results of an HIV or hepatitis test indicate that you (or your child) are HIV or hepatitis positive, you will be told about these results and given information about the disease, treatment resources, and other options.

***(If the research involves pregnant women or women of child-bearing potential and involved an investigational product or procedures whose risk profile in pregnancy is not well known, add)*** If you think you are pregnant or if you become pregnant during the study, you must tell the study doctor right away. It is important to tell your doctor because there may be risks to you or your baby if you continue in the study. Some of these risks may be known, but some risks may not be known and may not be foreseeable. Because the risks to embryo/fetus/unborn babies and babies who are breast feeding may not be known or foreseeable, pregnant women and nursing mothers are not allowed to join this study. If you are a woman who can get pregnant, you should not become pregnant during this study.

Women who can get pregnant must have a negative pregnancy test before being allowed to join in this study. ***Define* *if pregnancy test needs to be blood or urine* *as defined by study protocol.***

***(If the research involves genetic testing, profiling, or sequencing, add)*** A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.  However, you should 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.

***(If the research involves an investigational product or procedures whose risk profile is not well known, add)*** In addition to these risks, this research may hurt you in ways that are unknown. If we learn of new risks that we think might affect your desire to stay in the research we will tell you. It is possible, if major risks are discovered after the study is finished, the sponsor may attempt to contact you.

***(If the research involves collecting personally identifying sensitive information (e.g. sexual practices, sexually transmitted diseases, alcohol addiction, illegal drug use, controlled substance addiction, illegal conduct, mental health diagnoses and corresponding medications, HIV status) add)*** In this study, we will collect sensitive information about ***[specify].*** This information is necessary to conduct the research. We will keep this information as confidential as possible, but we cannot guarantee complete confidentiality.

***(For ALL NIH funded research and any other research with a Certificate of Confidentiality:)***

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

***Will I need to pay for any of the tests or procedures in the study?***

***(If the research may result in additional costs to the participant, add:)*** Taking part in this research study may lead to added costs to you. ***(Describe what these costs are. Indicate what will be charged to insurance and what will be paid for by the research study.)***

***(Required wording if procedure will be billed to insurance)*** You or your health insurance will be billed for this procedure. If your insurance company requires any co-payment or deductible, you will be responsible for making that payment.

***(Required wording for all adult DRUG (not device) clinical trial studies.)*** If your insurance is through Medicare Advantage, any routine care that is part of this study and not being paid for by the sponsor will be directed to traditional Medicare for payment. The traditional Medicare deductibles will be waived, but you will be responsible for any co-payments. Please talk to the study doctor if you have any questions about this.

***Will being in this study help me in any way?***

***(If there are no benefits and the research is not a clinical trial, this section may be deleted.)***

***(If there are benefits to participation)*** We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***(Then describe the potential benefits of participation. First describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. For example, an investigational drug provided for free may not be available at the end of the research or may no longer be provided free if the drug becomes available for marketing. Monetary reimbursement for participation is not a benefit and should be described in a later section)***

***(For clinical trials with no benefit to participation)*** There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***(Describe any benefits to others such as a better understanding of your disease or illness; or the development of new ways to diagnose and treat your disease. Monetary reimbursement for participation is not a benefit and should be described in a later section.)***

***How will the information identifying me be kept confidential?*** Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

* The Investigator and his/her research staff
* WMU Homer Stryker M.D. School of Medicine staff or its agents
* The WMU Homer Stryker M.D. School of Medicine Institutional Review Board (IRB) and staff
* ***(If the research is FDA-regulated)*** Food and Drug Administration (FDA)
* ***(If the research is funded by the DHHS)*** Department of Health and Human Services (DHHS)
* ***(If the research is funded by the NIH)*** National Institutes of Health (NIH)
* ***(If the research is funded by an external group)***The Sponsor(s) of the research ***<<must insert name of sponsor here>>*** or its agents (monitors, auditors)
* ***(If the research is funded by an external group)*** Other collaborating institutions
* Agencies that accredit the hospital or the research program

Some of these organizations may be given direct access to your medical records for verification of the research procedures/data involved. By signing this document you are authorizing this access.

***(Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.)***

***[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]***

***[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:***

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

***OR***

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

**Special Considerations**

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.

***Following is language to be included in this section:***

Your samples may be used for development of a marketable product or for research and development. The samples may be used for commercial profit (even if the identifiers are removed). ***[choose one] You will or 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.

***Genetic Research***

***If specimens are retained for future genetic research, explain what is meant by genetic information, how and where the specimens and genetic information will be stored, and who owns the specimens and related genetic information (e.g. “Like all tissues and cells in your body, these tissues/cells have genes.***  A ‘gene’ is the basic ‘instruction book’ for how to build a cell.  Your genes determine your physical characteristics, such as your height and hair and eye color.  Your genes can also help determine whether you have a chance of developing a certain illness or medical condition.”  ***Describe the risks of this information being collected or misused.***

***For research involving biospecimens you must include 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)***

***(For clinical trials add)*** We may publish the results of this research. However, we will keep your name and other identifying information confidential.

***(If a HIPAA authorization is required:)*** Federal law provides additional protections of your personal information. These are described in a later section.

***Can I be removed from the research without my OK?***

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include ***(add additional reasons why the participant may be withdrawn, if appropriate. For example, failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer in your best interest...)*** The sponsor can also end the research study early.

***What if I’m injured or made sick from the research?***

***(Delete this question/answer section if the research involves no more than minimal risk.)***

***(The below options are provided for general reference. The injury compensation language must coincide with the terms and conditions of the contract between WMU Homer Stryker M.D. School of Medicine and the study sponsor. Thus contact the individual handling contract negotiations at WMU Homer Stryker M.D. School of Medicine/Sponsored Programs on the investigator’s behalf for guidance and review of this section of the ICF. They will be able to determine if the sponsor is paying (has funds set aside) for medical care costs incurred as a result of the research-related injury/adverse reaction.)***

**(Option 1 – Funds set aside)**

As a research participant, there is the possibility you may be harmed as a result of being in this study. It is the nature of medical research that not all adverse events (unfavorable side effects) are preventable or can be predicted. If you are injured as a result of taking part in this research study and need medical care, please tell your study doctor right away. Medical care will be made available to you just as it is to the general community.

The sponsor has set aside funds to pay for necessary and reasonable medical expenses for illness or injury which is directly caused by your participation in the study and is not covered by your insurance or if you have no insurance. However, no additional funds have been set aside to compensate you for any lost wages, disability or discomfort experienced related to a research-related injury or illness. Provided you and your study doctor are following all sponsor study instructions, reimbursement is limited to medical expenses determined to be directly related to your study participation by the sponsor.

**(Option 2 – No funds set aside)**

As a research participant, there is the possibility you may be harmed as a result of being in this study. It is the nature of medical research that not all adverse events (unfavorable side effects) are preventable or can be predicted. If you are injured as a result of taking part in this research study and need medical care, please tell your study doctor right away. Medical care will be made available to you just as it is to the general community.

However, neither the sponsor nor WMU Homer Stryker M.D. School of Medicine has funds set aside for financial compensation for research-related injury and any associated cost of medically treating the injury. Therefore, medical care for a research-related injury will be billed to either you and/or your insurance. Your insurance may not be willing to cover the entire cost for treating a research-related injury. If you have no insurance, you may be responsible for all costs associated with medical care for a research-related injury.

***(For both option 1 and 2 include the following:)***

Contact the investigator for more information. By signing this consent form you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

***What else do I need to know?***

***(When participants will be paid)*** If you agree to take part in this research study, you will receive \_\_\_\_\_\_\_\_ ***(indicate amount and method of payment)*** for your time and effort. ***(Indicate if the amount is pro-rated for research visit completion.)*** To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the Sponsored Programs Department. This payment to you may be considered taxable income by the IRS. Should the payment exceed $600 for all studies in which you are participating in a single year, you will be issued an IRS 1099-Misc Form.

[Choose 1:]

***[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens,]*** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will/will not*** contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself. ***[OR for when information only (no biospecimens) is being collected]*** If the research with your identifiable information gives results that do have meaning for your health, the researchers ***will/will not*** contact you to let you know what they have found.

***(REQUIRED STATEMENT if your study is FDA regulated)*** A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

*HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes*

This form describes the way that Bronson / Borgess can share your information with the researchers, research team, sponsor, and people with oversight responsibility for this study. The information we are asking to collect, use and share is called Protected Health Information (PHI). PHI is protected by a federal law called the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

***Why am I being asked to sign this form?***

You have been asked to participate in this research study. If you sign this Authorization Form, you agree to the use and disclosure (release) of your health information for the research study, as described in this Authorization Form. Your health information will be used to ***(describe the purpose of the requested use or release which typically is the objective of the research)****.*

***What health information will be collected and used?***

Your health information may be ***accessed (used***) for this research study by <covered entity>, the Principal Investigator, and their representatives (***the study team may also include residents and students who approved to do research at <covered entity i.e. Bronson or Borgess>).***

To collect the study data, we will need access (see) to your identifiable health information in *(****describe the source document(s) which will be accessed to collect the study data, e.g., medical records****).*

The following health information about you will be ***collected and disclosed*** for this research study: (***insert complete description of the information that will be collected about research participants in the study for example…. (Note: the information listed here should be consistent with the case report forms)***

* demographic information,
* results of physical exams, blood tests, x-rays,
* Diagnostic and medical procedures as well as medical history etc. (describe the time period in the medical record from which you will be accessing the records for ex: Jan 2004 through Dec 2008, the last five years or the time from your heart attack until the end of the study.

***(If the information to be collected will be de-identified/will not include any direct identifiers, include a statement here to that effect: i.e., none of the information listed above will directly identify you.)***

***What information will be disclosed?***

The health information listed above that we collect for this study will be ***disclosed (shared)*** to the following people and organizations: ***(Include specific identification of the person(s), or class of persons, to whom WMU Homer Stryker M.D. School of Medicine will disclose study data. The following is an example to be modified to accurately reflect your study)***

* Public health agencies and other government agencies (including non-U.S.) as authorized or required by law
* The Food and Drug Administration (FDA)
* Department of Health and Human Services (DHHS)
* National Institutes of Health (NIH)
* The Sponsor(s) of the research ***(must insert name of sponsor here)*** or its agents (monitors, auditors)
* Other collaborating institutions ***(insert name of collaborating institutions receiving PHI here)***

In addition to disclosing the study data, as listed above, there may also be instances when certain information may be accessed by both WMU Homer Stryker M.D. School of Medicine and non- WMU Homer Stryker M.D. School of Medicine personnel for study-related purposes. For instance, the sponsor of the study or an outside company or government agency may need to review the study information (including your medical record and other study data) for purposes of auditing or validating the study. In those instances, these outside parties may see your identifiable health information (e.g., information in your medical record). However, we will take steps to make sure that these outside parties do not copy or record any information that identifies you.

The following people and organizations may need to see your identifiable health information for purposes of auditing or validating the study: *(****insert as applicable****)*

* Public health agencies and other government agencies (including non-U.S.) as authorized or required by law
* The Food and Drug Administration (FDA)
* Department of Health and Human Services (DHHS)
* National Institutes of Health (NIH)
* The Sponsor(s) of the research ***(must insert name of sponsor here)*** or its agents (monitors, auditors)
* Other collaborating institutions ***(insert name of collaborating institutions receiving PHI here)***
* WMU Homer Stryker M.D. School of Medicine IRB
* WMU Homer Stryker M.D. School of Medicine offices of Compliance, Research Integrity and others at WMU Homer Stryker M.D. School of Medicine that have the responsibility to oversee the conduct of research.

The people who see your health information for this research study might not be required to follow HIPAA. It is also possible that anyone who receives your health information may re-release it. Because some of these individuals who receive your health information for this study may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves <covered entity>. Therefore, we will share your information only if necessary for the study and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

***How will my health information be protected?***

**(*Insert language regarding how the PHI will be gathered and protected*)**

All the information that is collected for this study will be captured and stored within a secure web based program or on protected drives within WMU Homer Stryker M.D. School of Medicine’s secure network. We will make every effort to safeguard your information. (***describe the protection measures taken by sponsors to ensure privacy and security of the data***)

***How long will my PHI be used?***

This authorization will remain valid with no expiration date unless and until you decide to revoke (take back) this authorization.

***Can I stop my Protected Health Information from being collected and disclosed?***

Yes, you may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization *(****name, class of persons at the covered entity involved in the research****)* may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the research study.

To revoke this authorization, you must write or email ***(list investigator’s name and address and email)****.*

You may also write to the WMU Homer Stryker M.D. School of Medicine Privacy Department at <covered entity> to revoke this authorization.

***What happens if I do not want you to collect and/or release my information?***

If you decide not to authorize the collection and release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use and release of your PHI.

**Request for Donation of Specimens for Future Research**

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part. You can also allow your specimens and health information to be used for future research. Your authorization to use your specimens for future research will remain valid with no expiration date unless and until you decide to withdraw permission. Please read each sentence below and think about your choice. After reading each sentence, please select a response to indicate your preference. ***(include only applicable questions)***:

1. You may keep the following for future research related to ***(specify subject of this research, e.g. cancer)***. ( ***Subject may circle the applicable options that he/she wants to authorize to)***

Tissue YES------ NO ------

Blood YES------ NO ------

Other YES------ NO ------

1. You may keep my ***(tissue/blood/data)*** for future research to learn about, prevent or treat other health problems such as ***(specify, e.g. diabetes, genetic research, heart disease, etc.)***

YES ------ NO ------

1. You may contact me in the future to ask me to take part in other research studies.

YES ------ NO ------

**Request for Use of Protected Health Information for Future Research**

***(This section should only be used if PHI is collected AND disclosed as part of the main study AND the recipient would like to retain and use the PHI for future research. This section is not necessary if only de-identified data will be disclosed as part of the study.)***

The researchers would like to ask your permission to use the information collected as part of this study for the following optional research activities. You can choose whether or not to participate in these activities and it will not affect your ability to be in the main research. Please initial on the line next to the optional activities to give your permission. Your authorization to use your health information for future research will remain valid with no expiration date unless and until you decide to withdraw permission.

My information may be disclosed for the **(*Title of the optional research study*)**. This additional research is explained in detail in the consent form and consent process that accompany this form.

YES ------ NO ------

My information may be disclosed for the following future research activities: **(*Adequately describe purposes such that it would be reasonable for the participant to expect that his or her PHI could be used or disclosed for such future research.)***

YES ------ NO ------

***\*\*\*\*INFORMATION REGARDING SIGNATURE PAGE\*\*\*\****

***There are four signature block examples attached to this template consent. Adapt the signature page for your study based on the study population. For Example:***

* ***Omit the signature block regarding children (i.e. do not include parent/guardian signature line(s)) if you do not plan to enroll children in the study.***
* ***Omit the signature block for adults unable to consent for themselves (i.e. do not include legally authorized representative signature line) if your protocol does not permit inclusion of cognitively impaired subjects.***
* ***Omit the signature page entirely if written documentation of consent is not required for the study.***

**Signature Block for Capable Adult: Long Form**

|  |
| --- |
| Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. ***[Remove latter section if there is no HIPAA authorization]*** You will receive a signed copy of this complete form. |
|  |  |  |
| Signature of participant |  | Date |
|  |  |
| Printed name of participant |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***The following signature block is to be used when an impartial witness is needed for non-readers or visually impaired participants.***

|  |
| --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant.  I witnessed that all of the participant’s questions were addressed.  I witnessed the subject freely giving consent to participate in this study. |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  |
| Printed name of Impartial Witness |

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature below documents your permission for the participant named below to take part in this research and to the use and disclosure of this person’s protected health information. ***[Remove latter section if there is no HIPAA authorization]***  You will receive a signed copy of this complete form. |
|  |  |  |
| Printed name of participant |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |  |
| Printed name of legally authorized representative |  | Relationship to participant |
|  |  |  |
| Signature of person obtaining consent and assent **[Remove latter section if assent will not be obtained]** |  | Date |
|  |  |  |
| Printed name of person obtaining consent and assent **[Remove latter section if assent will not be obtained]** |  |  |

***[Add the following block if you will document verbal assent of the participant on this consent form. If you will be documenting written assent add an assent signature line, printed name line and date line to the consent form or have a separate assent form. ]***

|  |  |
| --- | --- |
| Assent | * Verbal Assent Obtained
* Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.
 |

***[The following signature block will be completed if an impartial witness is required for LAR that is a non-reader]***

|  |
| --- |
| I witnessed the entire consent discussion and attest that the information in the consent document and any other written information were accurately read to the participant.  I witnessed that all of the participant’s questions were addressed.  I witnessed the subject freely giving consent to participate in this study. |
|  |  |  |
| Signature of Impartial Witness |  | Date |
|  |  |
| Printed name of Impartial Witness |

**Signature Block for Children**

|  |
| --- |
| Your signature below documents your permission for the child named below to take part in this research and to the use and disclosure of this child’s protected health information. ***[Remove latter section if there is no HIPAA authorization]*** You will receive a signed copy of this complete form. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or guardian |  | Date |
|  | * Parent
* Guardian (See note below)
 |
| Printed name of parent or guardian |
| **Note on permission by guardians:** An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child’s general medical care. Attach the documentation to the signed document. |

***[The following second parent or guardian block is required if your study is greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge about the child’s disorder or condition*** *45 CFR 46.406 & 21 CFR 50.53.****]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of second parent or guardian |  | Date |
|  | * Second Parent
* Guardian (See note above)
 |
| Printed name of second parent or guardian |
| If signature of second parent not obtained, indicate why: (select one) |
| * Second parent is deceased
* Second parent is unknown
* Second parent is incompetent
 | * Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document verbal assent of children on this consent form. If you will be documenting written assent add an assent signature line, printed name line and date line to the consent form or have a separate assent form. ]***

|  |  |
| --- | --- |
| Assent | * Verbal Assent Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent **[Remove latter section if assent will not be obtained]** |  | Date |
|  |  |  |
| Printed name of person obtaining consent and assent **[Remove latter section if assent will not be obtained]** |  |  |