**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Title:** Title (H number)

## Protocol No.: Sponsor’s protocol number {delete this line if not applicable}

## Sponsor: Name {Indicate the PI’s department if there is no external funding}

## Investigator: Name

Address

City, State, Zip Code

**Daytime Phone Number:** Phone Number

**24-Hour Phone Number:** Phone Number {Required if study is more than minimal risk}

**Consent Version:** Number or date {You can delete this line and use the header or footer instead, but be advised that eIRB requires a one-inch margin in the footer for the approval stamp. See *How to Manage Files in eIRB* for tips on version control and file naming. See *How to Print Stamped Consent Forms* to make sure the approval watermark is visible. https://www.umassmed.edu/ccts/irb/eirb2/job-aids-ii/}

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

{Remove this paragraph if it doesn’t apply} In this form, “you” generally refers to the person who takes part in the research. If you are being asked as the legally authorized representative, parent, or guardian to allow someone else to take part, “you” in the rest of this form generally means that person.

**INSTRUCTIONS:** If the body of the consent form will be longer than **three pages**, the consent must have a Key Information section and a Study Details section. This is because the consent must start with an initial summary. The initial summary should **not exceed three** pages.

The Key Information section should include a summary of the main information that research participants need to know to make a decision about whether they would want to participate in the study or not (what a reasonable person would want to know). It should be concise, focused, and use lay language. Organize this summary in a way that helps research participants understand what they are being asked to consider. Defer the specific details of the study until the Study Details section of the consent. The Key Information should include:

* The fact that consent is being sought for research
* That participation is voluntary
* How much time and the number of visits/interactions involved in the study
* The main purposes of the research in simple terms
* A summary of the main procedures to be followed in the research
* The reasonably foreseeable risks or discomforts to the prospective participant
* The benefits to the prospective participant or to others that may reasonably be expected from the research
* What the standard of care is and appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant

Organize the remaining consent information in sufficient detail in a way that helps participants understand the reasons why they might or might not want to participate. Do not merely provide lists of isolated facts. The key information and study details should be integrated in a way that limits redundancy and helps research participants ask questions and make a decision.

**Key Information**

The following is provided as an example and must be customized to your research study. This may involve reorganizing the flow of information, changing or adding bolded portions as headers, removing or adding text, etc. Throughout the key information and study details, use simple language and easy to understand explanations.

**You are being invited to participate in a research study** because you {state reason why, such as having a particular medical condition}.

If you have questions or don’t understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

**The main question this study is trying to answer** is {indicate the main purpose(s) of the study in very simple language}.

**If you join this research,** you will be randomly assigned (like pulling a name out of a hat) to receive either:

* A OR
* B

As part of the study, you will need to return for follow up for a physical exam at 30 days. We will also call you at 12 and 18 months to see how you are doing. We will continue to collect information from your medical record for as long as 5 years.

**You may not want to be in this study if you are uncomfortable with:**

* The fact that neither you nor your doctor will get to pick which group you are in
* Having to wait a bit longer for treatment to start
* Receiving a small amount of additional radiation
* Sharing your private information with researchers
* Drug/Pregnancy/Genetic testing

**Risks:** Do not include the complete list of reasonably foreseeable risks from the study details section of the consent form. This section should identify only the most important risks. For a cancer trial, for example, consider the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them. The section should also emphasize how the risks are different from or in addition to standard of care risks.

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

There may also be risks that we do not know yet.

**Benefits:** Describe any potential benefits to others. Your participation will help us to gain knowledge that may help treat X in the future.

* If there are possible benefits to the participant:

We cannot promise any benefits to you if you take part in this research. You may benefit from Describe any potential direct benefits to the participant. If benefits from taking part may not continue after this research has ended, describe this. Avoid stating that being in the study and being monitored is a direct benefit.

* If there are no expected benefits to the participant but possible benefits to others/scientific knowledge:

However, there is no direct benefit to you.

**Alternatives:** Clearly state here what the standard of care is for this condition/situation and that the participant could receive the standard of care if not in the study. If there is no standard of care – state that.

You do not have to be in this study to receive care for your {condition}. Other choices include {describe any other options the subject may have}.

If research participants could receive the intervention without being in the research:

You do not have to be in this study to receive {the study drug/device/intervention}.

If there are no alternatives, state: Your alternative is to not take part in the research.

**Conflict of Interest:** Insert any conflict of interest disclosures or remove this section if there is nothing to disclose

**If you think you might like to participate in this research, please continue reading to learn more about the details of this study.**

**STUDY DETAILS**

## Why is this research being done? Delete this and any other section that has been covered in full in the key information section

## The purpose of this research is to {describe in simple terms}.

**How many people will take part in this research?**

About X people will take part here at UMass Medical School. About X people will participate nationwide/worldwide.

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

Explain so that research participants understand their active time commitment and how long you will collect information about them.

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

Tell the participant what to expect using simple terms. Include all procedures done because the participant is taking part in this research, including procedures to monitor participants for safety. The information outlined below should be organized in a way that helps research participants understand and decide.

Do not describe procedures that will be performed regardless of whether the participant takes part in this research, unless they are absolutely necessary to clarify subjects’ participation in terms of time commitment or safety (e.g., study labs or samples are drawn at the same visit/time as standard of care labs or samples, so subjects do not have to have an extra study visit or procedure).

When appropriate for your research, include the following items:

* Describe where this research will be done
* Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule (please use lay terms when possible).
* Describe each group or arm
* If the research involves random assignment, describe this and the probability of assignment to each group. For example:

You will be put into a study group by chance (like pulling names out of a hat). X people will be in Group 1 and X people will be in Group 2. You cannot choose your study group.

* If the research involves blinding, include language describing a single (participant only) or double (participant and research team) blind, as appropriate. For example:

During the research, you (or you and the study doctor) will not know which group you are in. (Your study doctor can find out in case of an emergency).

* Identify all hospitalizations, outpatient visits, and telephone or written follow-up
* Indicate the length and duration of visits and procedures
* Identify all unapproved drugs, devices, tests, and procedures as experimental. For studies conducted under an IND, IDE, or abbreviated IDE, state:

Name of the product or device is investigational. This means that it is not approved by the Food and Drug Administration (FDA).

* Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental
* Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed
* For research on investigational drugs or devices, list any options for the participant to get the drug/device after the research, and who will pay for this.
* Describe any planned extension or follow-up study, but exclude discussion of biospecimens. Describe the future research and whether participants will be asked to sign a separate consent form.
* Indicate whether the study treatment will be available at the end of the study.

**Will you be collecting any specimens from me?**

* Use simple language to describe what will be collected and how often
* If blood will be drawn, indicate the amount in English units
* Indicate if collection of specimens is for present or future use
* If specimens will be used in future research, indicate that consent to future research is optional and provide a way for the participant to opt out (mandatory collection would require a robust justification in the study plan)
* Choose one to addresswhether whole genome sequencing will or will not be conducted:

The research will or might include whole genome sequencing (Provide a definition of 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; search [www.genome.gov](http://www.genome.gov) for sample consent forms that help explain genetic testing in simple terms).

The research will not include whole genome sequencing.

* + **If samples for whole genome sequencing are collected on children under age 18 – describe the process for obtaining informed consent for the retention and continued testing of these specimens once the subject reaches age 18.**

**Could being in this research hurt me?**

In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.

List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks, and consider bolding them or making them stand out in some way so the participant is made aware of the most serious risks associated with study participation.

If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.

Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.

Describe the side effects of any comparator drugs.

Describe any risks of washout, withholding treatment, or randomization.

Consider:

* Physical risks (for example, medical side effect)
* Psychological risks (for example, embarrassment, fear or guilt)
* Privacy risks (for example, disclosure of private information)
* Legal risks (for example, legal prosecution or being reported for child abuse)
* Social risks (for example, social ostracizing 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)

Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product:

In addition to these risks, taking part in this research may harm you in unknown ways.

Include for research that involves pregnant women or women of child-bearing potential and known risks to an embryo or fetus:

Taking part in this research may hurt a pregnancy or fetus in the following ways:

Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known:

Taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

EXAMPLE LANGUAGE:

* For some studies with investigational drugs: This is the first time the experimental drugs are being used together. For this reason, we do not know all the possible side effects, and we do not know how frequently they might occur or how serious they might be.
* For studies with venipuncture: The risks of having blood drawn include slight pain when the needle is inserted. You may develop a harmless black and blue mark, and your arm may be sore. Infection, light-headedness, and fainting are also possible, but unlikely.
* For studies with ECG: The risks include skin irritation and a rash from wearing or removing the patches that stick to your skin or from the gel that is used with them.
* For studies with CT scans: CT scans give detailed images of the inside of your body. The amount of radiation a person receives during a CT scan is moderate (more than you would receive from a dental or chest X-ray and about the same as the dose we get from normal background radiation over four or five years). We know that radiation is harmful, but the risk to your health is hard to measure. If you have had many X-rays or scans or if you might be pregnant, you should ask the study doctor about this risk.
* For breach of confidentiality – delete the sentence regarding misuse of genetic information if it does not apply: There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot make guarantees.
* For studies with genetic testing: Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but it may grow in the future.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you do not share information about taking part in this study, you may reduce this risk.

## Will being in this research help me in any way? Delete this and any other section that has been covered in full in the key information section

Describe any potential benefits to others. Your participation will help us to gain knowledge that may help treat X in the future.

* If there are possible benefits to the participant:

We cannot promise any benefits to you if you take part in this research. You may benefit from Describe any potential direct benefits to the participant. If benefits from taking part may not continue after this research has ended, describe this. Avoid stating that being in the study and being monitored is a direct benefit.

* If there are no expected benefits to the participant but possible benefits to others/scientific knowledge:

However, there is no direct benefit to you.

Include for research involving prisoners. Being in this research study will not help you with housing or correctional program assignments. Being in this research study will not help you get parole and it will not help you get out of jail.

## What other choices do I have besides taking part in this research? Delete this and any other section that has been covered in full in the key information section

Clearly state here what the standard of care is for this condition/situation and that the participant could receive the standard of care if not in the study – if there is no standard of care – state that.

You do not have to be in this study to receive care for your {condition}. Other choices include {describe any other options the subject may have}.

If research participants could receive the intervention without being in the research:

You do not have to be in this study to receive {the study drug/device/intervention}.

If there are no alternatives, state: Your alternative is to not take part in the research.

## Will it cost me any money to take part in this research?

* Include for research that may result in additional costs to the participants:

Taking part in this research may lead to added costs to you, such as {describe these costs}.

* Include for research where insurance will be billed:

You or your insurance will not have to pay for tests and procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

* If this study involves the use of an experimental drug or agent, add the following language: Drug name or agent will be provided to you at no cost; however, you or your insurance may be billed for the administration of this drug or agent.
* Include for research where insurance will not be billed:

No, there is no cost to you.

## Will I be given any money or other compensation for being in this study?

* If participants will not be paid:

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

* If participants will be paid:

You may be paid up to a total of $X. Your compensation will be broken down as follows:

* Describe payment schedule in terms of amount
* Describe when payments will be made
* Describe the amount of payment if the participant drops out

In order for us to pay you, you may need to give us private information like your address and phone number, and possibly your social security number. We will then share this information with the business offices and companies that need it to process the payment. If you receive $600 or more in a calendar year from being in research studies at UMass Worcester, UMass Worcester may report this to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research team will destroy this information no later than six years after study closure.

* If the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit, choose one of the following statements. (Modify if profit is anticipated or if participants will share in commercial profit.)
  + At this time, we do not think that the results of the research or the use of your specimens (even if identifiers are removed) will lead to commercial profit. In the event it does, there are no plans to share profits with you.
  + Your specimens (even if identifiers are removed) may be used to make new products, tests, or findings. These may have value and may be developed and owned by the study staff, University of Massachusetts, and/or others, including for-profit companies. If this happens, there are no plans to provide money to you.

## What happens if I am injured because I took part in this research?

**Use the following language for industry sponsored research.** This language is consistent with the clinical trial agreement for all studies that are greater than minimal risk. You will cause delays if you submit consent forms that deviate from the boilerplate below as most deviations are inconsistent with UMMS requirements for clinical trial agreements. (<https://www.umassmed.edu/globalassets/ccts/ccts-media/human-research-protection-program-hrpp/industry-collaborations/subject-injury-coverage-statement.pdf>)

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

If you are injured or have any harmful effects as a direct result of the administration of X (the study drug or device) or any procedure required by the research, necessary medical treatment will be made available to you at UMass Memorial Medical Center (UMMMC). The sponsor, X, will pay the reasonable and necessary medical costs for study-related injury.

To pay these medical expenses for a research injury, the sponsor will need certain information about you, such as your name, date of birth, and social security number. This is because the sponsor has to check to see if you receive Medicare. If you do, the sponsor must report the payment it makes to Medicare. The sponsor cannot use your information for any other purpose.

The sponsor has no plans to pay for medical expenses for injuries that are not directly related to your research participation or that are caused by the natural course of your disease. The sponsor has no funds set aside for any other form of compensation in the event of a research injury.

You do not give up any of your legal rights by signing this form.

**If the study is not funded or being supported by a federal grant, or institutional funding mechanism, please use the following language:**

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

**What are my responsibilities if I take part in this research?**

If you take part in this research, you will be responsible to: Describe the responsibilities of the participant.

* Describe any warning or precautions that the participant needs to know
* Describe any warnings regarding pregnancy or fathering a child
* Describe any requirements for the participant or the participant’s partner to abstain from sexual relations or use contraception
* Describe any requirements to avoid certain activities or refrain from taking certain drugs
* Describe any requirements to keep research articles out of the reach of children or others
* Describe any requirements to promptly report certain side effects to the investigator
* Describe requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.
* Describe any requirements to avoid or minimize contact with others
* Describe any situations where the participants should immediately contact the investigator or immediately seek medical attention
* Follow the directions of the study doctor and research staff.
* Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.
* Tell your other health care providers that you are in a research study.

## What happens if I say yes, but I change my mind later?

Include if there are procedures for orderly termination of taking part in the research.

If you decide to leave this research, contact the research team so that the investigator can {Describe the procedures for orderly termination by the participant}.

Include if there are potential adverse consequences to a participant who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include {Describe the adverse consequences}.

For your safety it is important to {If appropriate, discuss what might happen if there are risks to dropping out of the study or if there is a need to be slowly weaned off of a medication. In some cases it might be impossible to drop out of a study due to irreversible effects of research-related procedures such as a bone marrow transplant. Explain as necessary}.

If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

If collecting biospecimens (be sure to use wording that is consistent with actual plans, including sponsor plans) You may ask us to destroy your specimens at any time. However, we will not be able to destroy any research data that has already been created. We also will not be able to destroy specimens that have already been shared outside of UMMS.

## Can I be removed from the research without my approval?

Include for research where there is a meaningful possibility of removal – otherwise delete this section. The person in charge of this research study can remove you even if you want to continue. This may happen if Describe reasons why the participant may be withdrawn.

* It is in your best interest
* You have a side effect that requires stopping the research
* You need a treatment not allowed in this research
* You become pregnant
* The research is canceled by the FDA or the sponsor
* You are unable to take the research medication
* You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

## How will my information and specimens be stored and when will it/they be destroyed?

Describe how data and specimens will be stored such that they are kept confidential. Indicate when they will be destroyed.

We will remove your name and any other information that could directly identify you from your data and specimens. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data and specimens.

We will keep specimens and paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data and specimens. We will destroy the master list of identifiers {describe when}.

**Choose one** of the following or use the sponsor’s comparable language:

* We will not use or share your data and specimens for any future research unrelated to this study, even if identifiers are removed.
* It is possible that we might use the research data and specimens in other future research. We may also share data and specimens with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

## Who has access to my information?

For studies using protected health information (PHI)

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

* Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
* Related medical information like family medical history, and current and past medications or therapies
* Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
* All tests and procedures that will be done in the study

PLEASE NOTE: If you plan to collect data about the following: Abortion, Alcohol/Drug Abuse, psychiatric health, sexual assault counseling, domestic violence counseling, HIV/AIDS test results/treatment, sexually transmitted diseases – you must specifically indicate this in the consent document.

{Delete if not applicable} In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to {insert PI name} and their research staff.

For every study; remove *health information* if not using PHI: Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

* The research sponsor
* People and companies who work with the research sponsor
* Federal and state government agencies, such as {if applicable} the Food and Drug Administration and state auditors
* The Institutional Review Board (IRB) that reviewed this research {delete if not using an external IRB}
* The University of Massachusetts Medical School and UMass Memorial Health Care, including their Institutional Review Board (IRB) and research, billing, and compliance offices {delete billing if this office does not apply}
* Health care providers who provide services in connection with this study
* People and companies who work with UMMS and UMMHC on activities related to the research
* List others with whom private information will be shared

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

When the consent will be in the medical records and/or procedures include communicable disease testing or possible disclosures mandated by state law

Your medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

{Delete if not applicable}We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases. If you test positive for HIV, Hepatitis B, or Hepatitis C, these tests results will be reported to the local Board of Health and Massachusetts Department of Public Health.

When the research will be conducted in accordance with ICH-CGP

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data. These individuals have been trained to protect confidentiality.

For studies using protected health information (PHI)

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

{Delete this paragraph if it does not apply; if it will apply, the study plan should explain what information is restricted, e.g., information about study group assignment that would un-blind participants}You may not be allowed to review some of the research-related information in your medical record until after the study is completed. When the study is over, you will have the right to access the information again.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Unless you have obtained a Certificate of Confidentiality, include for research involving prisoners.

If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Include this section if you are enrolling adolescent females

If you could get pregnant, you will have pregnancy testing as part of this study. Only you will be told the results. If you are a minor and are found to be pregnant, we will talk to you about getting appropriate healthcare and the support of an adult. A positive pregnancy test means that you cannot be in this study. Because you will be asked to leave the study, your parents may find out that you are pregnant. If you are uncomfortable with pregnancy testing, then you should not be in this study.

**Include for all NIH research that was commenced or ongoing on or after December 13, 2016, and will collect identifiable sensitive information as defined here** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>. It is especially important to read the definition if you collect biospecimens or generate individual level, human genomic data from biospecimens. You will need to ensure that the overall consent and the use cases for which you seek permission are consistent with the Certificate of Confidentiality. The language below is adapted from Vanderbilt University.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from those specimens, if they are combined with other information.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials add the following language verbatim: (If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may use this language or a variation of this language. The IRB does not require this information when not required by FDA, even if the study will be listed.)

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.

## Will you share any results with me?

If applicable, describe how you will handle incidental findings; explain whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.

Describe any ways you might share information.

## It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

## We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition. They will be available when.

## Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or [irb@umassmed.edu](mailto:irb@umassmed.edu) for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

**Signature Block for Capable Adults**

Example signature block for studies that only involve adult participants able to consent

Your signature documents your consent to take part in this research.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of adult research participant |  | Date |
|  |  |  |
| Printed name of adult research participant |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

**Signature Block for Adults Unable to Consent and Capable Adults**

Example signature block for studies that may or will involve adults unable to consent and may also include adults that have capacity to consent

Right click your mouse to delete or adjust table rows

Add one of the following:

* All research participants unable to consent are required to assent, unless the investigator determines that the capability of the individual is so limited that they cannot reasonably be consulted.
* All research participants unable to consent are required to assent.
* The assent of adult research participants unable to consent is not required.

If assent will be obtained, add one of the following:

* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the research participant sign the consent form, unless the investigator determines that the individual is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for you or the individual named below to take part in this research. | | |
|  |  |  |
| Signature of adult capable of consent or adult’s legally authorized representative |  | Date |
|  |  |  |
| Printed name of research participant or their legally authorized representative |  | Date |
|  |  |  |
| Explain representative’s relationship to, and authority to act on behalf of, the research participant |  |  |
|  | | |
| Printed name of research participant if they did not personally sign |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the research participant’s capability, and they have agreed to be in the study.   OR   * The research participant is not able to assent because their capability is so limited that they cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |

If documentation of assent is by having the participant sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of research participant |  | Date |

**Signature Block for Children and Capable Adults**

Example signature block for research that may or will involve children as participants and may also include adult participants that have capacity to consent

Right click your mouse to delete or adjust table rows

Add one of the following for children:

* All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
* All children are required to assent.
* Assent of children is not required.

If assent of the child will be obtained, add one of the following:

* If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is not capable of signing.
* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the child sign the consent form, unless the investigator determines that the child is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for you or the individual named below to take part in this research. | | |
|  |  |  |
| Printed name of research participant |  |  |
| Signature of adult participant capable of consent, child participant’s parent, or individual authorized to consent to the child’s general medical care |  | Date |
|  |  |  |
| Printed name of child participant’s parent or individual authorized to consent to the child’s general medical care |  |  |
| Explain signer’s relationship to, and authority to act on behalf of, the child |  |  |

**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.

If applicable, add:

|  |  |  |  |
| --- | --- | --- | --- |
|  | |  |  |
| Signature of second parent | |  | Date |
| 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 | | |

Always add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent |  | Date |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the research participant’s capability, and the child has agreed to be in the study.   OR   * The research participant is not able to assent because their capability is so limited that they cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |

If documentation of assent is by having the child sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of child |  | Date |

**Signature Block for Witness**

Add on an as needed basis to the last page if a witness will observe the consent process. Be sure that the study plan describes when a witness will be use, e.g., with the short form of consent documentation and an interpreter, or research participants who are unable to read or physically unable to sign. Do not add to every consent document unless every research participant will have a witness to the consent process.

|  |  |  |
| --- | --- | --- |
| My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the research participant, and that consent was freely given by the research participant. | | |
|  |  |  |
| Signature of witness to consent process |  | Date |

**Signature Block for Continued Participation After Gaining Capacity to Consent**

Example signature block for consent to continue participation in research for children who reach the age of majority or adults that regain capacity to consent during their participation in research

Previously, you could not legally agree to take part in research. You took part in research based on the permission of someone else. Now that you can consent for yourself, you are being asked for your consent to continue to take part. Please read the entire document before signing below.

|  |  |  |
| --- | --- | --- |
| Your signature documents your consent to take part in this research. | | |
|  |  |  |
| Signature of adult capable of consent |  | Date |
|  |  |  |
| Signature of person obtaining consent |  | Date |

**Signature Block for Continued Participation After Losing Capacity to Consent**

Example signature block for consent to continue participation in research for adult participants who have lost capacity during their participation in the research and are unable to continue providing consent

The study doctor has determined that the research participant is no longer capable of providing consent and now requires consent to be provided by a legally authorized representative.

Add one of the following:

* All research participants unable to consent are required to assent, unless the investigator determines that the capability of the individual is so limited that they cannot reasonably be consulted.
* All research participants unable to consent are required to assent.
* The assent of adult research participants unable to consent is not required.

If assent will be obtained, add one of the following:

* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the research participant sign the consent form, unless the investigator determines that the individual is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for the individual named below to take part in this research. | | |
|  |  |  |
| Printed name of research participant |  |  |
|  |  |  |
| Signature of adult’s legally authorized representative |  | Date |
| Printed name of legally authorized representative |  |  |
| Explain representative’s relationship to, and authority to act on behalf of, the research participant |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the research participant’s capability, and the individual has agreed to be in the study.   OR   * The research participant is not able to assent because their capability is so limited that they cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |

If documentation of assent is by having the research participant sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of research participant |  | Date |