**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

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

**FACT SHEET (version Number or Date)**

**IMPORTANT: Do NOT use this template if your research involves:**

* **Protected health information (PHI)**
* **Any possibility of sharing identifiable data or biospecimens**
* **Any possibility of sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen**

If your research involves any item listed above, use the regular consent form template, which includes additional required language for these cases.

This template is appropriate for a simple minimal risk study involving no procedures that require a signature outside of the research context. Be sure to adjust the wording to fit your specific study. You may need to reorganize sections so that the information is easier to understand.

Be sure to remove all instructions and highlighting before submitting. The IRB recommends leaving the footer blank as eIRB requires a one-inch margin for the approval stamp. Use simple language and easy to understand explanations.

**Title:** Title (H number)

**Investigator:** Name of Principal Investigator

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

1. We are inviting you to participate in a research study.
2. 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.
3. The purpose of this study is {indicate the main purpose(s) of the study in very simple language}.
4. If you agree to participate, {describe procedures, time commitment, and if applicable, location}.
5. There is a risk {describe any risks other than breach of confidentiality using simple everyday language, e.g., you may feel uncomfortable answering the survey questions}.

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. {Delete if no blood draws}

There is a risk that someone could get access to the information about you and misuse it. To help protect your personal information, we will store your name separately from your research data and code your research data with a subject ID. We will keep paper documents under lock and key. We will keep electronic information on secure computer networks. These computer networks have many levels of protection. {If data are recorded anonymously with no direct or indirect identifiers, adjust the template accordingly}

1. There is no limit on the length of time we will store your data and specimens. We will destroy the list that links your identity to your data {describe when}.
2. Your blood sample will not be used for whole genome sequencing. {Delete if not applicable; revise to account for specimens more generally, if applicable}
3. 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.
4. 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. {Delete if not applicable}
5. At this time, we do not think that the research data or the use of your specimens (whether linked to you or with identifiers removed) will lead to commercial profit. In the event it does, there are no plans to share any financial gain with you.

OR

The research data and specimens (linked to you or with identifiers 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 share any financial gain with you.

1. Your participation may help us to gain knowledge about X. However, there is no direct benefit to you.
2. As a thank you for your participation, you will receive X {delete if there is no incentive}.

## 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.

## {Revise as applicable} 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.

1. We will try to limit access to your personal information to people who have a need to review this information. We cannot promise complete privacy. The University of Massachusetts Medical School, including the Institutional Review Board (IRB) and research, billing, and compliance offices, may see your information.

In order to receive a stipend for study participation, you will need to give us private information like your name, address and phone number [*if social security number is required please add that here or delete].* 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 [insert when you will destroy this data – must be no later than six years after study closure].

{Add other organizations/individuals such as sponsors, FDA, monitors, etc., that may have access to the subject’s records. HIPAA language should not be listed in this section. Use the full consent form template if you will use or access protected health information}.

1. 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 participating in this research.
2. If you have any questions, concerns, or complaints, or think that the research has hurt you, you can talk to the Principal Investigator at {insert contact information for the PI or revise this section to include the appropriate contact for the study team}. This research has been reviewed and approved by an Institutional Review Board. You can reach them at (508) 856-4261 or irb@umassmed.edu if you would prefer to speak with someone not associated with the study or have questions about your rights as a research subject.