APPROVED BY IRB ON: (FOR OIC USE ONLY) *EXPIRES ON:*

Template for Consent Forms

Instructions:

1. The following template provides the required elements that you will need to complete your consent form.

2. Do not remove anything in bold. Fill in the relevant information about your study below each bolded question or section. If you think that one of the required elements is not applicable to your study, please provide a statement to that effect.

3. Instructions for each section are given in [brackets and italic type]. These italicized instructions should be deleted from the final document.

4. Please put your IRB Study # at the top of the first page.

5. Please put the PIs Last Name in the footer of each page.

6. Verify you've included all necessary elements using the Consent Form Checklist

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IRB# _____

Informed Consent to Participate in Research
The University of Massachusetts Dartmouth

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigator (the person in charge of this research) or his/her representative will provide you with a copy of this form to keep for your reference, and will also describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

Title of Research Study:

Principal Investigator(s) (include faculty sponsor), UMD affiliation, and Telephone Number(s): *[Only use "Dr." if you possess an MD and are a licensed physician. Instead, use "Professor or Ph.D. or Pharm.D., etc."]*

Funding source: *[Please indicate "Not applicable" if the study is not funded.]*

What is the purpose of this study? *[Please describe the overall goal and the number of subjects to be included in the study.]*

What will be done if you take part in this research study? *[Please include experimental procedures]*

The Project Duration is: [*please indicate the duration of this project]*

What are the possible discomforts and risks?

*[***Please describe any risks in a language appropriate to the reader. If applicable, state that there may be risks that are unknown at this time.*

*** Include a statement to the participant, such as "If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form."*

***Only when applicable, consider the following information, and use the IRB manual suggested phrasing as indicated:*

- *For studies that involve psychological risk and/or emotional risk (many of the studies that are done by UMD faculty/students do not involve physical risk, but rather the possibility of psychological and/or emotional risk from participation: For these studies, the principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk. They should be given the names and telephone numbers of agencies that may alleviate their mental concerns, such as a crisis hot-line. If the principal investigator or the faculty sponsor of a student investigator is qualified to treat mental health problems, that person may be listed as a resource.*
- *For studies that involve blood samples or physical risk: "Blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study a trained technician will obtain a 30 ml (about 2 tablespoonfuls) sample of your blood that will be analyzed for…"*
- *For studies that involve drugs: The participants must be given a statement of known side effects, warned about possible drug interactions (including interactions with alcohol), and warned about activities that may be dangerous (such as driving with a drug that has a sedative effect).*
- *For studies that involve risk to a fetus: The female participant must be informed of the risk and the methods to be used (such as a pregnancy test) to minimize the risk.*
- *If the risks of any research procedure are not well known, for example because of limited experience in humans: A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.*
- *If the research includes women of child bearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses is not well known: A statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.*

What are the possible benefits to you or to others? *[Please note that reimbursement for participation is not considered a benefit. Also note that there may not be any benefits to participation. If no benefit exists then indicate "No benefit exists at this time"]*

If you choose to take part in this study, will it cost you anything? *[Please describe any costs, if any, that may be associated with participation, e.g., study medication.]*

Will you receive compensation for your participation in this study? *[Please include subject pool credit, extra-credit, class-credit, research credit, monetary compensation, and gift certificates, etc. When research involves more than minimal risk, state "The University has no plan to provide compensation for a physical or psychological injury."]*

What if you are injured because of the study?

*[***If the study involves physical risk, assess the risk and add a statement such as, "The University has no program or plan to provide treatment for research related injury or payment in the event of a medical problem. In the event of a research related injury, please contact the principal investigator."*

****If emergency treatment for research-related injuries is arranged by (for example) having a medical doctor available for emergency treatment, it should be clearly stated. However, a statement for extended care should be put into the consent form, such as, "The University has no program or plan for continuing medical care and/or hospitalization for research-related injuries or for financial compensation."*

****If all of the participants are UMD students, it is appropriate to state, "If injuries occur as a result of study activity, eligible University students may be treated at the usual level of care with the usual cost for services at the Student Health Center, but the University has no policy to provide payment in the event of a medical problem."]*

If you do not want to take part in this study, what other options are available to you? *[Please indicate to participants, "Your participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future relationships with The University of Massachusetts Dartmouth (and or participating sites or other organization).*

****If you are using a subject pool or students as your participants list other options available for credit, as applicable]*

How can you withdraw from this research study and who should you call if you have questions?

[If there are anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent: Anticipated circumstances under which participation may be terminated by the investigator without the participant's consent.

If there are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Consequences of a participant's decision to withdraw from the research.

If there are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Procedures for an orderly termination of participation]

[Please include the bold statements below, exactly as they are written, and fill in any blanks where indicated]

If you wish to stop your participation in this research study for any reason, you should contact the principal investigator: *[PI Name]* **at (508)** *[PI Phone #]*. **You should also call the principal investigator for any questions, concerns, or complaints about the research. You are free to withdraw your consent and stop participation in this research study at any time without penalty or loss of benefits for which you may be entitled. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study.**

In addition, if you have questions about your rights as a research participant, or if you have complaints, concerns, or questions about the research, please contact Professors Cathy Neto, Ph.D., or Frank Scarano, Ph.D., Co-Chairs, The University of Massachusetts Dartmouth Institutional Review Board for the Protection of Human Subjects at (508) 910-6928 or (508) 999-9239, or the Office of Institutional Compliance at (508) 910-9880.

How will your privacy and the confidentiality of your research records be protected?
[Please describe the protections you will implement to protect participant privacy and the confidentiality of research data. Also, please include the bold text below:]

If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, then The University of Massachusetts Dartmouth will protect the confidentiality of those records to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study.

> *[***If the study is funded the sponsor has the right to review research data – if so include the following, "If the research project is sponsored (e.g., receives funding from outside UMD) then [put sponsors name here] will also have the legal right to review your research records."*
>
> ****Please note that for* ***studies with audio or video recordings****, participants must be told: "(a) that the interviews or sessions will be audio or videotaped; (b) that the cassettes will be coded so that no personally identifying information is visible on them; (c) that they will be kept in a secure place (e.g., a locked file cabinet in the investigator's office); (d) that they will be heard or viewed only for research purposes by the investigator and his or her associates; and (e) that they will be erased after they are transcribed or coded. If you wish to keep the recordings because of the requirements of your professional organization with respect to data or because you may wish to review them for additional*

analyses at a later time, the statement about erasing them should be omitted and you should state that they will be retained for possible future analysis."

****If the research will be* ***published or presented at conferences*** *then include, "If the results of this research are published or presented at scientific meetings, your identity will not be disclosed." If you wish to present the recordings at a convention or to use them for other educational purposes, you should get special permission to do so by adding, after the signature lines on the consent form, the following statement, "We may wish to present some of the audio / video tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with your recorded data."*

**** If the research* ***collects genetic information****, the consent form must include the following language:*

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- *Health insurance companies and group health plans may not request your genetic information that we get from this research*
- *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*
- *Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow this law by May 22, 2009. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination on the basis of a genetic disease or disorder that you already know about.

By signing the consent form, you acknowledge that you have voluntarily donated your [indicate type such as blood, saliva, etc] specimen to The University of Massachusetts Dartmouth for research purposes. The University has no plans to compensate you for any commercial uses of the products that may be derived from the specimen. The University of Massachusetts Dartmouth will maintain ownership of the specimen.

Will the researchers benefit from your participation in this study*? [Please indicate any potential benefits to researchers, beyond publishing or presenting the results.]*

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Signatures: *[Please include all of this bolded text:]*

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

Signature and printed name of person obtaining consent **Date**

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Printed Name of Subject **Date**

Signature of Subject **Date**

Signature of Principal Investigator **Date**

*[***If you are requesting academic records (grades) from the registrars office please include a line requesting information necessary to obtain the grade]*