

## CONSENT FORM 2

*IRB APPROVED ON: (OIC USE ONLY)*

*EXPIRES ON:*

### INSTRUCTIONS FOR COMPLETING CONSENT FORM 2:

1. **Title:** this should match your project title unless reason exists for it to be different (i.e. desire to avoid any stigmatization in title of consent form, or to simplify title in laymen's terms.)
2. **Conducted by:** List your name and contact information (department and phone); for student researchers also include contact information for faculty sponsor. Include funding source.
3. **Purpose:** complete this statement by describing the purpose / aim of the study, as specifically as possible. Include the number of subjects in the study.
4. **Procedures:** Using bullets, list the activities that subjects will perform; identify any experimental procedures under a separate "experimental procedures" heading.
5. **Time:** approximate the amount of subject's time the research will require.
6. **Risks / Benefits:** use the bullets to list the risks and benefits of being in the study. If no risk exists indicate, "The risk associated with this study is no greater than everyday life." Remember to include psychological risk / mental stress and loss of confidentiality. If appropriate, disclose alternative procedures or courses of treatment and the alternative's advantages to the subjects. If applicable, indicate any anticipated circumstances under which the PI may terminate the subject's participation without regard to the subjects consent. If applicable, list any consequences of subject's decision to withdraw and the process for orderly termination from research. Indicate any benefits – if none exist indicate, "There are no benefits for participation in this study."
7. **Compensation:** List any compensation provided (include extra credit); if applicable indicate alternatives for subject pool credit; If applicable, list any costs to subjects that may result from participation in the research, then also change heading to "**Compensation / Costs:**" and describe any costs associated with participation.
8. **Confidentiality and Privacy Protections:** Describe positive steps taken to maintain and protect the confidentiality of research data and participant's privacy. Indicate any conditions under which confidentiality will be broken, for example, criminal activity, child neglect, child / elder abuse, or a clear, serious, and direct harm to self or others. If conditions exist under which confidentiality may be broken, then indicate to whom necessary information would be reported (i.e., the police, CPS, school counselor, parent, or appropriate professional).

**Studies with audio or video recordings,** participants must be told:

- (a) interviews or sessions will be audio or videotaped;
- (b) tapes will be coded so that no personally identifying information is visible on them;
- (c) tapes will be kept in a secure place (e.g., a locked file cabinet in the investigator's office);
- (d) tapes will be heard or viewed only for research purposes by the investigator and his or her associates;
- (e) tapes 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, "To make possible future analysis the investigator will retain the recordings," and modify (a)-(e) above appropriately.

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 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 tape. In this case, add another signature line prefaced by, I hereby give permission for the video (audio) tape made for this research study to also be used for educational purposes.*

*PUT PI LAST NAME HERE*

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This procedure makes it possible for a participant to agree to being taped for research purposes and to maintain the confidentiality of the information on that tape.

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.*”

If you are requesting academic records (grades) from the registrar’s office: include the request in the study procedures section; add an additional participant signature line for the release of specific grade information, “*I consent to the release of my (indicate grade(s) being release) from the registrar’s office.*” You must detail specific information being requested for release in both the procedures and signature section i.e., GPA, psychology 301 class grade etc. After the additional signature line include a request for the information necessary to obtain the grade(s).

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.*

***PUT PI LAST NAME HERE***

## CONSENT FORM 2

### ***IRB APPROVED ON: (OIC USE ONLY)***

Title

Conducted By:

Of The University of Massachusetts Dartmouth:

*Department / Office;*

Telephone:

### ***EXPIRES ON:***

IRB PROTOCOL #

You are being asked to participate in a research study. This form provides you with information about the study. The person in charge of this research will also describe this study to you and answer all of your questions. Please read the information below and ask any questions you might have before deciding whether or not to take part. Your participation is entirely voluntary. You can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You can stop your participation at any time and your refusal will not impact current or future relationships with UMD or participating sites. To do so simply tell the researcher you wish to stop participation. The researcher will provide you with a copy of this consent for your records.

**The purpose of this study** is to

**If you agree to be in this study, we will ask you to do the following things:**

•

**Total estimated time to participate** in study is

**Risks** of being in the study

- This [treatment, procedure, intervention, or describe other] may involve risks that are currently unforeseeable. 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.

**Benefits** of being in the study

**Compensation:**

•

**Confidentiality and Privacy Protections:**

•

- 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.

The records of this study will be stored securely and kept confidential. Authorized persons from The University of Massachusetts Dartmouth, members of the Institutional Review Board, and (study sponsors, if any) have the legal right to review your research records and will protect the confidentiality of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify you as a subject. 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.

**Contacts and Questions:**

If you have any questions about the study please ask now. If you have questions later, want additional information, or wish to withdraw your participation call the researchers conducting the study. Their names, phone numbers, and e-mail addresses are at the top of this page. If you have questions about your rights as a research participant, complaints, concerns, or questions about the research please contact Andrew Karberg, The University of Massachusetts Dartmouth Office of Institutional Compliance at (508) 910-9880 or email: [akarberg@umassd.edu](mailto:akarberg@umassd.edu).

*You will be given a copy of this information to keep for your records.*

*PUT PI LAST NAME HERE*

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**Statement of Consent:**

***EXPIRES ON:***

I have read the above information and have sufficient information to make a decision about participating in this study. I consent to participate in the study.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Person Obtaining Consent Date: \_\_\_\_\_

Signature of Investigator: \_\_\_\_\_ Date: \_\_\_\_\_