

**UNIVERSITY OF NEW ENGLAND  
CONSENT FORM TEMPLATE**

**Note: this page should not be part of your consent form**

**INSTRUCTIONS:** The consent form serves as a means of providing information to potential participants and documenting the consent **process**, ensuring that a participant's voluntary decision is based on an understanding of his/her rights and the nature of the project. This sample consent form can be modified, as some sections may not be applicable to your project; however, **general requirements** are identified and should be included in your consent form. Please retain section headings. Sections that are **highlighted** are guidelines and should be replaced with your own text to fit the needs of your project or removed. Please address the individual directly in the consent form, e.g., "You will be asked to..."

**Readability**

Program for Readability In Science & Medicine (PRISM) is a Group Health Research Institute initiative to improve the readability of consent forms and other print materials used in communication with study participants.

There is a free online training plain language tutorial created for researchers.

<http://prism.grouphealthresearch.org/start.htm>

Additionally, there is a toolkit available which is an excellent resource:

[http://prism.grouphealthresearch.org/documents/PRISMReadabilityToolkit\\_ThirdEdv6\\_062210.pdf](http://prism.grouphealthresearch.org/documents/PRISMReadabilityToolkit_ThirdEdv6_062210.pdf)

**Researchers are strongly encouraged to review both of the above links before drafting the consent document(s) for your project.**

The UNE IRB welcomes any feedback on this template, any problems, and suggestions for improvement. Please email your feedback to [irb@une.edu](mailto:irb@une.edu). It will have no effect on your application.

## UNIVERSITY OF NEW ENGLAND CONSENT FOR PARTICIPATION IN RESEARCH

**Project Title:** *[insert project title here]*

**Principal Investigator(s):** *[names, titles, institutions, and contact information. If this is a student project and there is a faculty advisor on the project include his/her information as well.]*

### **Introduction:**

#### **General requirement language:**

- Please read this form, you may also request that the form is read to you. The purpose of this form is to provide you with information about this research study, and if you choose to participate, document your decision.
- You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. You can take as much time as you need to decide whether or not you want to participate. Your participation is voluntary.

#### **Why is this study being done?**

- Briefly explain the purpose of your study in lay language.
- If you and/or members of the investigative team have a consultative or financial interest relating to the study please precisely state the nature of the relationship to the participants.  
Examples include: A paid (or unpaid) consultant to the company sponsoring this study; Paid membership on the advisory board; Receiving payment for lectures from the company sponsoring the study; Have stock in the company that is sponsoring the study; Hold a patent for the product being investigated in this study.

#### **Who will be in this study?**

- Explain why the individual has been identified as a potential participant; include any inclusion and exclusion criteria.

Optional language:

- You must be at least 18 years of age to participate.
- Include the approximate number of participants involved.

#### **What will I be asked to do?**

- Provide an explanation of all research activities, their purpose and duration.
- Identify any procedures or interventions that are experimental or unusual.
- What is the expected duration of the individual's participation in the project?
- Disclose and explain any randomization.
- What types of measures will be used? Who will administer them?
- Will the participant receive any reimbursement or compensation for participation in this project? For time, travel etc.

### **What are the possible risks of taking part in this study?**

- Describe any reasonably foreseeable risks and/or discomforts that may result from participation and how they will be minimized.
- If there are no reasonably foreseeable risks associated with participation it is acceptable to state just that.

Optional language:

- There are no foreseeable risks associated with participation in this study.
- How will problems or discomfort be addressed if they occur? Will support services be available?
- For more than minimal risk research: Indicate whether treatment and/or compensation are available if illness or injury occur and, if so, what it consists of, who is responsible for the costs and how to obtain further information.
  - *NOTE: Do not use exculpatory language. Researchers cannot include language that appears to ask individuals to waive any of their legal rights.*
  - As appropriate, include a statement that the treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

### **What are the possible benefits of taking part in this study?**

- Can any benefit be reasonably expected from the research and if so, what? Distinguish between direct benefits to the individual and indirect benefits.

Optional language:

- There are no direct benefits to you for participating in this study. There may be a benefit to others, the organization, etc. ...

### **What will it cost me?**

- A statement about whether or not you expect participants to incur any costs, including travel as a result of participation in the research.
- If costs are expected, will participants be reimbursed and, if so, for what? What documentation will be needed from the individual to be reimbursed?
- If the individual has insurance will the cost be billed to the insurance company? Is it the individual's responsibility to confirm, in advance that his/her insurance company will cover the cost? If the individual does not have insurance or his/her insurance company refuses to pay who will cover the cost? Will the individual be responsible for it?

### **How will my privacy be protected?**

- What provisions are in place to protect the privacy of the participant?
- Is the setting where the intervention will take place sufficiently private?
- Please state in what form and with whom the results of the project will be shared. If you know how you will be publishing your results, please disclose this information to the participants. Examples of publishing include a "Thinking Matters" presentation, a Muskie Capstone project, a journal article and a report to a third party agency.

**How will my data be kept confidential?**

- Please indicate if data collection and participation are anonymous.

## Optional language:

- This study is designed to be anonymous, this means that no one, can link the data you provide to you, or identify you as a participant.
  - *NOTE: anonymous means that no one (including the researcher) can link data to an individual. Researchers should not promise complete anonymity, especially in the case of research conducted via the internet.*
- Please outline for the participants how data will be kept confidential. Explain where the data will be kept secure after it is collected; what, if any, identifying information will be collected; who will have access to the data and what will happen to the data once the study is complete. What are the protections in place for the electronic transfer of data? Include the data security standards you included in your research protocol here.
  - Examples include:
    - Research records will be kept in a locked file in the locked office of the Principal Investigator ;
    - [Business sensitive data](#): Data will be stores on a password protected computer and on a USM network drive.
    - [Compliant data](#): Data will be stored on a secure server at USM that is only accessible from USM owned computers. All computers that will be used to access research data will have its hard drive encrypted.
    - Individually identifiable data will be destroyed after the study is complete;
    - Data will be coded
    - Data will be encrypted using industry standards.
    - No individually identifiable information will be collected.

**General requirement language:**

- Please note that sponsors, funding agencies, regulatory agencies, and the Institutional Review Board may review the research records. *Please remove sponsors or funding agencies from this language if they are not applicable.*

**General requirement language:**

- A copy of your signed consent form will be maintained by the principal investigator for at least 3 years after the project is complete before it is destroyed. The consent forms will be stored in a secure location that only members of the research team will have access to and will not be affiliated with any data obtained during the project.
  - If you intend to maintain consent forms for longer than 3 years please revise this language accordingly. If you have received a waiver of documentation of consent this language does not apply.
- If relevant, disclose any mandatory reporting requirements.
- If applicable, state if there is a [certificate of confidentiality](#) being sought or in place for this project.

- For focus groups state that members of the focus group will be asked not to repeat what is discussed but the researcher cannot ensure that they will respect other participants' privacy.
- If audio or video tape recordings are made, explain specifically who will have access to them, what they will be used for, and when and how they will be erased/destroyed. If recordings are optional provide a checkbox at the end of this form.
- If the study will include the use of an on-line survey, or, will transfer collected data over the internet, explain to the participant what measures will be used to keep all the transferred data secure.
- Please state any intent to use the data for future research purposes.
- Will research findings be provided to participants? Can they request findings? If so, how?

### **What are my rights as a research participant?**

#### **General requirement language:**

- Your participation is voluntary. Your decision to participate will have no impact on your current or future relations with the University [*or with other cooperating institutions (insert name)*]. If this project involves students as participants mention that their decision to participate will not impact their standing as students. If employees are involved, that their decision to participate will not impact their relationship with their employer.

#### **General requirement language:**

- You may skip or refuse to answer any question for any reason.

#### **General requirement language:**

- If you choose not to participate there is no penalty to you and you will not lose any benefits that you are otherwise entitled to receive. You are free to withdraw from this research study at any time, for any reason. If you choose to withdraw from the research there will be no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.
- Additional element as appropriate: You will be informed of any significant findings developed during the course of the research that may affect your willingness to participate in the research.
- If applicable, state the anticipated circumstances under which the individual's participation may be terminated by the investigator without regard for the subjects consent.

### **What other options do I have?**

- What other options does the participant have? Disclose any appropriate alternative procedures or courses of treatment, if there are any that might be advantageous to the individual.

#### **Optional language:**

- You may choose not to participate.

**Whom may I contact with questions?**

**General requirement language:**

- The researchers conducting this study are [*insert name(s) of investigators, including the PI*]. For questions or more information concerning this research you may contact her/him/them at [*telephone number and email address of researcher and/or faculty mentor*]. **Note: Do not use "Dr." Please use precise initials.**

**General requirement language:**

- If you choose to participate in this research study and believe you may have suffered a research related injury, please contact [*specify name of researcher or your faculty mentor if PI is a student*] at [*telephone number and email address*].

**NOTE: Student researchers are required to have the faculty advisor listed. The faculty advisor is expected to take an active role in students' research activities and provide supervision throughout the duration of their research study. The faculty advisor is legally responsible for all research activities.**

**General requirement language:**

- If you have any questions or concerns about your rights as a research subject, you may call Olgun Guvench, M.D. Ph.D., Chair of the UNE Institutional Review Board at (207) 221-4171 or [irb@une.edu](mailto:irb@une.edu).

**Will I receive a copy of this consent form?**

**General requirement language:**

- You will be given a copy of this consent form.

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**Participant's Statement**

**I understand the above description of this research and the risks and benefits associated with my participation as a research subject. I agree to take part in the research and do so voluntarily.**

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Participant's signature or  
Legally authorized representative

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Date

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Printed name

**Researcher's Statement**

**The participant named above had sufficient time to consider the information, had an opportunity to ask questions, and voluntarily agreed to be in this study.**

\_\_\_\_\_  
Researcher's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name