

**University of New England
CONSENT FORM TEMPLATE**

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

INSTRUCTIONS

The consent document is part of the informed 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, required elements are identified and should be included in your consent form. 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. Address the individual directly in the consent form, e.g., "You will be asked to..." You are NOT required to use this template however, if you choose not to please note the required language and guidelines included here.

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

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. It will have no affect 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:

- Insert a general statement about your research study here
- Required language: "Please read this form. 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 how and why the individual has been identified as an invited participant; include any inclusion and exclusion criteria.
- Include the approximate number of participants involved.

What will I be asked to do?

- Provide an explanation of all research activities and their purpose.
- Explain how much time is being requested of the individual. What is the expected duration of the individual's participation in the project?
- What types of measures will be used? Who will administer them?

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

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

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.

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.

How will my privacy be protected?

- **Please indicate if data and participation are anonymous. *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 consider adding the following language: “This survey is designed to be anonymous, please do not include any information anywhere on the survey that may individually identify you or anyone else.”***
- Please outline for the participants how data will be kept confidential. Explain where the data will be kept secure after it is 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? *Note: absolute confidentiality should not be promised to participants.*
Examples include:
 - Research records will be kept in a locked file in the office of the Principal Investigator;
 - Data will be encrypted using industry standards.
- Optional language: “Please note that the Institutional Review Board may review the research records.”
- Please state how and with whom the results of this 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.
 - **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.**

What are my rights as a research participant?

- **Optional language: “Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University [or with other cooperating institutions (insert name)].”**

- Optional language: “You may skip or refuse to answer any question for any reason.”
- Optional language: “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.”
- Optional 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.”
- Optional language: “The Institutional Review Board (IRB) for the Protection of Human Subjects at the University of Southern Maine has reviewed the use of human subjects in this research. The IRB is responsible for protecting the rights and welfare of people involved in research.”

What other options do I have?

- A statement that the individual can choose not to participate.

Whom may I contact with questions?

- Required 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.**
- Required language: “If you have any questions or concerns about your rights as a research subject, you may call the USM Human Protections Administrator at (207) 228-8434 and/or email usmirb@usm.maine.edu.”
- **Required if applicable: Student researchers are required to have the faculty mentor(s) listed. The faculty mentor is expected to take an active role in students’ research activities and provide supervision throughout the duration of their research study. The faculty mentor is legally responsible for all research activities.**

Will I receive a copy of this consent form?

- Required language: “You may print/keep a copy of this consent form.”

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