**University of Southern Maine**

**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 must 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…”

**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. <https://prism.kpwashingtonresearch.org/course_introduction/splash_page_before_registration.html>

Additionally, there is a toolkit available which is an excellent resource: <https://www.kpwashingtonresearch.org/application/files/6415/5500/0956/PRISM_readability_toolkit.pdf>

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

The Office of Research Integrity and Outreach (ORIO) and the USM Institutional Review Board (IRB) welcome any feedback on this template, any problems, and suggestions for improvement. Please email your feedback to the USM Office of Research Integrity and Outreach at [usmorio@maine.edu](mailto:usmorio@maine.edu). It will have no effect on your application.

**University of Southern Maine**

**CONSENT FOR PARTCIPATION 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. You may also request that the form is read to you. You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. 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.
* Identify any procedures or interventions that are experimental or unusual.
* Explain how much time is being requested of the individual. 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 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.

**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.
* 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 participant 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.

**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?**

* 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 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? *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;
* Individually identifiable data will be destroyed after the study is completed;
* Data will be coded
* Data will be encrypted using industry standards.

***Optional language:***

* The records of this study will be kept confidential to the extent allowed by law.
* 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.*
* 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.
* 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 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.

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

***Required 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)].*
* You may skip or refuse to answer any question for any reason.
* 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 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.
* If applicable, state the anticipated circumstances under which the individual’s participation may be terminated by the investigator without regard for the participant’s consent.
* If applicable, state the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant.
* The Institutional Review Board (IRB) for the Protection of Human Subjects at the University of Southern Maine has approved the use of human subjects in this research. This approval is indicated by the IRB date-stamp on this consent form. The IRB is responsible for protecting the rights and welfare of people involved in research.(this statement is for research approved through the expedited or full review process).

**What other options do I have?**

* Are there any appropriate alternative procedures or courses of treatment available that might be advantageous to the participant?
* 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.*
* 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***].**

***Required language:***

* If you have any questions or concerns about your rights as a research participant, you may call the USM Office of Research Integrity and Outreach at (207) 780-4517 and/or email [usmorio@maine.edu](mailto:usmorio@maine.edu). [Information for research participants](https://usm.maine.edu/orio/irb-information-for-research-participants/).

***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 will be given/may print a copy of this consent form.