Informed Consent

Except where specifically waived or altered by the IRB under Section I.K.3-4 of the University of Maine’s Policies and Procedures for the Protection of Human Subjects of Research, all human subjects research will require written informed consent. For projects exempt from further review, documentation (signature) of informed consent is not required, but the same basic elements of an informed consent should be applied. The following two paragraphs were taken from the Office for Human Research Protections (NIH) website on the protection of human subjects of research.

“Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.”

“Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.”

NOTE: For studies requiring continuing review, approval information (with expiration date) will be added to the approved informed consent document; that version will be provided to the researcher and must be used in obtaining consent. This procedure helps ensure that only the current, IRB-approved informed consent document is presented to subjects and serves as a reminder to the investigator of the need for continuing review.
Informed Consent Checklist

Include these items in the form: (NOTE: The form should be written at no higher than an eighth grade reading level. FOLLOW THE SAMPLES [INCLUDING HEADINGS] found on the IRB website.)

1) With the Revised Common Rule that went in effect in January 2019 studies with longer consent forms (more than 1 page) or Federally funded studies a concise summary is required. The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.

The summary should include the following 5 elements:
1) A statement that the project is research and that it is voluntary.
2) A summary of the research (purpose, overview of procedures etc.)
3) Any foreseeable risks or discomforts
4) Any expected benefits to participants (if applicable)
5) If applicable, alternative procedures to course of treatment

2) A statement that the potential subject is being asked to participate in a research project. Include the name of the person who is conducting the research and his/her title/department. If the principal investigator is a student, the faculty sponsor should also be identified with his/her affiliation.

3) An explanation of the purpose of the research.

4) A description of the procedures to be followed. Include sample questions from any instruments that may be used (not required for mail/internet surveys where the questionnaire is enclosed/follows the consent).

5) An estimate of the amount of time it may take to participate.

6) A risk statement (reasonably foreseeable risks or discomforts). Examples: in some studies, answering questions may cause people to become uncomfortable; for studies involving standard blood draws, the possibility of bruising exists. For studies that have no foreseeable risks, examples include, “There is no more risk to you in participating than in everyday living.” or “Except for your time and inconvenience, there are no risks to you from participating in this study.” Do not state that there are no risks – all studies have risks even if only time and inconvenience! Do not state “You could become uncomfortable answering questions and except for your time and inconvenience, there are no risks to you from participating.” If someone could
become uncomfortable answering questions, the risk is more than time and inconvenience – it’s one or the other.

7) A description of any potential benefits to the subject or to others that may reasonably be expected from the research. It is possible that a study will have no direct benefit to the participant! (e.g., “While this study will have no direct benefit to you, this research will help us learn more about…”). **There should be two statements** – benefit of the research to the participant and benefit of the research in general.

8) A description of compensation, if applicable. List any compensation for participation (money, course credit, etc.). Also indicate how compensation will be handled if a participant withdraws from the study. Do not include if there is no compensation.

**NOTE:** If the compensation exceeds $75 in value, the following language should be added to the Compensation Section (See [Human Subjects Payment Guidelines](#) for additional information.).

*Basic information (your name and address, date of payment, value of payment, my name as researcher) will be given to a University office for tax reasons:*

- Employee of UMaine (including student employee): Information will be sent to the Human Resources Department. The value of the compensation may be added as wages and subject to taxation.

- Non Employee: Information will be sent to the Purchasing Department. If you receive $600+ during a calendar year (January 1 – December 31) from participating in UMaine research projects, Form 1099 will be generated and mailed to you. If you do not receive that much money, information will be destroyed at the end of the calendar year (i.e., December 31st).

9) For treatment studies only, include a description of appropriate alternative procedures or courses of treatment that might be advantageous to the subjects.

10) A description of confidentiality. Will names be associated with the data? Will the data be coded and linked to a master list of names (key)? Who will have access to the data? Where will the data be stored (e.g., locked office, password protected computer)? If you are keeping the key electronically, you need to encrypt it (see [guidelines on encryption](#)). Explain the retention of the data (including any audio, video, or film recordings): a) if coded, when will the key be destroyed? and b) How long will the data be kept (e.g., destroyed by date, kept indefinitely, etc.)? Is the study anonymous? Don’t confuse anonymity and confidentiality. If names are connected to data (even if you have coded the data), you can’t tell participants that their identity will remain anonymous! You can only guarantee anonymity if no one, including you as the researcher, can identify participants. If participants will be involved in a group interview, you can assure them that you will keep their
responses confidential and will ask other participants to do the same, but you cannot absolutely guarantee that other group members will keep their responses confidential. Use dates (month/year) for destroying keys, data, etc., if applicable. Do not simply say “upon completion” or “when all data have been collected.” Participants don’t know when that will be!

11) A statement that participation is voluntary. If subjects choose to participate, they may stop at any time or skip any questions they do not wish to answer. If the study involves compensation such as payment or course credit, make sure it is clear what happens if they drop out (e.g., do they have to complete the entire study to receive the compensation, is there partial compensation for completing part of the study, or do they receive the compensation regardless of the length of participation (e.g., “you may stop at any time without loss of research credit”).

For an anonymous mail survey, include the statement, “return of the questionnaire implies consent to participate” (if electronic, use “submission”).

12) An explanation of who to contact for answers to questions about the research (include name, phone, e-mail). If a student is the principal investigator, also include the same information for the faculty sponsor. Also include a statement directing people to the Office of Research Compliance, University of Maine, 207-581-2657, umric@maine.edu, if they have questions about their rights as a research participant.

13) A statement that their signature (if not exempt) indicates they have read and understand the information and agree to participate. Indicate that they will receive a copy of the form. The investigator should NOT sign the consent form – doing so gives the appearance of a contract, which is not accurate.

Other suggestions:

- Use familiar words, e.g., “cholesterol” instead of “blood lipids.”
- Avoid using scientific, medical, or legal terms – if you must use them, define them.
- Avoid abbreviations or acronyms.
- Use bullets if procedures are lengthy.
- For ease of reading, have “white space” on the form.
- Know your target population. For example, if you are studying the elderly, use a larger font size.
- Have someone else outside your discipline read the informed consent for readability/comprehension.