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 Forms and Samples page 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 form).

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 this section 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 participate in 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 the second person "you" to present study details. (For example, "there are no direct benefits to you").
- Scientific terms should be replaced with lay language (For example, say "blood draw" instead of "venipuncture").
- Avoid abbreviations or acronyms.
- Format document to make it easy to read – use bullets, additional spacing, font size etc.
- Tailor the document to your subject 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.

Please also see additional Informed Consent Guidance.