https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

Informed Consent Checklist

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1. A statement that the study involves **research**
2. A statement that participation is **voluntary,** No penalty for refusal to participate
3. An explanation of the purposes of the research
4. The expected duration of the subject's participation
5. A description of the procedures to be followed
6. Identification of any procedures which are experimental
7. A description of any reasonably foreseeable risks or discomforts to the subject
8. A description of any benefits which may reasonably be expected from the research
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
10. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. **Mandatory statement**:

> *If you have any questions or concerns before, during or after your participation regarding your rights as a participant, to obtain information, offer input, or whom to contact in the event of a research related injury, you may contact the USM Office of Research Integrity and Outreach at 207-780-4517 and/or email usmorio@maine.edu. Information for participants*

11. Appropriate alternatives advantageous to subject
12. For more than minimal risk research, compensation/treatment available in case of injury
13. May discontinue participation without penalty

Consent – Exempt, Expedited/Full Board reviews
All human subjects (or their legally authorized representatives) must give consent to participate in research.
The general requirements for informed consent must be reviewed by all investigators and can be found here with consent form templates. https://usm.maine.edu/orio/irb-guidance-and-resources/

Informed Consent
All research subjects will be completely informed regarding aspects of the study.

Waiver of Documentation of Informed Consent
-An IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects.
-Potential participants are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.

Alternation of Informed Consent
An IRB may approve a consent procedure, which alters some of the elements of informed consent.
-A list of all required elements is given below. Indicate which of these elements you would like to have altered. (In the case of a study involving deception or concealment, the IRB must waive the requirement to use all elements that are not truthfully presented in the initial consent document.)

Waiver of Informed Consent
An IRB may approve a consent procedure, which does not include all of the elements of informed consent.

Parental Permission, Informed Consent
Parents or legally authorized representatives of the research subjects will be completely informed regarding aspects of the study.

Waiver of Documentation of Parental Permission
-An IRB may waive the requirement for an investigator to obtain a signed consent form Parents or legally authorized representatives.
- Parents or legally authorized representatives are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.

Alteration of Parental Permission
An IRB may approve a consent procedure, which alters some of the elements of informed consent.

Waiver of Parental Permission
An IRB may waive the requirement to obtain documentation of parental permission (waiver of consent). Explain how this research study meets of the following criteria:
-The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, AND provided further that a waiver is not inconsistent with federal, state, or local law.

[Child] Informed Assent Background
In general, investigators must obtain the affirmative agreement of children. In the United States the legal age of adulthood is a matter of state and local law. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 17 year old is not usually suitable for a 7 year old child).

Informed Assent
All child research subjects will be completely informed regarding aspects of the study. Assent is in addition to Parental Permission/Informed Consent.

Waiver of Documentation of Informed Assent
-An IRB may waive the requirement for an investigator to obtain a signed assent form for some or all subjects.
-Potential participants are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.

Alteration of Informed Assent
An IRB may approve an assent procedure, which alters some of the elements of informed assent.

Waiver of Informed Assent
An IRB may waive the requirement to obtain documentation of informed assent (waiver of assent). Explain how this research study meets of the following criteria:
-The research protocol is designed for conditions or for a subject population for which assent is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, AND provided further that a waiver is not inconsistent with federal, state, or local law.