

# Participant Protections

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## Participant Protection

**\* Potential Risks**

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

- List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. Consider that the risk of breach of confidentiality is common to almost all research studies.
- Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risks(s) associated with each research procedure or test.

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**\* Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

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**\* Potential Benefits**

Describe the potential benefits for subjects (if any). Include the probability, magnitude, and duration of the potential benefits.

- Direct benefits to subjects (if applicable)
- Indirect benefits to society

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**\* Explain how the potential benefits justify the potential risks involved in participation in this research.**

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**\* Data & Safety Monitoring**

Indicate if this project either:

- Poses greater than minimal risk.
- Includes a Data & Safety Monitoring Plan or Data Safety & Monitoring Board/Committee Charter.

Yes  
 No

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**Deception**

**\* Will deception be used as a method of data gathering?**

Yes  
 No

**\* Deception Justification**

Justify and support the use of deception in the project.

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**Debriefing Script**

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

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\* Consent

Choose type of consent(s) being used in this project:

- **Consider:** Waiver of documentation is waiver of signature, not waiver of consent
- **Templates** can be found on the [Guidance and Resources webpage](#).
- **Required 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](mailto:usmorio@maine.edu). [Information for participants](#)"

- Informed Consent/Child Assent/Parental Permission
- Alteration of Consent/ Child Assent/Parental Permission
- Waiver of Consent/ Child Assent/Parental Permission

Guidance and Resources: <https://usm.maine.edu/orio/irb-guidance-and-resources/>

**Required 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](mailto:usmorio@maine.edu). [Information for participants](#)"

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Alteration/Waiver of Consent/Assent/Parental Permission

\* Justification of Alteration or Waiver of Consent/Assent/Parental Permission

Explain why any identified waivers or alterations of consent are necessary for this project. In particular address how:

- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practically be carried out without the waiver or alteration (e.g., it would be impossible to perform this research otherwise).
- Whenever appropriate, the subjects, their parent or legally authorize representative will be provided with additional pertinent information after participation.
- 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 those 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.

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\* Does the research present no more than minimal risk of harm to subjects, and involves no procedures, for which written consent would normally be required outside of the research context?

Yes  
 No

If this presents more than minimal risk, you may need to return to **Data & Safety Monitoring**

## Informed Consent Process

All human subjects (or their legally authorized representatives) must give consent to participate in research.

### \* Type of Informed Consent

Check all that apply to this project

- Informed Consent:** All research subjects will be completely informed regarding aspects of the study. Signed form.
- 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.
- Parental Permission**  
 Parents or legally authorized representatives of the research subjects will be completely informed regarding aspects of the study. Signed form.
- 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.
- 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. Assent should be written at the child's level of understanding.  
**Consider:** Child Assent, 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).
- 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.

## Type of Waiver or Alteration to the Informed Consent Process

\* Check all that apply for in part or in full to this project:

**Alteration 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.

**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.

**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.

\* List of elements, check all that apply

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 alter the requirement to use all elements that are not truthfully presented in the initial consent document.)

- Study involves research
- Purposes of the research
- Duration of participation
- Procedures to be followed
- Identification of experimental procedures
- Foreseeable risks/discomforts
- Benefits to subjects or others
- Appropriate alternatives advantageous to subject. For most non-clinical trial studies the alternative is to not participate.
- Maintenance of confidentiality
- For more than minimal risk research, compensation/treatment available in case of injury
- Voluntariness of participation
- No penalty for refusal to participate
- May discontinue participation without penalty
- Contact for questions about research
- Contact for questions about participants' rights
- Contact for questions about research injury
- Other

Other reason, please explain

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\* Consent Process

\* Who will obtain subjects' consent? Check all that apply

- Principal Investigator(s)
- Research Staff
- Other

Please explain

\* Describe the procedures for obtaining informed consent.

Include what steps being taken to determine that a potential subjects are competent to participate in the decision-making process.

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\* Non-English Speaking Subjects

If consent is being obtained from non-English speaking subjects, explain the translation process for all documents seen by subjects, including consent documents. Describe the consent process in these circumstances.

Note: Provide copies of translated and back-translated consent documents and provide the translator's credentials.

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\* Would the only record linking the subject and the research be the consent document where the principal risk would be the potential harm resulting from a breach of confidentiality?

Yes

No

If no, please explain

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\* Consent, Parental Permission & Assent Form(s)

Attach any consent, assent, short forms, etc. as applicable. In multiple languages, as applicable.  
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

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HIPAA

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HIPAA

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (PHI) is being obtained, used, or released/ disclosed by a [Covered Entity](#) for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is [Not Engaged](#) in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a [Covered Entity](#).
- Protected Health Information (PHI) = health information + one or more of the [18 identifiers](#)

\* Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity?

Yes

No