UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Informed Consent

1.0 Objective

1.1. To describe policies and procedures for fulfilling the regulatory and ethical requirements for obtaining and documenting informed consent/assent and for reviewing and requesting a waiver of informed consent or a waiver of documentation of informed consent for non-exempt human subject research.

2.0 Responsibility

2.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA) Institutional Review Board (IRB), and Principal Investigators (PI) to execute this Standard Operating Procedure (SOP).

3.0 General Description

3.1. To ensure an effective informed consent process, the IRB and PIs comply with the U.S. Department of Health and Human Services (DHHS) Common Rule and the U.S. Food and Drug Administration (FDA) requirements for all human subject research.

3.2. Before involving a human subject in research, an investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR) (unless the requirement has been waived by the IRB or the research is exempt, meets the requirements for exception from informed consent at 21 CFR 56.23 or 24, or is subject to a Secretarial Waiver of some or all of the requirements of consent.)

3.2.1. Information for the IRB to evaluate the consent process including:

3.2.1.1. The person who will conduct the consent interview.
3.2.1.2. The person who will provide consent or permission.

3.3. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted under the Common Rule.

3.3.1. Broad consent is not currently recognized in FDA regulation or guidance.

3.3.2. When following DHHS requirements to allow the use of the broad consent, the IRB determines:

3.3.2.1. Researchers must provide all required disclosures for broad consent to each participant or participant's legally authorized representative:

3.3.2.1.1. Contact information for the research team for questions, concerns, or complaints.

3.3.2.1.2. Contact information for someone independent of the research team for problems, concerns, questions, information, or input.
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*

3.3.2.2. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3.4. Vulnerable Subjects

3.4.1. When a research study involves populations with diminished decision-making capacity not covered by specific policies and procedures the ORIO staff screen the application for the informed consent process and documentation to evaluate the consent process for these populations. (*HRPP-032 Vulnerable Subjects*)

3.4.2. When research involves pregnant women, fetuses, or neonates, the IRB follows Subpart B of the DHHS regulations or equivalent laws or regulations to approve an appropriate consent process.

3.4.2.1. The IRB determines whether the approval criteria for consent and

permission are met when research involves pregnant women or fetuses. The IRB determines and documents that:

3.4.2.1.1. The consent of the mother is obtained in accordance with the regulations.

3.4.2.1.2. If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father is also obtained in accordance with the regulations, except that the father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

3.4.2.1.3. Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

3.4.2.2. The IRB determines whether the approval criteria for consent and permission are met when research involves neonates of uncertain viability. The IRB determines and documents that:

3.4.2.2.1. Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3.4.2.2.2. The legally effective consent of either parent of the neonate is obtained in accordance with the regulations.

3.4.2.2.2.1. If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is obtained.

3.4.2.2.2.2. The consent of the father or his legally authorized representative does not have to be obtained if the pregnancy resulted from rape or incest.

3.4.2.3. The IRB determines whether the approval criteria for consent and permission are met when research involves nonviable neonates. The IRB determines and documents that:

3.4.2.3.1. Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3.4.2.3.2. The legally effective consent of both parents of the neonate is obtained in accordance with the regulations.

3.4.2.3.2.1. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent of a nonviable neonate is sufficient, except that the consent of the father does not have to be obtained if the pregnancy resulted from rape or incest.

3.4.2.3.2.2. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate is not allowed.

3.4.2.3.3. The waiver and alteration provisions are not applied.

3.4.3. When research involves prisoners as participants, the IRB follows Subpart C of the DHHS regulations or equivalent laws or regulations to approve an appropriate consent process that includes a determination that:

3.4.3.1. The information will be presented in language that is understandable to prisoners.

3.4.3.2. Each prisoner will be informed in advance that participation in the research will have no effect on his or her parole.

3.4.4. When research involves children as participants, the IRB follows Subpart D of the DHHS or FDA regulations or equivalent laws or regulations to approve an appropriate assent process for children and consent process for parents or guardians.

4.0 Definitions

4.1. **Assent** means a child's affirmative agreement to participate in research (clinical investigation).

4.2. **Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research or clinical investigation, under the applicable law of the jurisdiction in which the research will be conducted.

4.2.1. Since Maine State Law does not specifically address consent for research, the IRB will consider the definition of "minor" under the State of Maine Department of Health and Human Services as the applicable legal age of consent to research.

4.2.1.1. **Minor** means a person under 18 years of age.

4.2.1.2 Emancipated minors as defined under 15 M.R.S.A 3506-A will also be considered legally able to consent to research.

4.2.2. For research conducted in jurisdictions other than Maine, the research must comply with the laws regarding the legal age of consent in the relevant jurisdiction.

4.3. **Guardian** means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

4.3.1. Since Maine State Law does not specifically address consent for research, the IRB will consider the definition of "guardian" under the State of Maine Probate Code as the applicable authorized individual in research.

4.3.1.1. **Guardian** means a person that has accepted by a court or testamentary guardian appointment and has the powers and responsibilities of a parent who has not been deprived of custody of a minor and un-emancipated child.

4.3.2. For research conducted in jurisdictions other than Maine, the research must comply with the laws regarding guardianship in the relevant jurisdiction.

4.4. Legally Authorized Representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research or clinical investigation.

4.4.1. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research or clinical investigation.

4.4.1.1. Since Maine State Law does not specifically address consent for research, the IRB will consider the definition of "authorized representative" under the State of Maine Department of Health and Human Services as the authorized individual in research.

4.4.1.1.1. **Authorized Representative** means an individual's legal guardian, agent named in an advance health care directive or power of attorney, or other authorized representative.

4.4.1.1.1.1. For a minor, authorized representative means the minor's parent, legal guardian or guardian ad litem.

4.4.2. For research conducted in jurisdictions other than Maine, the research must comply with the laws regarding legally authorized representatives in the relevant jurisdiction.

4.5. Limited English Proficiency (LEP) means a person does not speak or read, or has a limited proficiency in, oral or written English.

4.6. Parent means a child's biological or adoptive parent.

4.7. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation.

4.8. **Stamped** consent form means the consent document(s) have been approved for use by the IRB. Stamped informed consent/assent/parental permission documents are included with an IRB approval and must be used to obtain consent from participants. The IRB approval stamp must be visible on each page of the printed consent form.

5.0 Types of Informed Consent

5.1. **Informed Consent:** All research subjects will be completely informed regarding all aspects of the research or clinical investigation and a signature is required.

5.2. **Waiver of Documentation of Informed Consent:** All research subjects will be completely informed regarding all aspects of the research or clinical investigation, but a signature is not required.

5.3. **Alteration of Information Consent:** All research subjects will be informed regarding the research or clinical investigation, but one or more required elements are altered or not included and a signature may or may not be required.

5.4. **Waiver of Informed Consent:** Research subjects are not informed regarding the research or clinical investigation.

5.5. **Broad Consent:** permits researchers to engage in research use of identifiable biospecimens and identifiable data without the requirement to obtain additional **consent** for the future storage, maintenance, or research uses, so long as the future activities are within the scope of the **broad consent**.

5.6. **Parental Permission:** Parents or guardian of all research subjects will be completely informed regarding all aspects of the research or clinical investigation and a signature is required.

5.7. **Waiver of Documentation of Parental Permission:** Parents or guardians of all research subjects will be completely informed regarding all aspects of the research or clinical investigation, but a signature is not required.

5.8. **Alteration of Parental Permission:** Parents or guardians of all research subjects will be informed regarding the research or clinical investigation, but one or more required elements are altered or not included and a signature may or may not be required.

5.9. **Waiver of Parental Permission:** Parents or guardians of research subjects are not informed regarding the research or clinical investigation.

5.10. **Informed Assent:** All research subjects will be completely informed regarding all aspects of the research or clinical investigation and a signature is required.

5.11. Waiver of Documentation of Informed Assent: All research subjects will be completely informed regarding all aspects of the research or clinical investigation, but a signature is not required.

5.12. Alteration of Informed Assent: All research subjects will be informed regarding the research or clinical investigation, but one or more required elements are altered or not included and a signature may or may not be required.

5.13. Waiver of Informed Assent: Research subjects are not informed regarding the research or clinical investigation.

6.0 Drafting Informed Consent

6.1. Language

6.1.1. The information that is given to the subject or LAR shall be in language understandable to the subject or LAR.

6.1.2. To the extent possible, the language should be understandable by a person who is educated to 8th grade level and layman's terms shall be used in the description for the research.

6.1.2.1. The IRB may require or allow different readability standards based upon the characteristics of the target subject population.

6.1.3. For subjects with LEP, informed consent must be obtained in a language that is understandable to the subject or LAR.

6.1.3.1. The informed consent discussion must include an interpreter when the prospective subject does not understand the language of the person who is obtaining consent.

6.1.3.1.1. The IRB may require a certified interpreter on a case-by-case basis.

6.1.3.2. Consent documents and any other subject materials must be translated into a language that the prospective subject understands that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

6.1.3.2.1. The IRB may require a certified interpreter on a case-by-case basis.

6.1.4. No informed consent may include exculpatory language through which the subject or LAR is made to waive or appear to waive any of the subject's legal

rights, or releases or appears to release the PI, the sponsor, the institution, or its agent from liability for negligence.

6.2. Presentation

6.2.1. Informed consent must be organized and presented in a way that facilitates comprehension.

6.2.2. The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

6.2.3. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research.

6.2.4. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

6.3. Elements

6.3.1. **Basic Elements:** When obtaining informed consent, the following basic elements will be provided to each subject or LAR (unless the IRB has approved a waiver or alteration of informed consent):

6.3.1.1. **Key information**: a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research.

6.3.1.2. **Research statement**: a statement that the study involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures which will be experimental.

6.3.1.3. **Risks:** a description of any reasonably foreseeable risks or discomforts to the subject.

6.3.1.4. **Benefits:** a description of any benefits which may reasonably be expected from the research. State if there is no direct benefit. Direct benefit is something of positive value related to health or welfare.

6.3.1.5. **Alternatives**: a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

6.3.1.6. **Confidentiality:** a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6.3.1.7. **Compensation:** for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.

6.3.1.8. **Contact:** 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.
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

6.3.1.9. **Subject rights:** a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

6.3.1.10. **Future use:** For research possibly involving future use of data or specimens, a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

6.3.1.11. **No future use:** For research not possibly involving future use of data or specimens, a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

6.3.1.12. **Clinical trials:** For FDA regulated clinical trials, the following statement: "A description of the clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

6.3.2. **Additional Elements**: Federal regulations require the following elements be provided to each subject or LAR as applicable to the research:

6.3.2.1. **Pregnancy:** a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

6.3.2.2. **Discontinuation:** anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.

6.3.2.3. **Costs:** any additional costs to the subject that may result from participation in the research.
6.3.2.4. **Withdrawal:** The consequences of a subject's decision to withdraw for orderly termination of participation by the subject.
6.3.2.5. **New findings:** a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6.3.2.6. **Participants:** the approximate number of subjects involved in the study.
6.3.2.7. **Commercial profit:** a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
6.3.2.8. **Return of results:** A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
6.3.2.9. **Genome sequencing:** for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.)

6.3.3. **Broad Consent Elements**: When obtaining broad consent, the following additional elements must be provided to each subject or LAR:

6.3.3.1. **Summary:** An explanation of the research or clinical investigation.
6.3.3.2. **Risks:** A description of any reasonably foreseeable risks or discomforts to the subject.
6.3.3.3. **Benefits:** a description of any benefits to the subject or to others which may reasonably be expected from the research
6.3.3.4. **Confidentiality:** a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6.3.3.5. **Subject rights:** a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
6.3.3.6. **Types:** A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.
6.3.3.7. **Future use:** A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information.
6.3.3.8. **Storage:** A description of the period of time that the identifiable private information or identifiable biospecimen may be stored and maintained

(which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).

6.3.3.9. **Future research:** a statement that they may not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.

6.3.3.10. **Results:** a statement that clinically relevant research results, including individual research results, may not be disclosed to the subject.

6.3.3.11. **Contact:** an explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of research related harm.
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

6.3.4. **Additional Elements:** Federal regulations require the following elements be provided to each subject or LAR as applicable to the research:

6.3.4.1. **Commercial profit:** a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

6.3.4.2. **Genome sequencing:** for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.)

6.4. Documentation

6.4.1. Informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or LAR (unless the requirement has been waived by the IRB).

6.4.1.1. The ICF may be either a written consent document or a short form written consent document.

6.4.2. A written consent document must comply with all informed consent drafting requirements.

6.4.2.1. The PI must allow the subject or LAR adequate opportunity to read the written consent document before it is signed.
6.4.2.2. Alternatively, the informed consent document may be read to the subject or LAR.
6.4.2.3. A written copy must be given to the person signing the ICF.
6.4.2.4. Written ICF must have the IRB Stamp visible on each page.

6.4.3. A short form written consent document (Short Form) must state that all informed consent drafting requirements have been presented orally to the subject or LAR.

6.4.3.1. There must be a witness to the oral presentation.
6.4.3.2. The IRB must approve a written summary (Script) of what is to be said to the subject or LAR.
6.4.3.3. The Short Form must be signed by the subject or LAR.
6.4.3.4. The witness must sign both the Short Form and a copy of the Script.
6.4.3.5. The person actually obtaining consent must sign a copy of the Script.
6.4.3.6. A copy of the Script must be given to the subject or LAR in addition to a copy of the Short Form.

7.0 IRB Review of Informed Consent

7.1. General

7.1.1. During its review of the informed consent process, the IRB confirms that the following requirements are met:

7.1.1.1. Adequate opportunity is provided to the subject or the subject's LAR to read the consent document and ask questions regarding the study before the informed consent document is signed;
7.1.1.2. The consent process minimizes the possibility of coercion or undue influence. The consent discussion is in language understandable to the subject to the subject's legally authorized representative;
7.1.1.3. The information communicated to the subject or the subject's legally authorized representative during the consent process does not include any exculpatory language that waives or appears to waive any legal rights that the subject may have, or releases or appears to release the PI, the sponsor, the institution or its agents from liability for harm caused by their negligence;
7.1.1.4. The ICF includes all of the basic elements of consent except those which can be waived, or altered, according to regulation; and
7.1.1.5. Additional elements that would meaningfully add to the protection of the rights and welfare of the research subject are included in the ICF.

7.1.2. Before approving research, the IRB also ensures the following, as applicable:

7.1.2.1. The IRB member can clearly describe the study after reading the IC;

7.1.2.2. For studies involving medical treatments, the IRB member can distinguish standard of care from research procedures;
7.1.2.3. The ICF was easy to read and did not require being re-read for understanding;
7.1.2.4. A junior high school student could explain the study after reading the ICF;
7.1.2.5. If grammatical and/or spelling errors exist they are minor enough to not impact human subject protection; and
7.1.2.6. The ICF does not include instructional text intended for PIs only.

7.2. Broad Consent

7.2.1. During its review of a broad consent process, the IRB confirms that the following requirements are met:

7.2.1.1. All requirements of a general informed consent process;
7.2.1.2. The IRB submission includes:
7.2.1.2.1. The circumstances under which broad consent will be obtained;
7.2.1.2.2. The proposed ICF;
7.2.1.2.3. Any other informed consent materials.

7.2.2. If a broad consent procedure is used:
7.2.2.1. An IRB may not omit or alter any of the required elements of disclosure, and when appropriate, any of the additional elements of disclosure.
7.2.2.2. If a study requests broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

7.3. Waiver of Documentation of Informed Consent

7.3.1. In order to approve a request from a PI to waive the requirement to document consent, the IRB must determine and document that at least one of the following criteria is met:

7.3.1.1. The research or clinical investigation presents no more than minimal risk to subjects and involves no procedures for which consent is normally required outside of the research or clinical investigation context;
7.3.1.2. The only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking the participant with the research, and the participant's wishes will govern; or

7.3.1.3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent is obtained; and

7.3.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.4. Alteration of Informed Consent

7.4.1. In order to approve a request from a PI to alter the requirements of informed consent, the IRB must determine and document that at least one of the following criteria are met:

7.4.1.1. General Alteration

7.4.1.1.1. The research or clinical investigation involves no more than minimal risk to subjects;

7.4.1.1.2. The research or clinical investigation could not practicably be carried out without the requested alteration;

7.4.1.1.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

7.4.1.1.4. The alteration will not adversely affect the rights and welfare of the subjects; and

7.4.1.1.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

7.4.1.2. Public Benefit or Service Programs Alteration

7.4.1.2.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine;

7.4.1.2.2.1. Public benefit or service programs

7.4.1.2.2.2. Procedures for obtaining benefits or services under those programs;

7.4.1.2.2.3. Possible changes in or alternatives to those programs or procedures; or

7.4.1.2.2.4. Possible changes in methods or levels of payment for benefits or services under those programs; and

7.4.1.2.2. The research could not practicably be carried out without the requested alteration.

7.4.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.5. Waiver of Informed Consent

7.5.1. In order to approve a request from an PI to waive the requirement of informed consent, the IRB must determine and document that at least one of the following criteria are met:

7.5.1.1. General Waiver

7.5.1.1.1. The research or clinical investigation involves no more than minimal risk to subjects;

7.5.1.1.2. The research or clinical investigation could not practicably be carried out without the requested waiver;

7.5.1.1.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not practicably be carried out without using such information or biospecimens if an identifiable format;

7.5.1.1.4. The waiver will not adversely affect the rights and welfare of the subjects; and

7.5.1.1.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

7.5.1.2. Public Benefit or Service Programs Waiver

7.5.1.2.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine:

7.5.1.2.2.1. Public benefit or service programs;

7.5.1.2.2.2. Procedures for obtaining benefits or services under those programs;

7.5.1.2.2.3. Possible changes in or alternatives to those programs or procedures; or

7.5.1.2.2.4. Possible changes in methods or levels of payment for benefits or services under those programs; and

7.5.1.2.2.5. The research could not practically be carried out without the waiver.

7.5.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.6. Waiver of Documentation of Assent

7.6.1. In order to approve a request from a PI to waive the requirement to document assent, the IRB must determine and document that the following criteria is met:

7.6.1.1. Documentation of informed assent is not warranted due to consideration of the subjects' age, maturity, degree of literacy, or any other reasonably appropriate reason.

7.6.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.7. Alteration of Informed Assent

7.7.1. In order to approve a request from a PI to alter the requirements of informed assent, the IRB must determine and document that at least one of the following criteria are met:

7.7.1.1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;
7.7.1.2. The intervention or procedure involved in the reproach or clinical investigation holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research or clinical investigation;
7.7.1.3. General Alteration
7.7.1.3.1. The research or clinical investigation involves no more than minimal risk to subjects;
7.7.1.3.2. The research or clinical investigation could not practicably be carried out without the requested alteration;
7.7.1.3.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not practically be carried out without using such information or biospecimens in an identifiable format;
7.7.1.3.4. The alteration will not adversely affect the rights and welfare of the subjects; and
7.7.1.3.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation; or

7.7.1.4. Public Benefit or Service Programs Alteration
7.7.1.4.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine:
7.7.1.4.1.1. public benefit or service programs;
7.7.1.4.1.2. procedures for obtaining benefits or services under those programs;

7.7.1.4.1.3. possible changes in or alternatives to those programs or procedures; or
7.7.1.4.1.4. possible changes in methods or levels of payment for benefits or services under those programs; and
7.7.1.4.2. The research could not practicably be carried out without the requested alteration.

7.7.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.8. Waiver of Informed Assent

7.8.1. In order to approve a request from a PI to waive the requirement for informed assent the IRB must determine and document that at least one of the following criteria are met:

7.8.1.1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;
7.8.1.2. The intervention or procedure involved in the research or clinical investigation holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research or clinical investigation;

7.8.1.3. General Waiver
7.8.1.3.1. The research or clinical investigation involves no more than minimal risk to subjects;
7.8.1.3.2. The research or clinical investigation could not practicably be carried out without the requested waiver;
7.8.1.3.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;
7.8.1.3.4. The waiver will not adversely affect the rights and welfare of the subjects;
7.8.1.3.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation; or

7.8.1.4. Public Benefit or Service Programs Waiver
7.8.1.4.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine:
7.8.1.4.1.1. public benefit or service programs;

7.8.1.4.1.2. procedures for obtaining benefits or services under those programs;
7.8.1.4.1.3. possible changes in or alternatives to those programs or procedures; or
7.8.1.4.1.4. possible changes in methods or services under those programs; and
7.8.1.4.2. The research could not practicably be carried out without the waiver.

7.8.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.9. Waiver of Documentation of Parental Permission

7.9.1. In order to approve a request from a PI to waive the requirement to document parental permission, the IRB must determine and document that at least one of the following criteria is met:

7.9.1.1. The research or clinical investigation presents no more than minimal risk to subjects and involves no procedures for which parental permission is normally required outside of the research or clinical investigation context; and
7.9.1.1. the only record linking the participants and the research would be the parental permission document and the principal risk would be potential harm resulting from a breach of confidentiality. Each parent will be asked whether they want documentation linking the participant with the research, and the parent's wishes will govern; or

7.9.1.2. The reproach is not subject to FDA regulations, the subjects or parents are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that parental permission was obtained.

7.9.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.10. Alteration of Parental Permission

7.10.1. In order to approve a request from a PI to alter the requirements of parental permission, the IRB must determine and document that at least one of the following criteria is met:

7.10.1.1. General Alteration
7.10.1.1.1. The research or clinical investigation involves no more than minimal risk to subjects;

7.10.1.1.2. The research or clinical investigation could not practicably be carried out without the requested alteration;

7.10.1.1.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

7.10.1.1.4. The alteration will not adversely affect the rights and welfare of the subjects; and

7.10.1.1.5. Whenever appropriate, the parents will be provided with additional pertinent information after subject participation;

7.10.1.2 Public Benefit or Service Programs Alteration

7.10.1.2.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine:

7.10.1.2.1.1. public benefit or service programs;

7.10.1.2.1.2. procedures for obtaining benefits or services under those programs;

7.10.1.2.1.3. possible changes in or alternatives to those programs or procedures; or

7.10.1.2.1.4. possible changes in methods or levels of payment for benefits or services under those programs; and

7.10.1.2.2. The research could not practicably be carried out without the requested alteration.

7.10.1.3. Parental Permission Specific Alteration

7.10.1.3.1. The research is designed to study conditions in children for which parental permission is not a reasonable requirement to protect the subject (for example, neglected or abused children);

7.10.1.3.2. The alteration is not inconsistent with federal, state, or local law; and

7.10.1.3.3. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

7.10.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

7.11. Waiver of Parental Permission

7.11.1. In order to approve a request from a PI to waive the requirement for parental permission, the IRB must determine and document that at least one of the following criteria is met:

7.11.1.1. General Waiver

7.11.1.1.1. The research or clinical investigation involves no more than minimal risk to subjects;

7.11.1.1.2. The research or clinical investigation could not practicably be carried out without the requested waiver;

7.11.1.1.3. If the research or clinical investigation involves using identifiable private information or identifiable biospecimens, the research or clinical investigation could not be practicably be carried out without using such information or biospecimens in an identifiable format;

7.11.1.1.4. The waiver will not adversely affect the nights and welfare of the subjects; and

7.11.1.1.5. Whenever appropriate, the parents will be provided with additional pertinent information after subject participation.

7.11.1.2. Public Benefit or Service Programs Waiver

7.11.1.2.1. The research or demonstration project is to be conducted by or subject to the approval of a state or local government official and is designed to study, evaluate, or otherwise examine:

7.11.1.2.1.1. public benefit or service programs;

7.11.1.2.1.2. procedures for obtaining benefits or services under those programs;

7.11.1.2.1.3. possible changes in or alternatives to those programs; and

7.11.1.2.1.4. possible changes in methods or levels of payment for benefits or services under those programs; and

7.11.1.2.2. The research could not practicably be carried out without the requested waiver.

7.11.1.3. Parental Permission Specific Waiver

7.11.1.3.1. The research is designed to study conditions in children for which parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children);

7.11.1.3.2. The waiver is not inconsistent with federal, state, or local law; and

7.11.1.3.3. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

7.11.2. When applicable, a review of relevant FDA regulations and guidance to determine if a waiver can occur.

8.0 Exempt Research

8.1. Before involving a human subject in research that has been determined exempt from IRB review, PIs must obtain the informed consent of potential participants.

8.2. While the ORIO may not require all elements of informed consent to be met, an informed consent process or request for a waiver or alteration must still be included in the research protocol.

9.0 References

9.1. 45 CFR 46.102;

9.2. 45 CFR 46.116 – 46.117;

9.3. 45 CFR 46.201 – 46.207

9.4. 45 CFR 46.301-306

9.5. 45 CFR 46.401 – 46.409;

9.6. 21 CFR 50.3;

9.7. 21 CFR 50.20 – 50.27;

9.8. 21 CFR 50.50 – 50.56;

9.9. 22 M.R.S.A. §1501