Title: **SARMC Institutional Review Board: Informed Consent Process and Documentation**

**Policy Statement:** Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. A fundamental requirement for human subject research is that people participate voluntarily. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. Informed consent for research conducted at SARMC should address the elements stipulated in federal regulations governing the conduct of research involving human subjects, specifically, 21 CFR 50.20 and 45 CFR 46.116.

**Procedure:**

**I. Process of Obtaining Informed Consent**

A. The consent process must assure that the potential participant understands the objective of the study, which includes, but is not limited to procedures, risks, benefits, and that participation in the study is voluntary. The obligation to provide complete information required for informed consent is the responsibility of the listed study investigator(s). The informed consent process involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. Consent is a continuing process and occurs throughout the conduct of the study. Failure of the subjects to ask questions should not be interpreted as understanding on the part of the subject.

B. A participant requires time to decide whether or not to participate, to ask questions and to confer with family or other personal advisors. It is not appropriate to seek consent in a rush or at the time of a procedure, diagnosis or under duress.

C. The process of discussing the study with a potential participant, as part of the informed consent process, may be delegated by the principal investigator to a member of the research study staff.

**II. Documentation of Informed Consent**

Informed consent must be documented in a manner that has been reviewed and approved by the IRB.

A. An approved written consent will contain the following information in the footer: initial approval date, revision date(s) and expiration date.
B. The written consent form must be signed and dated by the subject or the subject’s legally authorized representative; a witness for the subject; and the principal investigator or person obtaining the informed consent. If the consent is longer than one page, each page should be initialed and dated by the potential research participant.

C. Legally authorized representatives should have an order of priority, list of relatives per Idaho Law, and/or a designated individual with a notarized medical power of attorney (see also SARMC policy C-5, Consent for Medical Treatment).

D. A copy of the signed consent form must be given to the subject or subject’s legally authorized representative upon completion of the initial consent discussion. *(See Section V. for more information)*

E. A copy of the informed consent should be contained within the medical record where the research intervention is conducted.

### III. Informed Consent Content

A. General Information

1. Information in the consent document given to potential subjects or their representatives must be in language that is relatively easy to understand, limiting the use of technical or medical terms to the extent possible. The consent document should generally be written at the eighth grade reading comprehension level.

2. The consent process may not involve the use of exculpatory language through which the participant or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

B. The Federal regulations require that following information be provided to each subject in the consent form:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, number of participants, a description of the procedures to be followed, identification of any procedures which are experimental, and identification of investigator(s)

2. A description of any reasonably foreseeable risks or discomforts to the subject, including a statement regarding pregnancy/reproductive risks
3. A description of any benefits to the subject or to others that may be reasonably expected from the research,

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. This includes the following required language: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time."

6. For research involving more than minimal risk, an explanation as to whether any compensation will be provided, and/or whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained,

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research related injury to the subject,

8. 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.

Note: The practice of paying research subjects to participate in research is acceptable, providing that payments are to compensate for the individual’s cost or risk to participate, such as time or direct costs such as travel. Compensation to research subjects that appears coercive or designed to obscure the true potential cost of participating in the study will not be approved by the IRB. If anyone other than the individual subject is providing consent, such as a parent, relative or guardian, compensation for participation must be shown to accrue to the benefit of the subject. The consent document should include the details of the payment plan, including when the payment(s) will be received and the conditions under which a subject would receive partial payment. This should be included in the “Benefits” section of the informed consent.

C. The regulations further provide that the following additional information be provided to subjects, where appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the
subject is or may become pregnant) which are currently unforeseeable. Since the use of contraception will be defined in this section of the informed consent, the use of contraceptives can be addressed with any of the following approved language examples:

a) “If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin this study treatment. If you are sexually active, it is important that you not become pregnant because this medication may be harmful to your unborn child. **You must discuss your pregnancy plans with your doctor before enrolling in this study; you must also agree to use the type and duration of precautions approved by your doctor for the entire time you receive this study treatment.** For women, if you become pregnant or have reason to believe you might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a father.”

b) “If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin this study treatment. If you are sexually active, it is important that you not become pregnant for this medication may be harmful to your unborn child. **You must discuss your pregnancy plans with your doctor before enrolling in this study and agree that you will take the appropriate precautions not to become pregnant while enrolled in the study.** For women, if you become pregnant or have reason to believe you might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a new father.”

c) “If I am a woman able to have children, I understand that I must not be pregnant when I enter the study. I also must not become pregnant during the study. This study could seriously harm my fetus if I am pregnant or become pregnant. **I understand I must use a birth regulation method or abstain from sexual relations throughout the study and one week after completing the study.** These methods should be used by both female participants of childbearing potential and by males who are partners of such females. **I understand that only abstinence is 100% effective in preventing pregnancy.** If I enter the study and then think I might be pregnant, I will tell my
doctor right away. I also understand that there might be risks to a fetus if I become pregnant after the study is done. These risks are unknown. If I do want to become pregnant when the study is done, I will talk about it with my doctor.”

d) “If you are pregnant or plan to become pregnant, you cannot take part in this study. You will take a urine test to see if you are pregnant before you start treatment. If you are sexually active, your physician strongly recommends that you take precautions to avoid becoming pregnant or fathering a child for one or two months after discontinuing study medications because it is not known how these drugs could affect an unborn child. Should pregnancy occur while you are receiving study medications, you must tell your physician immediately.”

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for termination of participation by the subject;

5. A statement that if significant new findings develop during the course of the research which may be related to the subject's willingness to continue participation, the subject will be notified and given ample time to consider continued participation.

D. Consent Template

The SARMC IRB expects that all consent documents be drafted using the template provided on the forms page of the Internet/Intranet. Consent documents from study sponsors should be modified accordingly.

E. Pre-Review of the Written Consent Form

SARMC Research Integrity is available to consult on the language or structure of a proposed written consent form. Reviewing the written form with staff often will resolve issues such as the reading comprehension level of the form, or the proper structure for required items such signature lines, before the consent form is sent to the IRB for approval. This pre-review of the consent form may improve the utility of the form and may reduce the time required for IRB approval.
IV. Waiver of Informed Consent

Waivers of informed consent must be documented. Information regarding this process is in the Informed Consent - Waiver of Authorization.

V. Vulnerable Populations

Information regarding elements of informed consent/assent is listed in the Institutional Review Board: Vulnerable Populations.

Related Policies: Research Studies; Vulnerable Populations; Informed Consent – Waiver of Authorization

Related Forms: Informed Consent/HIPAA Authorization Template

http://www.saintalphonsus.org/forms-and-resources

References:


http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html