Title: **SARMC Institutional Review Board: Informed Consent - Waiver of Authorization**

**Policy Statement:** Documentation of informed consent is required in the majority of clinical research endeavors; however, there are cases in which a waiver of informed consent is appropriate. The fundamental requirement for obtaining a waiver is that it will not adversely affect the rights and welfare of the subjects. The SARMC IRB requires that a Waiver of Authorization application be completed with the research application. This form will address the rationale for applying for a waiver and the IRB will determine whether the waiver is appropriate and allowable.

**Procedure:**

I. Examples of the types of research that may be eligible for a waiver of authorization include:

   A. Retrospective chart review.
   B. The use of an anonymous survey.
   C. Research that in its entirety involves no greater than minimal risk of harm to participants and involves no procedures for which written consent is required outside of the research context.
   D. When the only record linking the participant to the research would be the consent document, and there is a risk of potential harm or significant risk resulting from breach of confidentiality. In such cases, the IRB may determine that participants be asked whether they want documentation linking themselves with the research, and the subjects wishes will govern the researchers’ actions.
   E. Emergency use, where:
      1. the human subject is confronted by a life-threatening situation necessitating the use of the test article;
      2. there is no available alternative method of approved or generally recognized therapy that provides equal or greater likelihood of saving the life of the subject;
      3. the subject is unable to consent due to a medical condition, or the legally authorized individual is not available to consent and this is documented by the study investigator(s);
      4. there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation;
      5. the clinical investigation could not practicably be carried out without the waiver;
      6. the investigator must submit a report of this activity to the
IRB Office within five working days after the use of the test article.

II. If the IRB determines that an investigation does not meet the criteria in the exception provided or because of other relevant ethical concerns, the IRB must document its findings and provide these findings in writing within five days of its receipt to the clinical investigator and to the sponsor, if applicable.

III. In the case of a waiver or script used for verbal consent, the IRB may require an informational/cover letter be given to study participants explaining the nature of the research goals and objectives or other salient information.

Related Policies: Research Studies; Informed Consent

Related Forms: Application for Waiver of Authorization

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

References:


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