5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Required Elements of Informed Consent

5.1.1 All informed consent documents are available in the online system to all NMREB members (in the case of full NMREB review), or to the applicable reviewers (under the delegated NMREB review process);

5.1.2 The NMREB members will review the proposed consent process for appropriateness, and the proposed consent form(s) for general readability, for appropriateness of the language and content, and for the inclusion of the applicable elements per the NMREB *Consent Form Template and Guidance document*;

5.2.5 An interpreter should be available to the study participant throughout the study;

5.2.6 The interpreter must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the participant;

5.2.7 If a participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent is obtained from the participant after the informed consent document and any other written information is read and explained to the participant. Signatures will be obtained from the participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by the participant, and that informed consent was freely given by the participant.

5.3 Consent update form for ongoing and completed study participants

5.3.1 The Investigator must inform research participants of any new information that might affect their willingness to continue their participation in the research;

5.3.2 The Investigator must obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the protocol or risk;

5.3.3 If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the participant sign an NMREB approved consent update form;

5.3.4 If applicable, oral information for the implementation of the consent update form may be provided by contacting the participant by phone and by documenting their agreement to continue;

5.3.5 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the NMREB;

5.4 Recruitment Methods

5.4.1 Research on Your own Students / Employees: If the potential participant is taught by or employed by the Investigator, the Investigator should not approach the potential participant directly so that the potential participant does not feel pressured or obligated in any way. In this instance, the potential participant's consent should also be obtained by an individual other than the Investigator. Any exceptions to this procedure must be appropriately justified and submitted to the NMREB for review;

5.4.2 In circumstances where the Investigator will obtain consent, the Investigator must ensure that the consent has been obtained without undue coercion or influence (actual, apparent, perceived or potential) and that there is no likelihood of therapeutic misconception, if applicable;

5.4.3 Timing of Consent: The amount of time required for a participant to consider whether or not they wish to participate in research is contextual. For low- to moderate-risk studies, participants can provide consent in a limited time, including on the same day as an intervention. However, for high-risk studies, more time is usually required for participants to weigh the advantages and potential disadvantages of participating in the research. Generally, Investigators should endeavor to provide as much time as is feasible for participants to make a decision about participation in research.

5.4.4 Advertising: The NMREB must first review and approve the text and the use of any advertisements, notices or media messages per 5.6 below.

5.5 Recruitment Materials

5.5.1 The NMREB reviews the recruitment materials (e.g., advertisements, letters, notices) for accuracy and for evidence of coercion or undue influence and consistency with the NMREB approved protocol and informed consent document;

5.5.2 Advertisements should be limited to the information that the prospective participant needs to determine their potential eligibility and interest. When appropriately worded, the following items may be included:

Full study title
The name of the Investigator,
The condition under study and/or the purpose of the research,

5.8.1 The NMREB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided that the NMREB finds and documents that:

The regulatory framework supports the waiver,
The research involves no more than minimal risk to the participants,
The waivered or altered consent does not involve intervention,
The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,
The research could not practicably be carried out without the waiver or alteration,
The information is used in a manner that will ensure its confidentiality,
The public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals,
Whenever appropriate, the participants will be provided with additional pertinent information after participation;

These findings and their justifications shall be clearly documented in the NMREB minutes or Recommendation Letter to the Investigator when the NMREB exercises this waiver provision.

5.9. Waiver of Informed Consent Requirements for Emergency Research.

5.9.1. The NMREB may approve research that will be performed in emergency settings without requiring informed consent from participants, under certain circumstances. For example, when

obtaining informed consent is not feasible,
the intervention under investigation must be administered before consent from the participants Substitute Decision Maker (SDM) is feasible