Elements Required by the Office for Human Research Protections (OHRP)

☐ 1) A statement that the study involves research.

☐ 2) An explanation of the purpose of the research.

☐ 3) Expected duration of the subject’s participation (time required/involved).

☐ 4) A description of procedures to be followed, including the location(s) of procedures.

☐ 5) Identification of any procedures which are experimental.

☐ 6) A description of any reasonably foreseeable risks or discomforts to the participant.

☐ 7) A description of any benefits to the participant or to others which may reasonably be expected from the research.

☐ 8) A disclosure of appropriate alternative courses of treatment, if any, that might be advantageous to the participant (usually biomedical research).

☐ 9) A statement describing the types of data that will be produced and the extent, if any, to which confidentiality of records identifying the subject will be maintained.

☐ 10) For research involving more than minimal risk, an explanation whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

☐ 11) An explanation of whom to contact for answers to pertinent questions about the research, subjects’ rights, concerns, or complaints, and whom to contact in the event of a research-related injury to the subject.

☐ 12) A statement that:
   • Participation is voluntary
   • Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and
   • The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
☐ 13) Consent form must be free of exculpatory language. According to 45 CFR 46.116, no informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Additional OHRP Requirements as Appropriate

☐ 14) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable. (Usually biomedical research)

☐ 15) Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent.

☐ 16) Any additional costs to the subject that may result from participation in research.

☐ 17) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. (Usually biomedical research)

☐ 18) 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.

☐ 19) The approximate number of participants involved in a study.

Elements Required by the University of St. Thomas Institutional Review Board

☐ 1) The study title and name(s) of primary investigator(s) must be written at the beginning of the consent form.

☐ 2) Identification of co-investigator(s), research advisor(s), and institutional affiliations.

☐ 3) The IRB tracking number must be at the beginning of the consent form.

☐ 4) A statement that the study has been approved for human subject participation by the University of St. Thomas Institutional Review Board.

☐ 5) The consent document must be written at a reading and comprehension level appropriate for the age and/or background of the participant (aim for 6th-8th grade reading level).

☐ 6) The document must be written in lay language (i.e. understandable to the people being asked to participate), especially the explanation of purpose, duration, risks and benefits, and voluntary nature of the study.

☐ 7) Signature lines, which must include space for participant and investigator(s) signatures, dates of signatures, and for individuals to print their names.
☐  8) When appropriate, a statement must be included to indicate agreement to audio tape (photography and video recording requires a separate permissions form).

☐  9) A statement that the participant will receive a copy of the consent form.

☐ 10) Where relevant, a statement of mandatory reporting requirements must be included.

**Elements Required in Addition to OHRP and UST Requirements for Parent/Guardian Informed Consent Forms**

☐  1) Statement that the researcher is asking for parent or guardian permission:
   - For their child to take part in research, and
   - To ask the child if they are willing to take part in the study (assent).

☐  2) Description of procedures explained in terms of what the child will be asked to do.

☐  3) Statement that the child may choose not to take part in the research even if the parent or guardian gives permission.

☐  4) Description of what, if any, study data about the child will be shared with the parent or guardian, if applicable.

☐  5) Purpose, risks, risk minimization, benefits, procedures, and confidentiality protections described in relation to the child as a participant.

☐  6) When relevant, a statement of mandatory reporting requirements must be included.

**Elements Required for Child Assent Forms**

☐  1) Explanation that the child’s parent or guardian knows the child is being asked to take part in the research.

☐  2) The research purpose, procedures, risks, benefits, and data confidentiality explained in age-appropriate lay language.

☐  3) Description of what, if any, information will be shared with the child’s parent or guardian, if applicable.

☐  4) Statement about audio taping, photography, or video recording if required for participation; a check box or signature line must be included so the child can opt out of media data collection.

☐  5) When relevant, a statement of mandatory reporting requirements must be included.