**SVSU IRB Consent Document Development Checklist**

*The following information* ***must*** be included in the consent documents. Mark (X) each of the requirements you have included. Omitted information must be justified in Item 5 of the Request for Project Approval.

**Leave a minimum top margin of 1.5 inches on all pages.** Submit the final version of the consent document without headers such as “Draft” or “Appendix .” That is, submit the consent materials that will be used with the participant(s). **Use font size no smaller than 10.**

**Heading**

University letterhead (if not using letterhead, a header that includes “Saginaw Valley State University, Department of ”), The title of the study, The researchers’ names, department/division affiliation, Title the Form “Consent Form.”

**Purpose of the Study**

Use language in the form of an invitation to participate **written** at a readability level appropriate for the participants. (Note that the average reading level in the United States is 7th grade.)

Explicitly identify the project as research—the word “research” must be used.

Explain the nature, purpose, overall duration of the study, and why the participant was selected to receive the invitation.

Conditions of participation; specify what qualifies the participants to be eligible to participate.

The approximate number of participants in the study.

**Study Procedures**

Explain the procedures to be employed in the research; describe exactly what the subject is expected to do.

**If Applicable:**  
 Description of blood or other tissue amounts in lay terms, examples of sensitive and personal questions, use of Medical or other personal records.

**Possible Risks**

Describe all reasonably foreseeable risks (possible harm, hazards, inconveniences, stresses, discomforts) the participant may undergo, so far as they are known, and explain how these risks will be minimized. If the exposure to risk is MORE than that encountered in ordinary daily life, please state.

The following statement ***must*** be included in all consents ***except*** those for **ANONYMOUS SURVEYS:** *“As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or additional treatment will be made available to the subject except as otherwise stated in this consent form.”* Any available compensation or treatment should then be specified, if appropriate (e.g., alternative treatments to the experimental treatment).

**Participant Rights**

Statement that the participant can withdraw his/her consent to the research or discontinue participation in the research at any time without prejudice, penalty, or risk of any loss of service he/she would otherwise have. Statement that participants may refuse to answer questions.

Description of any consequences of the participant’s withdrawal from the study

**Benefits**

Benefits to the participants. (If none, state none; if benefits to the general participant population are expected, state those.)

If the research is therapeutically related, disclose alternative procedures the participant might choose.

**Confidentiality**

How confidentiality will be maintained and any limits to confidentiality.

Who will have access to identifiable data.

How long identifiers will be retained and linked to the data.

**Questions or Concerns**

At least one researcher’s name and telephone number (students must also include the research supervisor’s name and telephone number) as well as the following statement: *“The participant may also contact the Chair, Human Subjects Institutional Review Board (989-964-7488; irbchair@svsu.edu) if questions or problems arise during the course of the study.”*

**Consent**

Do ***not*** use the terms “informed consent” or “I understand” anywhere in the document.

No language that would absolve the researcher of responsibility for negligence.

The following statements ***must*** be included in all consents (for signed consent forms, this statement should be placed **just above** the signature lines): *“This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and reference number in the upper right corner. Subjects should not sign this document if the corner does not show a stamped date and reference number.”*

A place for date and signature of participant and a witness line if required (e.g., with participants who are not legally competent); a place for parent/guardian/legally authorized rep. signature and date line, when appropriate; a place for date and signature of translator, if applicable; a place for date and signature (or initials) of individual obtaining the consent.

**The following are only to be included if appropriate:**

Indication that any significant new findings affecting risks will be promptly reported to the participant.

Description of Circumstances under which the researcher may terminate the participant’s participation.

Description of any additional costs the participant may have to bear.

Debriefing procedures.

Whom to call if subjects have an adverse event.

Description of who will bear financial responsibility for adverse effects, if appropriate.