CONSENT DOCUMENT DEVELOPMENT CHECKLIST

The following information must be included in the consent documents. Mark (✓) each of the requirements you have included. Omitted information must be justified on a separate sheet of paper.

☐ A header that includes “Western Michigan University, Department of _________” (if departmental letterhead is not used), the title of the study, and the researchers’ names

☐ Language in the form of an invitation to participate AND at a level appropriate for the participants (Note that the mean reading level in the United States is 7th grade.)

☐ The nature, purpose, and duration of the study

☐ Procedures to be employed in the research; exactly what the subject is expected to do

☐ Risks (hazards, inconveniences, discomforts) the subject may undergo, so far as they are known, and how any risks will be minimized

☐ 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).

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

☐ If the research is therapeutically related, disclose alternate procedures the subject might choose.

☐ Conditions of participation

☐ How confidentiality will be maintained and any limits to confidentiality

☐ 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

☐ The researcher’s name and telephone number (students must include faculty advisor’s name and telephone number) as well as the following statement: “The participant may also contact the Chair, Human Subjects Institutional Review Board (387-8293) or the Vice President for Research (387-8298) if questions or problems arise during the course of the study.”

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

☐ A place for date and signature of participant and a witness line if required (e.g., with subjects who are not legally competent); 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 statements must be included in all consents: “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 signature of the board chair in the upper right corner. Subjects should not sign this document if the corner does not show a stamped date and signature.”

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

☐ Leave a minimum top margin of 2 inches on all pages. Submit the final version of the consent document without headers such as “Draft” or “Appendix__.”

The following are only to be included if appropriate:

☐ Any significant new findings affecting risks will be promptly reported to the participant.

☐ Circumstances under which the researcher may terminate the subject’s participation

☐ Any additional costs the participant may have to bear

☐ Consequences of the participant’s withdrawal from the study

☐ The approximate number of participants in the study

☐ Debriefing procedures