INFORMED CONSENT FORM CHECKLIST
(Does not need to be submitted)

Does the consent form include the 8 required elements of informed consent? (45 CFR 46.116)

1) Research
   ___ Statement that the study is research
   ___ Who is doing the research
   ___ The purpose of the study
   ___ List and describe the procedures to be followed
   ___ Anticipated duration of the participant’s participation
   ___ If appropriate, state the condition(s) of participation, if any

2) Risk, discomforts
   ___ State the possible hazards, inconveniences, and risks the participant will undergo
   ___ If appropriate, state the procedure may involve unforeseeable risks
   ___ If appropriate, state that any significant new findings affecting risk will be reported to the participants
   ___ If appropriate, state circumstances under which the participant’s participation may be terminated
   ___ If appropriate, state any additional costs to the subject that may result from participation

3) Benefits
   ___ State the benefits to the participant or to others that might be expected from the research

4) Alternatives to participation
   ___ Disclose the alternate procedures the participant may choose

5) Confidentiality
   ___ Contain a statement of the extent to which the confidentiality of the data will be maintained
   ___ If appropriate, describe the procedures to be employed in maintaining confidentiality

6) Compensation for injury (If appropriate)
   ___ For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

7) Whom to contact
   ___ Include the name, address and telephone number of the investigator, the investigator's faculty sponsor (for student applicants), and the chairperson of the IRB
   ___ Instructions as to who and how to contact someone if questions or problems should arise later on

8) Right to refuse, or withdraw without penalty
   ___ Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
   ___ If appropriate, specify the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

   ___ Is the consent form absent any exculpatory language?
   **“Exculpatory language” is defined as language that would imply that the investigator is being released from responsibility for any adverse effects caused by the study.

   ___ Include appropriate signature and date lines (participant, investigator, and witness (if required)); this is not required for studies deemed exempt.

   ___ Include a statement that research was reviewed by the Texas A&M University--Kingsville IRB.

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