CONSENT-FORM CHECKLIST

This checklist is designed to assist researchers in drafting, and REB members in reviewing, research consent forms. The checklist enumerates elements that should be included in the research consent form. When preparing your consent form, check to ensure that the following elements are included.

The consent form **MUST** clearly identify the following:

1. ____ The name and address of the researcher(s). If the researcher is a student, the form should also identify the name and address of the student's supervisor;

2. ____ The sponsor(s) of the research.

3. ____ The proposed intervention is for research (i.e., test, drug, survey, interview, device, procedure, etc., used for research purposes).

4. ____ The purpose of the proposed research (i.e., why the research is being done).

5. ____ The nature of the proposed research (i.e., what the research involves: this should include details of what will happen to the participant, the need to discontinue standard practice or therapy, and any possible use of a placebo);

6. ____ The likely duration of participation (how long the research and each intervention will take).

7. ____ The potential harms and inconveniences associated with the research (i.e., the nature of the harms and inconveniences and the likelihood of their occurrence).

8. ____ The potential benefits associated with the research (i.e., the nature of the benefits to the participant or to others, and the likelihood of their occurrence).

9. ____ The alternative(s) to research participation, if applicable (e.g., available standard medical therapy, normal instruction in reading).

10 ____ Whether confidentiality will be protected and the measures taken to ensure it (i.e., Who will have access to the data? How will it be stored? Will participants be identified in publications?).

11. ____ Details regarding reimbursement.

12. ____ Possible conflict of interest or commercialization of the findings.

13. ____ Participation in research is voluntary (i.e., the right to refuse and the right to withdraw without prejudice).

The consent form **MUST ALSO BE** written:

1. ____ In the prospective participant's (or her or his substitute decision-maker's) preferred language.

2. ____ In "lay" terms (i.e., ordinary day-to-day language).

3. ____ At an appropriate level (taking into consideration the nature of the participant such as a child or adult).

4. ____ With simple explanations of all terms.

Please note that the consent form does **NOT** include:

1. ____ Any statement releasing the researcher(s), sponsor(s), institutions(s), or agents(s) from liability for negligence.