**IRB APPLICATION CHECKLIST**

Before submitting the application to the IRB, complete the following checklist:

If any item below is not applicable, please mark the item N/A and provide a brief rationale describing why the item does not apply or should not be required in the application.

**APPLICATION:**

1. [ ]  CITI Training certificate for each researcher, research assistants, and faculty advisor.

2. [ ]  Recruitment materials (i.e. fliers, advertisements, etc.).

3. [ ]  Appendices related to support for the project (approval for use of Institutional equipment, approval by appropriate person at site for collaboration with letter of support.

4. [ ]  Surveys, questionnaires, or interview questions.

5. [ ]  Consent and/or child assent forms.

6. [ ]  Conflict of Interest Disclosure has been completed and signed.

7. [ ]  Investigator and/or Faculty assurances have been signed.

**INFORMED CONSENT:**

1. Identify the **Flesh-Kincaid** grade level of the language used in the consent form and rationale for identified reading level: Click here to enter text.

2. [ ]  A foreign language translation must be included if the study will include participants whose first language of choice is not English.

Introduction/Background

3. [ ]  A statement that the study involves research, and an explanation of the purpose and a description of the

procedures to be followed.

4. [ ]  A statement of expected duration of the participant’s participation (e.g., one hour).

Benefits and Risks

5. [ ]  A description of all reasonably discomforts or foreseeable risks to the participant, as identified in the

study and any additional, known and unknown. ***This should match the risks described on the application.***

6. [ ]  A description of any benefits (indirect or direct) to the participant or others that may reasonably be expected from the research; if there is no benefits to the participant this should be stated.

7.[ ]  A statement of risk to human participants including availability of treatment if physical or psychological injury occurs and a statement regarding liability for any injury arising out of study participation.

Alternatives

8. [ ]  Disclosure of appropriate alternative procedures or treatment, if any, available to the participant

whether or not the participant elects to participate in the study. If the study is a treatment study, what alternatives to participation are available to participants and at what costs (i.e., free or not).

Confidentiality

 9. [ ]  A statement related to confidentiality of records, any exceptions to confidentiality.

Termination of Participation

10. [ ]  A statement to the effect that participation is voluntary, refusal to participate will result in no penalty or loss of benefits to which the participant is otherwise entitled; the participant may discontinue participation at any time without penalty.

Compensation

11. [ ]  A description of compensation or incentive (e.g., monetary, course credit, treatment) for participation and any criteria for receipt.

Questions

12. [ ]  The name of the contact person for information related to questions about the research (the Principal

Investigator), the rights of human participants (the IRB Chairperson), and whom to contact in the event of a research-related injury (the PI).

13. [ ]  A statement that the investigator has answered and will answer all questions posed by the participant now and in the future to the best of his/her ability.

Other

14. [ ]  A statement regarding injury compensation and institutional or PI liability for any injuries that might occur.

15. [ ]  A statement indicating voluntary consent has been obtained, including signature lines for participant and investigator, and date.

16. [ ]  A statement that the participant will receive a copy of the consent form (when an oral summary is read, and short consent form is used, the statement should read that a complete copy of the consent form will be provided to the participant).

17. [ ]  A statement that the IRB has approved the solicitation of participants for the study; this appears after the signatures.