**Study Proposal Application for Expedited or Full Review**

Catawba College Institutional Review Board

**Section I: Research Study Overview**

1. **Name of Principal Investigator(s) (must be a faculty member):** 
   1. **Names of any other investigators on this study proposal, including student investigators:**

**2. Date of submission:**

**3. Time span for the study:**

**4. The study is essentially a student project: Yes No**

**If Yes, the course for which the study will be submitted:**

**If Yes, the name(s) of Student Investigator(s):**

**5. Funding source(s) for the study (if none, so indicate):**

**6. Title of study proposal:**

**Section II: Study Description**

1. **Purpose of the study, stated clearly.**
2. **Include a brief summary of salient background information, what research issue is being addressed, the research question/hypothesis. Background literature with citations is required.**
3. **Describe the qualifications of the researchers to conduct this study.**
4. **Describe the study methodology, including data collection, management, analysis, storage, and elimination.**
5. **Describe *why* the use of human subjects is *necessary* for this study.**

*Example answer: Humans are needed to study this topic as the topic concerns humans because…*

1. **Describe the *benefits* to be gained by individuals and society.**
2. **Reference(s) for your intended procedures (including existing literature on this topic):**

**Section III: Participant Information**

1. **Expected Number of Participants:**
2. **Participants will come from one of these Vulnerable Groups:**

**Catawba College Students**

Children

Decisionally Impaired

Institutionalized

Non-Native English Speaking  Students from PI's Class(es)  Other:

1. **Obtaining Participants**
   1. **Recruiting Methods (Describe how prospective participants will be contacted):**
   2. **How will participants be selected?**
   3. **Describe the inducements used for participation (if none, so indicate):**
      1. **Describe the consequences of declining to participate (if none, so indicate):**
      2. **Describe the consequences of withdrawing from the study (if none, so indicate**
2. **Indicate the amount of time required for participation:**

**Section IV: Informed Consent Issues**

* 1. **Describe the method for obtaining Informed Consent:**
  2. **Answer the following questions regarding Informed Consent:**

**Participants are informed of their right to withdraw during the study** Yes No

**Participants are informed of any consequences of declining or withdrawing from the study**  Yes No

**Participants are informed of the pertinent attendant risks** Yes No

**Participant are informed about whom to contact for questions about the study and/or their rights.**

Yes No

**The study requires disclosure of personal information** Yes No

**The study ensures data are kept confidential and secure?** Yes No

**A copy of the "Informed Consent" Form is included in the appendix** Yes No

**All data collection tools are attached as appendices** Yes No

**Section V: Vulnerable Groups**

**Participants obtained from a VULNERABLE GROUP (as identified in Section 3, Item 2) require special attention to several aspects of "Informed Consent", e.g., participation truly is voluntary, requisite information for making a choice is understood, another person may be responsible for "consenting" for the potential participant. Describe the methods to be followed to obtain VOLUNTARY informed consent from participants obtained from vulnerable groups.**

1. **Summarize attendant risks to participants that may occur, e.g., physical, psychological, privacy; requests for personal information, use of deception, etc.** 
   * 1. **Evaluate the risks itemized above, e.g., how do the risks compare to those normally encountered in daily living?**
     2. **Discuss the "Risk/Benefit" Ratio as applied to this study:**
2. **Describe how you will minimize risks to your participants, including unintended stress arising from participation:**
   * 1. **If participants are asked to reveal personal, embarrassing, and/or sensitive information, describe how this information will remain anonymous and/or confidential (if not applicable, so indicate):**
     2. **If participants will be placed under any physical risk, describe the appropriate medical support services available if needed (if not applicable, so indicate):**
3. **Describe the "Debriefing" plans for these participants:**
4. **Describe how the data will be used, i.e., how confidentiality and/or anonymity will be maintained:**
5. **How long will the data be kept and when/how will they be destroyed?**

**PI Signature(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**