The purpose of this worksheet is to assist you in review of protocols submitted to the IRB for approval. Please use this sheet as a guide to develop questions/concerns regarding the protocol that you will share with the IRB chairperson or IRB members. You can circle the appropriate response and then make comments for discussion.

1. **Application Cover Sheet**
   a. Type of Review is labeled appropriately   Yes  No
   b. The contact information is completed   Yes  No
   c. The project title is completed   Yes  No
   d. The proposed start and end dates are included   Yes  No
   e. All investigators’ human subjects educational certificates are attached   Yes  No

2. **Research Assurance Statement**
   a. The research assurance form is signed by all researchers and data collectors   Yes  No
   b. The conflict of interest questions have been initialed by all researchers and data collectors   Yes  No
     - If there is a conflict of interest, are you convinced that it is not significant enough to influence the outcome of the research?   Yes  No

3. **Description of the Research**
   a. A clear description of the research is presented including:
     - Problem to be studied   Yes  No
     - Purpose of Research   Yes  No
     - Research Design   Yes  No
     - Brief description of data collection procedures   Yes  No
   b. Site where the data will be collected is presented   Yes  No
     - If a school site, is there a letter from the appropriate school official supporting the implementation of the research   Yes  No
     - If conducting research in another institution, is there a letter from the collaborating institution supporting the implementation of the research   Yes  No
   c. Does the researcher include a statement of his/her qualifications to conduct the study (provide information for each research team member)   Yes  No
     - Are you satisfied that the researcher(s) has (have) the expertise needed to conduct the study?   Yes  No
   d. Description of education provided to data collectors to assure human subjects protection   Yes  No

4. **Characteristics of subjects**
   a. Potential subject pool is described adequately   Yes  No
   b. Procedures to recruit and select subjects is adequately describe   Yes  No
• Recruitment notices, flyers, advertisements are attached  
  Yes   No  
c. The research sample is described including:
  • Proposed number of subjects  Yes   No  
  • Age (range)  Yes   No  
  • Gender  Yes   No  
  • Ethnic background  Yes   No  
  • Special considerations (health status)  Yes   No   Not Applicable  
  • Use of Special Populations (Circle all that apply)
     Children
     Pregnant Women
     Fetuses
     Mentally Disabled
     No Special Populations will be used
    If special population is proposed, is rationale provided and is it satisfactory?  Yes   No  
e. Frequency and duration of subject participation is stated  Yes   No  
f. Described rewards and/or compensation  Yes   No
  • Rewards and/or compensation are not at a level to be considered coercive
    Yes   No   Not Applicable  
  • If no, has the researcher described how coercion will be minimized?  Yes   No  
5. Procedures/Instrumentation
  a. Full description of data collection, including how demographic data will be collected  
     Yes   No  
  • Description of audio or video typing (if used)  Yes   No  
b. Copy of Instrument(s) and or guide questions are attached  Yes   No  
c. Alternative experience for classroom data collection are provided (if appropriate)  
   Yes   No   Not Applicable  
6. Benefits
  a. Benefits to subjects are described  Yes   No  
  b. Expected outcomes are stated  Yes   No  
7. Risks and Protections
  a. Full description of possible physical, psychological, social or economic risks or benefits, including any reactive effects (if anticipated)  Yes   No  
b. Professional intervention plan described for potential adverse effects to subjects (if needed)  
   Yes   No  
8. Privacy and confidentiality
  a. Description of precautions to protect privacy explained  Yes   No  
  b. Description of procedures to assure confidentiality of subjects’ data  Yes   No
  • If using deception, rationale is provided as well as debriefing procedures
    Yes   No  
    i. If using primary document (ie student records, charts) are access and permission procedures explained?  Yes   No   Not applicable
    ii. A description of subject withdrawal notification is provided if post consent inclusion or exclusion is a possibility  Yes   No   Not Applicable  
c. Data Collection
  i. Data storage procedures are appropriate  Yes   No   Not Applicable  
  ii. Explanation of access to data is appropriate  Yes   No   Not Applicable  
  iii. Length of data storage is stated  Yes   No   Not Applicable  
  iv. Description of how data will be destroyed following study completion  
     Yes   No
d. Risks for breach of confidentiality are described  
   - Procedures for minimizing breaches are explained  
   - Coding procedures are described  

e. For electronic data collection (audio or video taping)  
   i. Data transcription procedures protect anonymity of subjects  
      Yes  No  Not Applicable  
   ii. Procedures for coding and access to data are described  
      Yes  No  Not Applicable  
   iii. Description of data use outside of the study situation  
      Yes  No  Not Applicable  

f. Informed consent and child assent  
   - Request for waiver is appropriate  
     Yes  No  Not applicable  
   i. Procedures for obtaining consent or child assent is described  
     Yes  No  
   ii. Consent and/or child assent form is attached  
      Yes  No  
   iii. Procedures for obtaining parental or guardian consent are explained  
      Yes  No  Not applicable  
   iv. Language and style of writing is appropriate for subjects  
      Yes  No  

   - Elements of consent:  
     Includes the following:  
     - Purpose of the study  
       Yes  No  
     - Expected outcomes  
       Yes  No  
     - Duration of participation  
       Yes  No  
     - Description of data collection procedures  
       Yes  No  
     - Description of experimental procedures (if applicable)  
       Yes  No  
     - Description of risks and/or discomforts  
       Yes  No  
     - Description of anticipated benefits to subjects  
       Yes  No  
     - Disclosure of alternative treatments  
       Yes  No  
     - Description of how confidentiality and anonymity will be assured  
       Yes  No  
     - For studies with more than minimal risk  
       - Explanation of whether compensation is available for medical treatments if injury occurs  
         Yes  No  
     - Contact information to obtain answers to questions and/or report injury  
       Yes  No  
     - Statement including:  
       - voluntary nature of participation  
         Yes  No  
       - refusal to participate will not result in loss of benefits  
         Yes  No  
       - discontinuation of participation without penalty  
         Yes  No  

OTHER CONSIDERATIONS (NOT REQUIRED FOR ALL PROTOCOLS):  
   - For studies involving children – consent and assent forms are included  
     Yes  No  
   - Statement of unforeseeable risk, for higher risk studies  
     Yes  No
- Circumstances under which investigator can terminate participation by subjects
  Yes  No
- Any additional financial burdens related to participation  Yes  No
- Consequences of early withdraw or termination  Yes  No
- Statement of significant developments during the protocol implementation that can impact continued participation  Yes  No
- Approximate number of subjects in study  Yes  No