MISERICORDIA UNIVERSITY
Reviewer’s Worksheet
Evaluation of Protocols Involving Human Subjects

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 Yes No
   - Coding procedures are described Yes No Not Applicable

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