

# Truman State University IRB Reviewer's Review Sheet

Investigator's Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_

Faculty Sponsor: \_\_\_\_\_ Department: \_\_\_\_\_

Project Title: \_\_\_\_\_

**1. Does the research place subjects at no more than minimal risk?**  YES  NO

Minimal risk is defined as the probability and magnitude of harm or discomfort is no greater than that ordinarily encountered in daily life or during a routine physical or psychological examination or tests)

Notes: \_\_\_\_\_

**2. If more than minimal risk, does the merit of the project outweigh the risks and are benefits maximized and risks minimized?**  YES  NO

Notes: \_\_\_\_\_

**3. Are there any ethical issues regarding the study's design and conduct?**  YES  NO

Ethical issues may include but are not limited to the Belmont Report principles: respect for persons (voluntary, fully informed consent); beneficence (obligation to protect subjects from harm and secure their well-being); and, justice (benefits and burdens of research are fairly distributed).

Notes: \_\_\_\_\_

**4. Is subject selection equitable?**  YES  NO

If special populations are included the IRB should ensure that subjects can understand the research, give full consent, and voluntarily agree to participate, and they should consider any other possible special problems.

Are Vulnerable or Special Populations included in the research?

- Pregnant women
- Fetus/fetal tissue
- Prisoners
- Minors Under Age 18
- Elderly subjects
- Minority group(s) and non-English speakers
- Patients
- Mentally/Emotionally/Developmentally Disabled persons
- Behavioral Abnormalities, psychological or disease condition
- None of the Above, Normal Healthy Volunteers

Notes: \_\_\_\_\_

**5. Is the recruitment and consent process (including telephone scripts, ads, brochures, letters, compensation) fully described, appropriate, and non-coercive?**  YES  NO

Notes: \_\_\_\_\_

6. Are risks (physical, emotional, financial, legal) to subjects minimized?  YES  NO

Notes: \_\_\_\_\_  
\_\_\_\_\_

7. Confidentiality of Data:  
Are there procedures for protecting privacy and confidentiality?  YES  NO

Notes: \_\_\_\_\_  
\_\_\_\_\_

8. Is Informed Consent Included in the Application:  YES  NO

Stipulate Missing Elements:

- Is the PI identified along with affiliation with Truman?  YES  NO
- Is the study faculty sponsor identified? (if appropriate)  YES  NO
- Does the consent state the study purpose accurately?  YES  NO
- Is it clear what the subject(s) will be asked to do?  YES  NO
- Are risks or discomforts clearly and fully stated?  YES  NO
- Are benefits clearly and fully stated?  YES  NO
- Are alternatives listed? (if appropriate)  YES  NO
- Are confidentiality or anonymity issues addressed?  YES  NO
- Is contact information included?  YES  NO
- Is it stated that the subject can withdraw at any time?  YES  NO
- Is the consent understandable at an 8<sup>th</sup> grade reading level?  YES  NO

Assent Form  Not Required

- Is one needed (can the child really refuse to participate?)  YES  NO
- Is it one page or less?  YES  NO
- Is the language simple and sentences short?  YES  NO

Notes: \_\_\_\_\_  
\_\_\_\_\_

Additional Comments/Requirements by IRB: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**RECOMMENDATION:**

- Approve as Submitted
- Approval Deferred; add'l information required (additional IRB review required)
- Approved with Stipulations as Noted
- Not Approved

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_