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 8th 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: ___________________________