

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: _____