



**Missouri  
State**  
UNIVERSITY

Institutional Review Board

**Missouri State University Human Subjects  
Review Application Cover Sheet**

(Revised 12/18/2013)

For OSRP Use Only      Date Submitted: \_\_\_\_\_ Date Received: \_\_\_\_\_ Application #: \_\_\_\_\_

**A. INVESTIGATOR INFORMATION** *(Additional names and information on training are to be provided on an attached sheet.)*

**Principal Investigator:** \_\_\_\_\_ **College:** \_\_\_\_\_ **Department:** \_\_\_\_\_

Human Subjects Training has been completed: ☐ yes ☐ no **Email:** \_\_\_\_\_

Project involves Protected Health Information: ☐ yes ☐ no If yes, has HIPAA training been completed?: ☐ yes ☐ no

**Co-Worker:** \_\_\_\_\_ **College:** \_\_\_\_\_ **Department:** \_\_\_\_\_

Human Subjects Training has been completed: ☐ yes ☐ no **Email:** \_\_\_\_\_

Project involves Protected Health Information: ☐ yes ☐ no If yes, has HIPAA training been completed?: ☐ yes ☐ no

**Co-Worker:** \_\_\_\_\_ **College:** \_\_\_\_\_ **Department:** \_\_\_\_\_

Human Subjects Training has been completed: ☐ yes ☐ no **Email:** \_\_\_\_\_

Project involves Protected Health Information: ☐ yes ☐ no If yes, has HIPAA training been completed?: ☐ yes ☐ no

**Co-Worker:** \_\_\_\_\_ **College:** \_\_\_\_\_ **Department:** \_\_\_\_\_

Human Subjects Training has been completed: ☐ yes ☐ no **Email:** \_\_\_\_\_

Project involves Protected Health Information: ☐ yes ☐ no If yes, has HIPAA training been completed?: ☐ yes ☐ no

**Co-Worker:** \_\_\_\_\_ **College:** \_\_\_\_\_ **Department:** \_\_\_\_\_

Human Subjects Training has been completed: ☐ yes ☐ no **Email:** \_\_\_\_\_

Project involves Protected Health Information: ☐ yes ☐ no If yes, has HIPAA training been completed?: ☐ yes ☐ no

**B. PROJECT INFORMATION**

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

**Project Type:** ☐ New Project ☐ Renewal ☐ Change in Procedure/Personnel for Previously Approved Project

**Proposed Project Dates (up to one year):** **From:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ **To:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**Funding Agency or Research Sponsor:** \_\_\_\_\_

**C. IRB RECOMMENDATION**

**Recommendation of College IRB Representative:**

☐ Category I, Exempt, Sub-part A, Section 45.101 45 CFR 46, exempt category \_\_\_\_\_

☐ Category II, Expedited Approval, Sub-part A, Section 46.110; expedited category \_\_\_\_\_

☐ Category III, Full Committee Review

**IRB College Representative:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Action of the IRB Chairman:**

☐ Approved as Exempt

☐ Expedited Approval

☐ Recommended for Full Review

**Results of Full IRB Review:**

☐ Approved

☐ Deferred (see attached comments)

☐ Disapproved (see attached comments)

**Chairman of IRB:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**INSTRUCTIONS FOR THE MISSOURI STATE  
HUMAN SUBJECTS PROTECTION APPLICATION**

The application consists of:

- a. the cover sheet (above),
- b. the body of the application that addresses the areas noted below (using the areas as subheadings; 2-4 pages maximum),
- c. Human Participants Protection training certificate(s),
- d. HIPAA training certificates (if applicable),
- e. copies of questionnaire instruments to be used (if applicable),
- f. copies of Informed Consent forms to be used, and
- g. letter(s) of support/permission from data collection site(s) (if applicable) (where appropriate, include IRB approved protocol from other involved institution here).

**Application Content Areas**

1. Brief description of the purpose of the proposed project, including specific goals
2. Research protocol, that includes:
  - Description of participants to be used, including;
    - General demographics of target sample
    - Sample size
    - Sampling procedures
    - From where participants will be obtained
    - How long procedures will take participants
  - Procedures, including:
    - General progression of research
    - How informed consent will be obtained/addressed
    - Description of setting in which data is obtained
    - How data will be kept secure and confidential
  - Name and description of data gathering tool (attach a copy if possible)
  - HIPAA considerations/procedures (if applicable)
  - Description of any special situations/circumstances needing to be addressed in the study
  - Data disposition when the study is completed
  - How resulting information will be used/disseminated/shared
3. Benefits: Describe benefits to the individual and/or mankind from participation
4. Risks: Describe the risks to the participant. This includes physical, psychological, and/or sociological risks
5. Analysis of Risk:Benefit Ratio When Relevant: This is the researcher's own evaluation of the balance between potential risks for participants and potential benefits from the project
6. Procedures for Minimizing Risk: Describe precautions that will be taken to minimize the risks described above, including more detail about how data confidentiality will be maintained, and the final disposition of data
7. Procedures for obtaining informed consent (see guidelines for key elements to include in informed consent)
8. The project proposal shall end with the following, verbatim (including signature lines):

I hereby agree to conduct this study in accordance with the procedures set forth in my project description, to uphold the ethical guidelines as set forth in the Code of Federal Regulations 45 CFR 46, 45 CFR 160 and 164, and the Missouri State University HIPAA Policy, and to report to the IRB any outcomes or reactions to the experiment which were not anticipated in the risks description which might influence the IRBs decision to sustain approval of the project.

\_\_\_\_\_  
Department Head/Dean/VP

\_\_\_\_\_  
Date

\_\_\_\_\_  
Principal Investigator (Faculty/Staff)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Other Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Other Investigator

\_\_\_\_\_  
Date