Missouri State University
Human Subjects Protection
Institutional Review Board

APPLICATION FOR REVIEW AND APPROVAL OF ACTIVITY INVOLVING HUMAN SUBJECTS

Policy Statement:

The United States Department of Health and Human Services (DHHS) and Missouri State University have established standards and guidelines to protect individuals who may be at risk as a consequence of participation in a research activity. The Institutional Review Board for the Protection of Human Subjects *(IRB)* is responsible for insuring that adequate safeguards are established to protect any individual who may be at risk as a consequence of participation in research activities.

Standards for the committee's reviews are based upon

1. Protection of Human Subjects - Code of Federal Regulations, 45 CFR 46
2. Standards for Privacy of Individually Identifiable Health Information – 45 CFR 160 and 164, as described in the Missouri State University Health Insurance Portability and Accountability Act (HIPAA) Policy

Researchers are encouraged to refer to these codes in planning their research.

To what does this policy apply?

All research undertaken by university personnel that involves human subjects in any way, regardless of the source of funds, must be reviewed and approved by the IRB before the activity is undertaken. This includes activities in which a faculty member is supervising student research activities, such as graduate theses and dissertations.

According to 45 CFR 46, "*Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*"

The Health Insurance Portability and Accountability Act (HIPAA) imposes additional requirements for those involved in the collection, use, retention and destruction of research data that includes protected health information (PHI). According to 45 CFR 165.501, protected health information is defined, in part, as individually identifiable health information transmitted or maintained in electronic or any other form or medium.

All research projects must be renewed annually. Renewals (without changes) are sent directly to the IRB chair and typically require only a brief review. Any meaningful changes in procedures must also be reviewed. Applications involving changes in approved procedures are sent to the College Representative.

Training:

A. Human Participant Protection Training: Faculty, staff and students participating in the design of projects involving collection of data and/or the analysis of data from human subjects, must complete the CITI training program. This program consists of modules for Biomedical and Social/Behavioral Investigators and a Completion Certificate is issued through the CITI program. URL: https://www.citiprogram.org/default.asp

B. HIPAA Training: If the proposed research involves protected health information (PHI), researchers also must certify completion of the training required under the Missouri State HIPAA policy. This training is provided in two modules available on a secure Missouri State web site – http://www.privacy.missouristate.edu/hipaa.htm - HIPAA Privacy, Security and Research Training.

Institutional Review Board

Missouri State University Human Subjects Review Application Cover Sheet

(Revised 09/03/08)

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: Erin Buchanan **College:** CHHS **Department:** Psychology

Human Subjects Training has been completed: [X] yes [ ] no **Email:** ErinBuchanan@missouristate.edu

Project involves Proctected Health Information: [ ] yes [X] no If yes, has HIPAA training been completed?: [ ] yes [ ] no

Co-Worker: Kayla Jordan **College:** CHHS **Department:** Psychology

Human Subjects Training has been completed: [X] yes [ ] no **Email:** Jordan810@live.missouristate.edu

Project involves Proctected Health Information: [ ] yes [X] 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 Proctected 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 Proctected 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 Proctected Health Information: [ ] yes [ ] no If yes, has HIPAA training been completed?: [ ] yes [ ] no

B. PROJECT INFORMATION

Project Title: Exploring Word Associates of Moral Foundations

Project Type: [X] New Project [ ] Renewal or Continuation [ ] Resubmission

[ ] Change in Procedure for Previously Approved Project

Proposed Project Dates (up to one year): **From:** 1 / 19 / 15 **To:** 5 / 30 / 15

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) (if applicable), (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)

9. The project proposal shall end with the following, <u>verbatim (including signature lines)</u>:

   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	Principal Investigator (Faculty)
_____	_____
Other Investigators	Other Investigators
Date: _____	Date: _____