

## Campus IRB Expedited or Full Board Application

Project Number: 1145319

Review Number: 78349

### SECTION A - Project Summary

**(1) Research Staff (students must have an advisor listed)**

| Name               | Dept.                                | Role              | Educational Training Date |
|--------------------|--------------------------------------|-------------------|---------------------------|
| Joyce Arditti      |                                      | Pri- Investigator | 05-01-2009                |
| Jonathon Beckmeyer | Human Development And Family Studies | Key Personnel     | 08-25-2007                |
| Tammy Gillespie    | University Extension                 | Key Personnel     | 03-06-2008                |

**Restriction:** All key personnel are required to be certified for completion of a protection of human research participants education program that is approved by the Campus IRB. Applications will not be reviewed if the key personnel have not certified approved training.

**Restriction:** All applications must have a primary investigator selected unless they are a student. A student should list themselves as a "student investigator".

**Restriction: (STUDENT INVESTIGATORS):** Student applications must have an advisor listed. Applications will not be reviewed until:

- The student and advisor have current human subject training certification
- The advisor has completed the Advisor Approval Form for this application.

**NOTE:** (The Advisor Approval Form may be accessed under the IRB Forms section of eIRB, and must be submitted by your advisor before submitting this Application to the Campus IRB.)

**(2) Project Title \***

*Please provide the title of the proposed project.*

National Science Foundation (NSF): Parental Incarceration and Successful Prisoner Reentry

**(3) Project Description \***

*Provide a full description of the proposed research methodology.*

**(4) Research Activity**

**A. Is the proposed activity a systematic investigation, including research development, testing and evaluation? \***

Yes  No

**B. Is the activity designed to develop or contribute to generalizable knowledge? \***

Yes  No

**(5) Human Subjects \***

*Are you are planning to obtain data about living individuals through one or more of the following?  
(Check all that apply)*

- Physical procedures performed on those individuals
- Manipulation of those individuals
- Manipulation of those individuals` environments
- Communication with those individuals
- Interpersonal contact with those individuals
- Information that is both private AND individually identifiable

**(6) Appropriate Forum**

*If you mark "YES" to any item below, please contact the Campus IRB (882-9585) to determine if your project must be submitted to the Health Sciences IRB.*

**A. Is the research regulated by the Food and Drug Administration? \***

Yes  No

**B. Is the research regulated by the Veteran Affairs?**

Yes  No

**C. Affiliation**

*Is the Principal Investigator employed at any of the following? (Check all that apply)*

- Children`s Hospital
- Ellis Fischel Cancer Center
- Howard A. Rusk Rehabilitation Center
- Missouri Rehabilitation Center
- University Hospital and Clinics
- Columbia Regional Hospital
- School of Medicine
- School of Health Professions
- Charles and Josie Smith Sinclair School of Nursing
- School of Veterinary Medicine
- Harry S. Truman Memorial Veterans Hospital
- Missouri Institute of Mental Health

**D. Patients \***

*Does the subject population include patients (either inpatients or outpatients) in any of the institutions listed above?*

Yes  No

**E. Physical stress \***

*Does the research involve physical stress to the subjects (e.g., exercise physiology projects)?*

Yes  No

**F. Blood/Tissue \***

Does the research involve any collection of human blood or tissue?

Yes  No

**G. Fetus/Neonate \***

Does the research involve a delivered fetus, the delivery process, placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, or hospitalized neonates?

Yes  No

**SECTION B - Project Information**

**(1) Explain the purpose of the research. \***

**(2) Do you certify that the proposed activities have scientific or academic merit? \***

*All research proposals reviewed by the Campus Institutional Review Board (Campus IRB) shall undergo a rigorous review to assess the scientific quality, importance of the research to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific question.*

*The University of Missouri's mission is to provide a venue for research that is in compliance with the State, Federal and Local laws. It recognizes that research may be conducted for academic purposes only, but requires it to undergo a risk/benefit assessment to assure the methodology is appropriately designed to achieve the aim of the research. All academic research will require the advisor to certify academic merit for the purposes of assuring proper oversight of the student and activities to further protect human subject participants.*

Yes  No

**(3) If YES, provide an explanation briefly confirming the presence of scientific or academic merit.**

*All research proposals reviewed by the Campus Institutional Review Board (Campus IRB) shall undergo a rigorous review to assess the scientific quality, importance of the research to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific question.*

**(4) Please provide a statement certifying the scientific merit of this research by addressing how the design minimizes bias and has the potential to generate data that will answer the scientific question outlined in the research methodology proposed? \***

*All research proposals reviewed by the Campus Institutional Review Board (Campus IRB) shall undergo a rigorous review to assess the scientific quality, importance of the research to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific question.*

**(5) If NO, please provide an explanation of why you believe the proposed activities should be conducted.**

**(6) Describe the procedure(s) to be performed. \***

**(7) Please describe which procedures, if any, are standard treatment for diagnostic or**

**treatment purposes.**

**(8) List and describe all instruments to be used. \***

*List each of the instruments used in your study. When listing your instruments (i.e., surveys, questionnaires, inventories, observational techniques, etc.), define the purpose of each instrument and describe the estimated length of time the subject will be engaged in completing the act described in your study. Please add a statement in your consent form explaining each activity and stating the estimated length of time for each activity. UPLOAD all of your instruments.*

**(9) Describe the setting in which the research will be conducted. \***

**(10) Specify the primary location where you intend to collect your data. \***

**(11) Experience \***

*In detail, cite the key personnel's experience with this type of research. This includes ALL personnel listed on the IRB application. The Campus IRB will conduct a thorough review of this section to determine if all key personnel have the appropriate qualifications and experience to conduct the research.*

**(12) Project Dates**

*Provide the estimated start and end dates for your project. If your start date has already passed, please explain within the application.*

**A. Start Date \***

**B. End Date \***

**(13) Is this an international human subjects research project? \***

Yes  No

**(14) Is this a collaborative project? \***

Yes  No

**SECTION C - Conflicts of Interest**

**(1) Financial Conflicts of Interest**

**A. Do you have any financial conflicts of interest in this project? \***

*This includes, but is not limited to, disclosing any proprietary interests, equity interests, significant payments (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria), and whether you receive payment per participant or other incentive payments in this project.*

Yes  No

**B. If yes, please explain those financial conflicts of interest and the plan to manage this conflict.**

**C. Do you or other persons responsible for the design, conduct, or reporting of research, and your/their spouses and dependent children have any ownership interest, stock options, or other financial interest related to the research unless it meets the following four tests: 1) less than \$10,000 when aggregated for immediate family member, 2) publicly traded on a stock exchange, 3) value would not be affected by the outcome of the research, and 4) less than 5% interest in any one single entity?**

Yes  No

**D. If yes, please explain.**

**E. Do you or other persons responsible for the design, conduct, or reporting of research, and your/their spouses and dependent children have any compensation related to the research unless it meets the following two tests: 1) less than \$10,000 in the past year when aggregated for immediate family, and 2) value would not be affected by the outcome of the research?**

Yes  No

**F. If yes, please explain.**

**G. Do you or other persons responsible for the design, conduct, or reporting of research, and your/their spouses and dependent children have any proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement?**

Yes  No

**H. If yes, please explain.**

**I. Do you or other persons responsible for the design, conduct, or reporting of research, and your/their spouses and dependent children have any board or executive relationship related to the research, regardless of compensation?**

Yes  No

**J. If yes, please explain.**

**K. If you have disclosed a financial conflict of interest, have you submitted a Conflicts of Interest disclosure statement to the Office of Research Conflicts of Interest Committee?**

*Please view <http://www.research.missouri.edu/complia/coi.htm> for more information about Conflicts of Interest and view <http://www.research.missouri.edu/assets/forms/conflict.pdf> to access a disclosure form.*

Yes  No

## **(2) Professional Conflicts of Interest**

**A. Do you have any professional conflicts of interest in this project? \***

Yes  No

**B. If yes, please explain those professional conflicts of interest and the plan to manage the**

conflict.

**(3) Institutional Conflicts of Interest**

**A. Are there any institutional conflicts of interest? \***

Yes  No

**B. If yes, please explain those institutional conflicts of interest and the plan to manage the conflict.**

**(4) Personal Conflicts of Interest**

**A. Do you have any personal conflicts of interest in this project? \***

Yes  No

**B. If yes, please explain those personal conflicts of interest and the plan to manage the conflict.**

**(5) Other Conflicts of Interest**

**A. Are you aware of any conflicts of interests of other research team members or persons responsible for the design, conduct, or reporting of research; spouses; or dependent children? \***

Yes  No

**B. If yes, please explain and describe the plan to manage the conflict.**

**SECTION D - Funding Sources**

**If you are receiving internal or external funds, you must complete this section.**

None

**SECTION E - Collaborative Activities/Multi-Center Studies**

**(1) If the study involves Collaborative Sites, you must complete this section.**

*If you are involving other sites or institutions, please list them below. Please UPLOAD the IRB or research approval from the research site.*

**A. Name**

**B. Type**

**C. Contact Address**

**D. Contact Email****E. Contact Phone****F. Does the collaborative site have an IRB?**

Yes  No

**G. Has this project been reviewed by the other IRB? \***

*If this project has been reviewed by another IRB, you must submit a copy of the IRB application reviewed, copies of the supportive documents submitted with that IRB application, and that IRB's approval letter.*

Yes  No

**H. If yes, identify that IRB.**

*Remember that if this project has been reviewed by another IRB, you must submit a copy of the IRB application reviewed, copies of the supportive documents submitted with that IRB application, and that IRB's approval letter.*

**I. Has the site granted permission for the research to be conducted?**

Yes  No

**J. If the site has an IRB, do they plan to defer review to the UMC Campus IRB?**

*If yes, please upload the collaborative agreement.*

Yes  No

**K. How do you intend to manage information obtained from multiple sites that may be relevant to the protection of research participants?**

**(2) Please explain how you intend to manage information obtained in multi-site research that could be relevant to the protection of research participants, such as reporting unanticipated problems involving risks to participants or others.**

**(3) Please explain how you intend to manage information obtained in multi-site research that could be relevant to the protection of research participants, such as interim results.**

**(4) Please explain how you intend to manage information obtained in multi-site research that could be relevant to the protection of research participants, such as reporting unanticipated problems involving protocol modifications.**

**SECTION F - System Projects****(1) University of Missouri System Projects****A. Is this project involving other campuses in the University of Missouri**

system? \*

Yes  No

**B. If yes, choose the UM campuses involved in the study.**

Missouri University of Science and Technology

University of Missouri - Kansas City

University of Missouri - St. Louis

**(2) Did you obtain IRB or research approval from the research site?**

Yes  No

**(3) Did you upload the IRB approval form or permission letter to this application?**

*Please UPLOAD the IRB approval form or permission letter from an authorized individual.*

Yes  No

### SECTION G - Resources

**(1) Adequate Resources**

*The Campus IRB must ensure that you have adequate resources to protect participant rights and welfare.*

**A. Do you have adequate resources in terms of access to a population that will allow recruitment of the required number of participants? \***

Yes  No

**B. Please describe your resources in terms of access to a population that will allow recruitment of the required number of participants. \***

**C. Do you have adequate resources in terms of sufficient time to conduct and complete the research within the research period? \***

Yes  No

**D. Please describe your resources in terms of sufficient time to conduct and complete the research within the research period. Please describe the amount of time you intend to devote to conduct the research. \***

**E. Do you have adequate resources in terms of an adequate number of qualified staff? \***

Yes  No

**F. Please describe your resources in terms of an adequate number of qualified staff. \***

**G. Do you have adequate resources in terms of adequate facilities? \***

Yes  No

**H. Please describe your resources in terms of adequate facilities. \***

**I. Do you have adequate resources in terms of availability of medical or psychological resources that participants might require as a consequence of the research? \***

Yes  No

**J. Please describe your resources in terms of availability of medical or psychological resources that participants might require as a consequence of the research. \***

**K. Do you have adequate resources in terms of a process to ensure that all persons assisting with the research were adequately informed about the protocol and their research-related duties and functions? \***

Yes  No

**L. Please describe your resources in terms of a process to ensure that all persons assisting with the research were adequately informed about the protocol and their research-related duties and functions. \***

**M. Do you have adequate resources in terms of necessary equipment? \***

Yes  No

**N. Please describe your resources in terms of having necessary equipment to conduct this research. \***

**O. Do you have adequate ancillary resources? \***

Yes  No

**P. Please describe your ancillary resources. \***

## SECTION H - Risks/Benefits

### (1) Disclosure of Risks

**A. Would the disclosure of a participant's identity or response outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation? \***

Yes  No

**B. What level of risk will be imposed on the subjects during participation? \***

**C. Describe the risks associated with the research. \***

*The IRB is required to assess the risks and potential benefits of the research. The investigator should provide a description of any potential risks of the research, and can be associated with the research.*

**D. Describe all risks imposed on subjects in your project. \***

**E. How do you intend to minimize the risks to the subjects? \***

**(2) What benefits to society may result from this research? \***

**(3) What benefits to the subject may result from the research? \***

**(4) Does the research plan require provisions for monitoring the data to ensure the safety of participants? \***

*If the research involves more than minimal risk, the Campus IRB requires the researcher to submit a copy of the data safety monitoring plan and report, if applicable.*

Yes  No

**(5) If yes, provide a description of provisions for monitoring the data to ensure the safety of participants.**

**(6) If a DSMB (Data Safety Monitoring Board) is required, please describe the periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome.**

**(7) Please provide a description of the monitoring process external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.**

**(8) Coercion or Undue Influence**

**A. Will some or all of your participants likely be vulnerable to coercion or undue influence? \***

Yes  No

**B. If yes, provide a description of additional safeguards to minimize possible coercion or undue influence.**

**C. If some or all of the participants are likely to be vulnerable, please include a description of additional safeguards that will be included in the protocol.**

### SECTION I - Subject Characteristics

**(1) Number of Subjects \***

*Please identify the number of subjects to participate in your project.*

**(2) Children \***

*NOTE: You do not have to complete this section if children are not involved.*

**A. Will the target subject population include children/youth under 18 years of age? \***

*If the project does not involve participants under 18 years of age, please proceed to question #3.*

Yes  No

**B. If yes, please select the category below that best describes the level of risk posed to participants:**

*Note: The proposed research must fall into one of the categories listed in order to receive IRB approval for use of children.*

Research not involving greater than minimal risk

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants

Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition

Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

**(3) Wards**

*NOTE: You do not have to complete this section if wards are not involved.*

**A. Will the target population include wards of the State or another agency, institution, or entity? \***

*If the research does not involve wards, please proceed to question #4.*

Yes  No

**B. If yes, is the research related to the children's status as wards OR the research will be conducted in schools, campus, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards?**

Yes  No

**C. If yes, will one or more individuals be appointed as an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis*?**

Yes  No

**D. If yes, will The advocate or advocates have the background and experience to act in, and agree to act in, the best interests of the child for the duration of the child's participation in the research?**

Yes  No

**E. If yes, will the advocate or advocates be associated in any way (except in the role as advocate or member of the IRB) with the research, investigator(s), or guardian organization?**

Yes  No

**(4) Prisoners**

*NOTE: You do not have to complete this section if prisoners are not involved.*

**A. Will the target population include prisoners? \***

*If the project does not include prisoners, please proceed to question #5.*

Yes  No

**B. If yes, please select all of the following that apply to the proposed research:**

The research involves the study of possible causes, effects, and processes of incarceration, and of criminal behavior AND the research presents no more than minimal risk and no more than inconvenience to the participants.

The research involves the study of prisons as institutional structures or of prisoners as incarcerated persons AND the research presents no more than minimal risk and no more than inconvenience to the participants.

The research is conducted or supported by DHHS; OR the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics; OR the Secretary has published notice of his intent to approve such research

The research is on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons; and research on social and psychological problems such as alcoholism, drugs, etc.)

The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant

The research does not require the assignment of prisoners to control groups that may not benefit from the research

The sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases OR to study potential risk factor associations for a disease

The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants AND prisoners are not a particular focus of the research.

**C. Are any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired?**

Yes  No

**D. Please explain.****E. Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?**

Yes  No

**F. Please explain.****G. Are procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?**

Yes  No

**H. Please explain.**

**I. Will control participants be selected randomly from the group of available prisoners who meet the characteristics needed for the research project?**

Yes  No

**J. Please explain.**

**K. Does adequate assurance exist that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole?**

Yes  No

**L. Please explain.**

**M. Will each prisoner be clearly informed in advance that participation in the research will have no effect on his or her parole?**

Yes  No

**N. Please explain.**

**(5) Pregnant Women**

*NOTE: You do not have to complete this section if pregnant women are not involved.*

**A. Will the target population include pregnant women? \***

*If the project does not include pregnant women, please proceed to question #6.*

Yes  No

**B. Were scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, conducted to assess potential risks to pregnant women and fetuses?**

*Please upload all supportive literature.*

Yes  No

**C. Is the purpose of the activity to meet the health needs of the mother and fetus?**

Yes  No

**D. Please explain.**

**E. Is the risk to the fetus caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?**

Yes  No

**F. Is the risk to the fetus minimal?**

Yes  No

**G. Please explain.**

**H. Is the risk the least possible for achieving the objectives of the research?**

Yes  No

**I. Is the research designed to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses?**

Yes  No

**J. Please explain.**

**K. Are the expectant mother and father legally competent?**

Yes  No

**L. Does the research team intend to seek a waiver of the father's consent?**

Yes  No

**M. If seeking a waiver of the father's consent, please select the reason(s):**

*Check all that apply.*

- He is incompetent
- He is not reasonably available
- He is temporarily incapacitated
- His identity or whereabouts cannot reasonably be ascertained
- The pregnancy resulted from rape or incest
- The research is to meet the health needs of the mother

**N. Will each individual providing consent be fully informed regarding the reasonably foreseeable impact of the research on the fetus?**

Yes  No

**O. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?**

Yes  No

**(6) Other Vulnerable Subject Populations**

**A. Will the target population include EMPLOYEES? \***

Yes  No

**B. If yes, please list the precautions that will be used to protect the employee participants.**

**C. Will the target population include STUDENTS? \***

Yes  No

**D. If yes, please list the precautions that will be used to protect the student participants.**

**E. Will the target population include WOMEN OF CHILDBEARING POTENTIAL? \***  
 Yes  No

**F. If yes, please list the precautions that will be used to protect the female participants.**

**G. Will the target population include COGNITIVELY IMPAIRED PERSONS? \***  
 Yes  No

**H. If yes, please list the precautions that will be used to protect the cognitively impaired participants.**

**I. Will the target population include LOW-INCOME INDIVIDUALS? \***  
 Yes  No

**J. If yes, please list the precautions that will be used to protect the low-income participants.**

**K. Will the target population include MINORITIES? \***  
 Yes  No

**L. If yes, please list the precautions that will be used to protect the minority participants.**

**M. Will the target population include the ELDERLY? \***  
 Yes  No

**N. If yes, please list the precautions that will be used to protect the elderly participants.**

**O. Will the target population include INTERNATIONAL SUBJECTS? \***  
 Yes  No

**P. If yes, please list the precautions that will be used to protect the international participants.**

**(7) If your study involves any of the vulnerable subject populations mentioned above, please provide a description of additional safeguards included in your protocol.**

*Vulnerable Subject Categories Include: Children, Wards, Prisoners, Pregnant Women, Employees, Students, Women of Childbearing Age, Cognitively Impaired Individuals, Minorities, Elderly, and International Persons.*

**(8) Salient Characteristics \***

*List the salient characteristics of the targeted subject population in your study.*

**(9) Describe your inclusion criteria and explain whether prospective participants may be vulnerable to coercion or undue influence. \***

**(10) Describe your exclusion criteria. \***

**(11) What activities will your prospective subjects be asked to complete? \***  
*How will the subjects participate in the study (i.e., what do the subjects do)?*

**(12) List the number of times you will be interacting or intervening with your subjects. \***

### SECTION J - Subject Recruitment and Selection

**(1) Subject Recruitment \***

**A. Explain your recruitment process and enrollment procedures. \***

**B. Do you intend to use advertisements to recruit subjects? If so, please upload the final copy the advertisements. \***

*Upload all copies of printed advertisements and/or audio/video taped advertisements.*

Yes  No

**(2) Subject Selection**

*Please describe how subjects are selected and how the selection is equitable.*

**(3) Subject Participation**

**A. Will the subject's identity remain anonymous, confidential, or other? \***

*Please select from the following:*

**B. Please explain. \***

**C. Does your research involve an investigation into legal matters, illegal activities, admissions of guilt, any acts of violations, breaches of duties or noncompliant matters? \***

Yes  No

**D. If YES, please explain:**

**E. Do you intend to obtain a Certificate of Confidentiality? \***

Yes  No

**F. If you have already obtained a Certificate of Confidentiality, what is the expiration date of the certificate?**

**(4) Subject Inducement**

**A. Are you offering an inducement for the subjects' participation? \***

Yes  No

**B. If yes, describe the offered inducement.**

*Please include information about the amount, method, and timing of disbursement.*

**C. Have you contacted the Accounting Services Department at 882-3051 to assure the proposed payment distribution complies with the policies of the University of Missouri?**

**NOTE: If you are using personal funds, you do not need to submit to the Accounting Services Office for approval. Please state in the application that you are using personal funds, if applicable.**

*You must obtain approval if you are using internal funds or external funds.*

*If you intend to compensate research participants with payments, cash, or non-cash items such as credits to student accounts or other items of value, please contact Accounting Services at 882-3051 to implement a system consistent with accounting protocol prior to the distribution of such compensation. If you have any questions, please click on the above help link.*

Yes  No

**D. If you are offering extra credit incentives for student participation, describe the alternative assignment for students who may decline. The alternative assignment must be comparable in effort and time commitment.**

*Federal regulations require the Board to ensure there are no coercive elements in human research projects. Pursuant to 45 CFR 46.111(b), "When some or all of the subjects are likely to be vulnerable to coercion or undue influence...additional safeguards have been included in the study to protect the rights and welfare of these subjects."*

**E. In your opinion, will the subjects be influenced by the payments offered? Please explain.**

**(5) Access to Student Grades**

**A. Are you requesting information about student's grades through the Registrar's Office? \***

Yes  No

**B. Have you contacted the Registrar's Office?**

*You must UPLOAD the approval from the Registrar's Office prior to IRB approval.*

Yes  No

**C. Did you upload the approval from the Registrar's Office?**

Yes  No

**(6) Privacy**

**A. Please explain how you intend to protect the privacy interests of participants during the research. \***

**B. Please explain how you intend to protect the privacy interests of participants after their involvement in the research. \***

**(7) Questions/Concerns**

**A. Describe the procedure(s) in place for research participants to ask questions and voice concerns or complaints to the research investigator(s). \***

**B. Describe the procedure(s) in place for participants to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is not affiliated with the research project. \***

**SECTION K - Consent Process**

**(1) Informed Consent Process**

**A. What type of consent will be used? \***

- Child/Youth Assent
- Oral Consent (Short Form)
- Parental Consent
- Waiver - Secondary Data
- Waiver of Consent
- Waiver of Parental Consent
- Waiver of Written Documentation (Signature)
- Waiver of Youth Assent
- Written Consent Form
- Written Consent with Electronic Signature

**B. Describe the informed consent process in detail. \***

**C. Who will conduct the consent process? \***

**D. Describe the person or persons who will give consent or permission. \***

**E. What is the waiting period between informing the prospective participant and obtaining the consent? \***

**F. Describe the steps taken to minimize the possibility of coercion or undue influence. \***

**G. Describe the information to be communicated to the prospective participant or the**

representative. \*

**(2) Parental Consent: For projects involving children, you must complete this section.**

**A. Are children (under 18 years of age) included in the subject population? \***

*If children are not included, please proceed to question #3.*

Yes  No

**B. Does the research team intend to secure consent from both of each child's parents or guardians?**

Yes  No

**C. Does the research team intend to secure consent from only one of each child's parents or guardians?**

Yes  No

**D. If consent will only be obtained from one parent, please select the reason(s):**

*Check all that apply.*

- Research does not involve greater than minimal risk
- Research involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects
- One parent is deceased, unknown, incompetent, or not reasonably available
- Only one parent has legal responsibility for the care and custody of the child

**E. Does the research team intend to waive the requirement for parental consent?**

Yes  No

**F. If a waiver of parental consent is requested, please select the reason(s):**

*Check all that apply.*

- The research protocol is designed for conditions for which parental or guardian permission is NOT a reasonable requirement to protect the participants
- The research protocol is designed for a participant population for which parental or guardian permission is NOT a reasonable requirement to protect the participants
- An appropriate mechanism for protecting the children who will participate in the research is substituted

**(3) Language Barriers**

**A. Are there any language barriers between you and the subjects in your project? \***

Yes  No

**B. If yes, how do you propose to manage the language barrier?**

**C. Do you intend to use a translator?**

Yes  No

**D. If you intend to use a translator, please list their contact information below.**

**E. If the research materials (i.e. consent forms, recruitment materials, instruments, etc.) will be presented in a language other than English, have you uploaded the translated documents?**

Yes  No

**(4) Child Assent: For projects involving children, you must complete this section.**

**A. Does the research team intend to seek assent from all capable children?**

Yes  No

**B. Is each child capable of providing assent based on age, maturity, and psychological state?**

Yes  No

**C. Please explain.**

**D. Does the intervention or procedure involved in the research hold out a prospect of direct benefit that is important to the health or well-being of the children?**

Yes  No

**E. If yes, please explain.**

**F. Is the intervention or procedure involved in the research available only in the context of the research?**

Yes  No

**(5) Waiver of Written Documentation (Signature)**

**A. Are you requesting a waiver of the signature requirement for informed consent? \***

Yes  No

**B. Please list which subject population(s) in which you are requesting to waive the signature requirement.**

**C. Would the only record linking the participant to the research be the informed consent document?**

Yes  No

**D. Would the principal risk to participants be potential harm resulting from a breach of confidentiality?**

Yes  No

**E. Will each participant be asked whether the participant wants documentation linking the**

participant with the research?

Yes  No

**F. Will participants be provided with a written statement regarding the research?**

Yes  No

**G. Are you requesting a waiver of signature because this is an online survey?**

Yes  No

**H. Are you requesting a waiver of signature because this is a mailed survey?**

Yes  No

### SECTION L - Data Collection

#### (1) Data Anonymity/Confidentiality of Data

**A. Will the data collected be anonymous, confidential or neither? \***

*Data is anonymous if it is recorded in such a manner that human subjects cannot be directly identified, or through identifiers linked to the subjects. Data collected in a manner where it contains identifiers which can be linked to subjects is not anonymous, but can be kept confidential through means including, but not limited to, aggregate reporting, assigning codes, removal of identifiers, etc.*

Anonymous Data

Confidential Data

Neither Anonymous Nor Confidential

**B. How do you intend to protect the confidentiality of the data collected?**

#### (2) Data Sharing \*

**A. Do you intend to publish or share the DATA from this project? \***

Yes  No

**B. If yes, identify the person/entity with whom you intend to share or publish the data.**

#### (3) Result Sharing

**A. Do you intend to publish or share the RESULTS from this project? \***

Yes  No

**B. Please explain. \***

#### (4) Data & Records

**A. Are you a member of any one of the following entities: MU Health Care, Student Health**

**Center, Intercollegiate Athletics, the Consultation and Assessment Clinic, the Psychology Clinic, or the Counseling Center? \***

Yes  No

**B. Are you sharing data with any one of the following entities: MU Health Care, Student Health Center, Intercollegiate Athletics, the Consultation and Assessment Clinic, the Psychology Clinic, or the Counseling Center? \***

Yes  No

**C. Do you possess, or will you be obtaining health information or records of the subjects? \***

Yes  No

#### SECTION M - Blood Information

**(1) Do you intend to collect blood samples in this project? \***

Yes  No

**(2) If blood will be drawn, enter the following information**

**A. Explain the purpose for drawing blood sample(s).**

**B. Type of blood**

**C. Identify the location from where the blood is drawn.**

**D. How many times will blood be drawn from the subject?**

**E. Identify the amount of blood drawn each instance.**

**F. List the qualifications of the individual drawing the blood sample.**

**G. Identify the location where the blood will be stored.**

**H. Identify the individuals who have access to the blood sample.**

**I. Who is paying for having the blood drawn?**

**J. Identify persons/entities with which you intend to share data from the blood sample.**

#### SECTION N - Other

**(1) Will the activities involve the use of any type of drugs, herbs, caffeine, food-additives, or tobacco? \***

Yes  No

**(2) If you answered YES to Question 1, please provide a complete description of how you propose to incorporate the substance in the research activities.**