|  |
| --- |
| **This section to be completed by IRB Committee**  Protocol #:  Received Date:  Approval Date:  Expiration Date: |

**Southwest Minnesota State University**

**Institutional Review Board**

**Application to Conduct Research**

**Using Human Participants**

Complete the form (**please type)** and send via mail to the chair of the IRB committee.

**Administrative Data**

|  |  |
| --- | --- |
| Department: | |
| Principal Investigator (PI): | |
| Mailing Address: | |
| Phone: | Email: |
| Project Title: | |
| Faculty Advisor (if PI is a student): | |
| Phone: | Email: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Type of Submission: (Check all that apply)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initial Submission | | | |  | Revision | |  | | Renewal | | |  | | Change of PI | |  |  | | |  | | |  |  |  | |  | |
| Previous Protocol #: (if not Initial Submission) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If the originally approved protocol was Student-Directed Research, documentation of permission from original to new PI is attached. | | | | | | | | | | | | | | | | |
| *Academic Project Type:* | | | | | | | | | | | | | | | | | | | | | |
| Faculty Research | | | |  | | | Student-Directed Research | | | |  | | | Other (explain below) | |  | | | | | | |
| *Duration of Project:* | | | | | | | | | | | | | | | | | | | | | |
| Starting Date: | | | |  | | | | | | Ending Date: | | |  | | | | | | | | | |

**Part I:** Please check the appropriate response.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Will participants be identifiable to anyone other than the researchers through records, responses, or identifiers linked to the individual? | Yes |  | No |  |
| 1. Could participants be at risk of criminal or civil liability, damage to employability or financial standing, or undue embarrassment, if responses became known outside of the research project? | Yes |  | No |  |
| 1. Does the research deal with sensitive aspects of participants’ behavior, such as   illegal conduct, drug use, sexual behavior, or use of alcohol? | Yes |  | No |  |
| 1. Does the research involve the collection or study of existing data from sources   not publicly available (existing data can be documents, records, pathological  specimens or diagnostic specimens)? | Yes |  | No |  |
| 1. Will participants be videotaped? audiotaped? | Yes |  | No |  |
| 1. Does the research deal with participants who are under eighteen years of age? (If so, answer question 4 in Part II) | Yes |  | No |  |
| 1. Is there deception of participants? (If so, answer question 5 in Part II) | Yes |  | No |  |
| 1. Are participants free to withdraw at any time without penalty? | Yes |  | No |  |
| 1. Does the research deal with participants who are: |  |  |  |  |
| * Not legally competent adults? | Yes |  | No |  |
| * Mentally disabled? | Yes |  | No |  |
| * Physically challenged? | Yes |  | No |  |
| * Prisoners? | Yes |  | No |  |
| * Pregnant? | Yes |  | No |  |
| 1. Does the project involve: |  |  |  |  |
| * Administering drugs? | Yes |  | No |  |
| * Administering alcohol? | Yes |  | No |  |
| * Administering nutritional supplements? | Yes |  | No |  |
| * Taking tissue samples? | Yes |  | No |  |
| * Drawing blood? | Yes |  | No |  |
| * Giving injections? | Yes |  | No |  |
| 1. Does the project involve tasting food: |  |  |  |  |
| * With additives or ingredients above the recommended FDA, EPA, or USDA safe levels? | Yes |  | No |  |

(If any of the answers to question 10 are “yes,” then discuss qualifications in Part II, question 1.e.)

**Part II:** Please type responses to each question.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Summarize the proposed project, including | | | | | |
| 1. Goals/research purpose: | | | | | |
|  | | | | | |
|  | | | | | |
| 1. Hypotheses/research questions: | | | | |
|  | | | | |
|  | | | | |
| 1. Methodology: Explain in detail both study design and procedures. | | | | |
|  | | | | |
|  | | | | |
| 1. Data collection documents attached | | | | | |
|  |  | Questionnaire/s, | | | |
|  |  | Interview protocols | | | |
|  |  | Other. Specify: |  | | |
| 1. Specific licenses/qualifications described and attached as needed | | | | | |
|  | | | | | |
| 1. Identify any physical or psychological risks (here and in the consent form) that are beyond the risks normally encountered in everyday life. | | | | | |
|  | | | | | |
|  | | | | | |
| 1. What safeguards will you use to protect the participants from these risks, as well as to protect their rights, welfare, and privacy? | | | | | |
|  | | | | | |
|  | | | | | |
| 1. Participants will be informed of the risks through: | | | | | |
|  |  | Consent form (attach copy) | | | |
|  |  | Verbal (attach script) | |  | |

|  |
| --- |
| 1. Describe the benefits expected to be gained from this project. (This should include any direct benefits to the participants as well as any general gain in knowledge.) |
|  |

|  |
| --- |
| 1. If you will be using participants under the age of 18, |
| 1. Explain in detail how you will obtain parental consent. |
|  |
|  |
| 1. If consent will be obtained orally, supply a script of what you will say and how you will give children the opportunity to say “yes” or “no.” (See Policy 2.5 Informed Consent) |
|  |

|  |  |  |
| --- | --- | --- |
| 1. Does the proposed study involve deception? | | |
|  |  | Yes |
|  |  | No |

If “yes,” then answer the following:

|  |
| --- |
| 1. Describe the type of deception being used. |
|  |
|  |
| 1. Why is deception necessary to the research design? |
|  |
|  |
| 1. Are there alternative procedures that do not involve deception and why were the alternatives rejected? |
|  |
|  |
| 1. Describe the debriefing that will be used after the study. |
|  |

|  |
| --- |
| 1. Describe the methods used to safeguard the data. |
|  |

**Signature Page**

**Principal Investigator Certification**

I certify that the research procedures for this project and the method of obtaining consent (if any), as approved by the Institutional Review Board, will be followed during the period covered by this research project. Any future changes will be submitted for Board review and approval prior to implementation.

**Principal Investigator(s):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature: |  | Date: |  |
| Name: |  | Signature: |  | Date: |  |
| Name: |  | Signature: |  | Date: |  |
| Name: |  | Signature: |  | Date: |  |

**Faculty Advisor (If PI is a student):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature: |  | Date: |  |

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**For IRB use:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Approved |  | Full Review |
|  | Approved with Conditions |  | Expedited Review |
|  |  |  |  |
|  | Denied |  | Exempt |

|  |  |
| --- | --- |
| **Comments:** |  |

**Approval Signatures:**

|  |  |
| --- | --- |
| Name:­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |