****

For Office Use Only

Date Received \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proposal # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer #1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer #2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**APPLICATION TO THE INSTITUTIONAL REVIEW BOARD**

**FOR PROTECTION OF HUMAN SUBJECTS**

**Title of Project**:

**Name of Principal Investigator (PI):**

**PI is WSC:  Faculty  Staff  Undergraduate Student  Graduate Student**

**If PI is student, name of research advisor:**

**If class project, name of professor:**

**PI’s mailing address:**

**PI’s telephone number:**

**PI’s email address:**

**Are there human subjects involved in this project?** \_\_\_ Yes \_\_\_ No

Human subjects are involved in a project if it uses data from human responses, observations of human beings or human materials, whether such data are obtained directly from human sources or from secondary sources.

**If the answer to the above is “no,” do not complete or submit this form.**

**Certification Statement**

By making this application, I certify that I have read and understand Wayne State College’s policy governing research with human subjects and the Ethical Principles for the Conduct of Research with Human Subjects as formulated by the HSIRB. I shall comply with the letter and the spirit of those documents. Furthermore, I am aware that certain departments may have their own standards for conducting human research and that it is up to me to familiarize myself with them. I also acknowledge my obligation to obtain written approval for any significant deviations from the originally approved protocol before making those deviations and to report immediately all adverse effects of the study on the participants to the Chairperson of the HSIRB and to the Academic Vice President. I also certify that the rights and welfare of the subjects are adequately protected and that informed consent of subjects will be obtained by methods that are adequate and appropriate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Advisor Date

*(The advisor’s signature is required for graduate and undergraduate student applications.)***Section A. Research Proposal**

1. Research Project Start Date:

(we recommend “upon IRB approval” rather than a specific calendar date)

Research Project End Date:

(If the end date is more than one calendar year after the start date, you will need to apply for an extension as IRB approval can only be given for up to one year.)

2. **Research Problem**  
Please provide a brief statement (3-5 sentences) of the research problem.

3. **Participants**

a. Who are they?

b. How many?

c. Age(s)?

d. How will potential subjects be identified for purposes of recruitment?

*(class, phone book, membership lists, etc.)*

e. How will potential subjects be recruited and screened once they are identified?

*(Provide documentation of agreement from individuals or organizations that are cooperating with you to recruit subjects. If your research has outside organizations involved, a letter agreeing to the participation must be attached.)*

f. If participants are under 18 years of age, will parental permission be obtained?

\_\_\_ Yes \_\_\_ No \_\_\_N/A (participants will be 18 or older)

If no, please explain.

*Note: Persons under 18 years of age should be informed of their right to choose to*

*participate and to withdraw from participation, even if parental permission has been*

*obtained.*

g. Are subjects to be told that participation is voluntary and that they are free to withdraw at any time?

\_\_\_ Yes \_\_\_ No

If no, why?

4. **Procedures**

Step-by-step description from the point of view of the participants, what they will experience:

1. Participants will receive 2 copies of Informed Consent document to sign.

2. Participants keep one copy of signed Inform Consent document and return the other signed copy to the researcher.

3.

4.

5.

6.

7.

8.

5. **Debriefing Statement/Process**

Debriefing should be a part of the procedure. Debriefing generally includes a statement of appreciation to participants, an explanation of the overall purpose of the research, a way to learn about the results, and sometimes information resources to access assistance if subjects would benefit from a service related to the research problem. If the research involves deception, a written debriefing statement is required.

**Section B. Risk Evaluation**

A research subject is considered to be at risk if s/he may be exposed through the procedures of the proposed research to the possibility of physical or mental harm, coercion, deceit, or invasion of privacy. Examples of placing subjects at risk of harm include administration of drugs, requiring unusual physical exertion, deception, and public embarrassment and humiliation.

Coercion is a potential risk when subjects are not able to exercise their right to decline to participate. This is a special concern where the principal investigator or his/her advisor is in a relationship of greater power over the participants (e.g. professor-student relationship).

Additionally, risks arise when subjects could potentially experience discomfort, anxiety, invasion of privacy or loss of dignity. Risks also arise from the use of stored data or information that was initially obtained for other purposes.

1. **Risk Assessment**
   * Indicate whether or not the following risks are present in the research.
   * Provide a rationale for why you are using a special group, equipment, and/or procedure.
   * Describe and assess any potential risks. Consider this from the perspective of the participant. Could s/he feel frightened, intimidated, embarrassed, become ill, etc.? If another research method which would reduce potential risks was not chosen for use, please provide a rationale.
   * Describe procedures of the proposed research designed to protect against or minimize the potential risk. Assess the effectiveness of these procedures.

|  |  |  |
| --- | --- | --- |
| a. | **Students will be used as subjects.**  *(If using college or K-12 students – the risk is that they may feel coerced to participate; therefore, you will need to state this as a risk and how you plan to address this risk.)*  Rationale for using students as subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| b. | **Experimental drugs will be used.**  Rationale for using experimental drugs:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| c. | **Potential for medical problems exists.**  *(Must include referral in consent form.)*  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| d. | **Non-English speaking subjects will participate.**  Rationale for using non-English speaking subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| e. | **Minors (less than 18 years of age) will participate.**  Rationale for using minors:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| f. | **Mentally disabled subjects will participate.**  Rationale for using mentally disabled subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| g. | **Incarcerated subjects will participate.**  Rationale for using incarcerated subjects:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| h. | **Participants may experience physical discomfort.**  *(Must include referral in consent form.)*  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| i. | **Participants may experience mental discomfort.**  *(Must include referral in consent form.)*  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| j. | **Electrical equipment will be used.**  Rationale for using electrical equipment:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| k. | **Mechanical equipment will be used.**  Rationale for using mechanical equipment:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| l. | **Deception will be used.**  *(Debriefing statement is required).*  Rationale for using deception:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| m. | **Participants will be photographed or recorded (audio or video).**  Rationale for using photographs or recordings (audio or video:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |
| n. | **Internet survey will be used (see Internet Research Policy).**  Rationale for using internet survey:  Describe and assess potential risk:  Describe measures to minimize and address risk: | \_\_\_ Yes \_\_\_ No |

1. **Benefit Assessment**

a) Describe the benefits to the subjects.

b) Describe the significance of the study and contributions to the general knowledge in the field of inquiry.

**Section C: Managing and Storing Raw Data**

Describe procedures and recording and storing data and the final disposition of raw data or coding identifiers.

*For IRB purposes, Raw Data is any source material that can be linked to a specific individual. Raw data includes but is not limited to video files, audio files, transcriptions, questionnaires, surveys, numeric data, health history questionnaires, and coding identifiers. All forms of raw data that pertain to your study must be clearly addressed in this section.*

*Raw data containing Personally Identifiable Information (PII) about participants must not be accessible to parties who are not involved in the study. Paper files and USB drives identifying participants should be kept in locked locations, in an advisor’s office, such as file cabinet drawers. Computer files containing PII (other than USB drives) should only be kept in a WSC password-protected location.*

*The American Psychological Association protocol calls for raw data to be kept for a minimum of five years after completion of the study.*

1. Identify the raw data associated with your study.
2. How will the raw data be recorded? (Be sure to address how confidentiality will be maintained.)
3. Where will the raw data be stored? How long?
4. How will you dispose of the raw data?

**Section D. Consent Form**

Whenever possible, obtain informed consent (a signed form) from all participants. In online surveys, include a statement stating that completing the survey implies consent, following the Elements of Informed Consent below. Always use plain language. Avoid technical terms or discipline jargon. An example of a consent form is available in “Guidelines for Researchers.”

Include in your informed consent (please check as you complete):

\_\_\_\_ 1. Explanation of the purpose of the study, description of procedures to be followed.

\_\_\_\_ 2. Identification of individuals performing the procedures and their credentials.

\_\_\_\_ 3. Description of possible immediate and long-term discomforts, hazards and risks.

\_\_\_\_ 4. Description of any benefits to participants or potential benefits to society.

\_\_\_\_ 5. Offer to answer any questions concerning the procedures at any time.

\_\_\_\_ 6. A statement that participants are free to withdraw consent and to discontinue participation at any time without prejudice to their future relations with WSC, their professors, or the principal investigator.

\_\_\_\_ 7. Assurance that the identities of the participants will not be disclosed without the participant’s consent.

\_\_\_\_ 8. If a mental or physical risk is identified, include appropriate healthcare professional referral information (such as WSC Counseling Center or WSC Student Health or non-student community resources).

\_\_\_\_ 9. If subject is photographed or recorded (audio or video), consent must contain statement to be initialized by subjects.

\_\_\_\_ 10. Notification that if the participants are minors (less than 18 years of age), one parent or legal guardian must sign the consent form).

\_\_\_\_ 11. Faculty and staff provide each participant with the name and telephone number of the principal investigator. Graduate students must provide each participant with the name and telephone number of the principle investigator and research advisor. Undergraduate students must provide each participant with the name and e-mail address of the principle investigator and the name and telephone number of the research advisor.

**Section E. Materials and Apparatus**

To this document, **attach** copies of all written materials to which subjects will be exposed including questionnaires, survey, instructions, cover letters, consent/assent forms, debriefing statements (required when deception is part of study), etc.

If applicable, **attach** Human Performance Lab protocols, documentation of agreement from individuals or organizations that are cooperating with you to recruit subjects (i.e. school districts, team coaches), and/or letters of participation from outside organizations working with you.

**Section F. IRB Review Level**

The Federal government requires that copies of ALL research proposals involving human subjects be on file with the Institutional Review Board. Certain types of research may be exempt from full IRB review or qualify for expedited review. Exempt status does not relieve the researcher from the obligation to obtain consent from the subjects, their representatives, or cooperating organizations.

To help determine the level of review, please see “Guidelines for Researchers.”

Please check the level of review you are requesting:

\_\_\_ Exempt \_\_\_ Expedited \_\_\_ Full

Revised December 2017