



APPLICATION TO THE INSTITUTIONAL REVIEW BOARD
FOR PROTECTION OF HUMAN SUBJECTS

Title of Project

Name of Principal Investigator (PI)

If PI is student, name of advisor

If class project, name of professor

Name(s) of graduate assistant(s)

PI's mailing address

Telephone

E-mail address

Fax number

Anticipated starting and completion dates

Funding agency, if any

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

(Advisor's signature required for graduate and undergraduate student applications)

Section A: Research Proposal

1. Please provide a brief statement of the research problem with a short justification:

2. Participants

a. Who are they?

b. How many?

c. Age(s)

d. How will subjects be selected for purposes of recruitment? (class, phone book, membership lists, etc.?)

e. How will subjects be recruited 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 19 years of age, will parental permission be obtained?

Yes

No

If no, please explain.

Note: Persons under 19 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?

3. **Materials and apparatus.** Attach to this document copies of all written materials to which subjects will be exposed including questionnaires, instructions, cover letters, etc. If applicable, attach Human Performance Lab protocols.

4. **Procedures.** (Step by step description from the point of view of the participants, what they will experience):

1.

2.

3.

4.

5.

6.

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. Elements of debriefing might appear in a cover page to a survey, be done orally, or through a written debriefing statement distributed or read to subjects. If the research involves deception, a written debriefing statement is required.

Section B: Risk Evaluation

1. Risk Criteria.

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.

- | | | |
|---|------------------------------|-----------------------------|
| a. Students will be used as subjects. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Experimental drugs will be used. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Potential for medical problems exists. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Non-English speaking subjects will participate. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Minors (less than 19 years of age) will participate. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Mentally disabled subjects will participate. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Incarcerated subjects will participate. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Participants may experience physical discomfort. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| i. Participants may experience mental discomfort. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| j. Electrical equipment will be used. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| k. Mechanical equipment will be used. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| l. Deception will be used. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| m. Participants will be tape recorded, photographed or video-taped. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- Rationale for using special groups** (i.e. minors, mentally disabled, incarcerated individuals or any other groups whose ability to give voluntary consent may be in question).
- Describe and assess any potential risks** (physical, mental, or other). 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 for recording and storing data, and the final disposition of raw data or coding identifiers.** (The American Psychological Association protocol calls for raw data to be kept or three years after completion of the study. Destroy raw data as soon as feasible.) Be sure to address the confidentiality issues.
- If deception is used, provide a rationale for its use.**
- Describe procedures of the proposed research designed to protect against or minimize the potential risks. Assess the effectiveness of these procedures.**
- Describe the benefits to the subjects and contributions to the general knowledge in the field of inquiry.**

Section C: Request for Exemption from Full IRB Review

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. To help determine whether your research is exempt, place a mark next to the following categories that you believe apply to your research. Exempt status does not relieve the researcher from the obligation to obtain consent from the subjects, their representatives, or cooperating organizations.

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research about regular and special educational instructional strategies, or research about the effectiveness of or the comparisons among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), questionnaires, or information about subject history, if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 3. Research involving survey or interview procedures, where the subjects are legally competent and where the investigator identifies her/himself, and states that s/he is conducting a research survey or interview except where both of the following conditions exist:
 - a. responses are recorded in such a manner that the subjects can be identified directly or through identifiers linked to the subjects and
 - b. the subjects responses, if they became known outside of the research, could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subject's financial standing or employability; or the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug or alcohol use, or sexual behavior.
- 4. All research involving survey or interview procedures (without exception) if the respondents are elected or appointed public officials or candidates for public office.
- 5. Research involving the observation (including the observation by participants) of public behavior in places where there is no recognized expectation of privacy.
- 6. Research involving the observation (including the observation by participants) of public behavior in places where there is a recognized expectation of privacy unless both of the following conditions exist:
 - a. Observations are recorded in such a manner that the subjects can be identified directly or through identifiers linked to the subjects and
 - b. The observations recorded about the subject, if they became known outside of the research, could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subject's financial standing or employability, or the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug or alcohol use, or sexual behavior.
- 7. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- 8. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payments for benefits or services under those programs.

9. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome food without additives are consumed or (b) if the food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If your research does not fall into one of the above categories, then it will be subject to either Expedited Review or a Full IRB Review. The purpose of these reviews is to provide assistance to the principal investigator in regard to research design and ethics.

The Chair of the HSIRB Council will review your request for exemption. You will receive notice from the Chair if your request is granted. You may be asked to provide additional or revised information prior to approval being given. Do not begin your study until you receive approval from the HSIRB. Retain the exemption letter in your files.

Section D: Consent Form

Whenever possible, obtain informed consent (a signed form) from all participants. Always use plain language. Avoid technical terms or discipline jargon. Provide each participant with the name and telephone number of the principal investigator and advisor on the consent form or cover letter.

Elements of informed consent:

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. Notification that if the participants are minors (less than 19 years of age), one parent or legal guardian must sign the consent form.

Template for a Consent Form

You are invited to participate in a study of (*State what is being studied*). We hope to learn (*State what the study is designed to discover or measure*). You were selected as a possible participant in this study because (*State why and how the subject was selected*).

If you decide to participate, the researcher and his/her associates will (*Describe the procedures to be followed, how long they will take, and their frequency, if applicable. Describe any discomforts and inconveniences that can reasonably be expected. Estimate the total time required. Describe the risks and benefits reasonably to be expected.*).

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. (*If research will release information to anyone for any reason, state the persons or agencies to whom the information will be furnished, the nature of the information that will be furnished and the purpose of the disclosure.*).

(*If the participants will receive compensation or any other benefits, describe the amount or nature. Disclose any alternate ways that the benefits may be obtained. If participants may incur costs because of participation, disclose an estimate of the amount.*)

Your decision whether or not to participate will not prejudice your future relations with Wayne State College, (*name of professor and principal investigator*). If you decide to participate, you are free to discontinue participation at any time without prejudice.

If you have any questions, please ask us. If questions arise later, (*State name of principal investigator and advisor with telephone numbers and addresses*) will be happy to answer them.

Your signature indicates that you have read and understand the information provided above and have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.

Signature

Date _____

Signature of Parent or Legal Guardian

Date _____

(The last line should not appear on forms that will be given to legally competent participants.)

Expedited Review

The following are situations where expedited review is permissible. An expedited review consists of a review of research involving human subjects by the HSIRB chairperson and/or one or more experienced reviewers designated by the chairperson from among the members of the HSIRB. Special circumstances may require that the proposal receive full HSIRB review.

1. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, oral history, focus group, program evaluation, human factors evaluation of quality assurance methodologies. (This listing only applies to research that is not otherwise exempt.)
2. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - b. weighing or testing sensory acuity;
 - c. magnetic resonance imaging;
 - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography;
 - e. moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given age, weight, and health of the individual.
3. Collection of blood samples by finger, stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weight at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it is collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.
 4. Prospective collection of biological specimens for research purposes by noninvasive means:

Examples:

- a. hair and nail clippings in a nondisfiguring manner;
- b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- c. permanent teeth if routine patient care indicates a need for extraction;
- d. excreta and external secretions (including sweat);
- e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- f. placenta removed at delivery;
- g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

- h. supra-and subgingival dental plaque and calculus, provided the collection procedure is no more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - i. mucosal and skin cells collected by buccal scraping or swab, or mouth washings;
 - j. sputum collected after saline mist nebulization.
- 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: Some research in this category may be exempt. This list refers only to research that is not exempt.
- 6. Collection of data from voice, video, digital or image recordings made for research purposes.
- 7. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (a) an investigational device exemption application (21 CFR Part 812) is not required or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 8. Continuing review of research previously approved by the convened HSIRB as follows:
 - a. the research is permanently closed to the enrollment of new subjects, subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.