

**Human Subjects Institutional Review Board
Wayne State College
Guidelines for Researchers: 2003-2004**

I. Federal Guidelines:

Wayne State College HSIRB abides by the **Code of Federal Regulations, Title 45: Public Welfare**”, developed under the **Department of Health and Human Services division of the National Institutes of Health, Office for the Protection From Research Risks, Part 46: “Protection of Human Subjects”** (Dec. 13, 2001). This policy was developed as a guide to ethical research involving human subjects. The goal is to protect vulnerable individuals from unnecessary harm while maximizing the potential benefits resulting from research. It is the responsibility of all researchers to be knowledgeable of and follow Federal Guidelines for ethical research involving human subjects. Failure to do so not only compromises the integrity of the entire WSC community but may jeopardize federal funding for WSC. Following these guidelines protects both the subjects and the researchers. Some definitions are helpful:

1. **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research “are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

2. **Intervention:** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed *for research purposes*. Permission to *use* the data collected routinely in educational or medical settings regardless of research intentions, would then be evaluated on the basis of privacy concerns.

3. **Interaction:** Includes communication or interpersonal contact between investigator and subject.

4. **Private Information:** Includes information about behavior that normally occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

5. **Human Subjects:** A living individual about whom an investigator will obtain for research purposes, either:

- a. Data through intervention or interaction with the individual, or
- b. Identifiable private information

II. Types of HSIRB Reviews:

A. Exempt: Research in which the only involvement of human subjects will be in one of the following categories is exempt from review (They do not fall under the classification of “human subjects” as defined in #5). In general, the following summarizes the federal guidelines regarding proposals exempt from full IRB review:

- i. Research conducted in established or commonly accepted educational settings, involving *normal educational practices* (instructional strategies, techniques, curricula or management methods).
- ii. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey interview, or observation *as long as individual privacy is protected*, and information could not possibly be incriminating or produce civil liability or damage the subjects’ financial standing, employability or reputation.
- iii. Research that involves subjects who are elected or appointed public officials or candidates for public office.
- iv. Research conducted to evaluate program effectiveness – program assessment, where subject identity is not known.
- v. “Taste and food quality testing” where the foods are FDA approved.

NOTE: A request for exempt status must be received by the chair of the HSIRB committee. Upon review, the chair may concur with its exempt status, or may request a broader review by the HSIRB. All proposals regardless of exempt status will be kept on file in the graduate office.

B. Exemption of Research Involving Children: Research involving children is governed by the same document, (45 CFR 46:401-409: 48 Fed. Reg. 9818, March 8, 1993). To safeguard their interests, special regulatory considerations are in place for conducting research involving children. These regulations are summarized as follows:

a. Minor: Minors are classified under the state of jurisdiction in which the research will be conducted. ***In Nebraska, the legal age of consent is 19***, and includes WSC students who are under age 19, unless they have been declared an emancipated minor. Marriage confers this status, but parenthood does not.

b. Research involving children that is ***EXEMPT from IRB approval*** includes (Summarized from sections 46.401-402, Subpart D):

i. 46.101(b)(1): Research conducted in established or commonly accepted educational settings, *involving normal educational practices*, such as (i) research on regular and special education instructional strategies, (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (It is assumed that data collected will be compiled as “groups of students” with no possible way to identify individuals, or compromise privacy or confidentiality).

ii. 46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) also applies to children, however research involving surveys or interview procedures or observations of public behavior does NOT meet exemption classification. (in this case, privacy is compromised, or

intervention/interaction takes place). Information must be obtained and recorded in such a way, that subjects cannot be identified.

iii. 46.101(b)4: 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 in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.

The following guidelines are useful in determining the status of research proposals involving children (Adopted from UNL – IRB Guidelines for Research Involving Children): Research *not involving greater than minimal risk* (e.g., *most educational studies*, studies in which *behavior is not manipulated*) must meet the following requirements:

1. The potential risks must be outweighed or balanced by the potential benefits to the subject and/or society; *and*
2. Adequate provisions must be made for soliciting assent of the children and permission of the parents or guardians.
3. Parental or guardian permission is REQUIRED for minor human subjects, and assent is also REQUIRED for subjects over age 7, and recommended for minors under age 7 when possible. When no more than minimal risk is involved, one parent may sign. However, if there is greater than minimal risk, consent of both parents must be obtained unless one is deceased, unknown, incompetent or not reasonably available or when one parent has sole legal responsibility for the care and custody of the child.
4. Assent involves a child giving agreement to participate. It shows respect for a child's developing autonomy. Failure for a child to object to participation is not considered assent. Assent is agreement to participate, and is obtained according to the age and cognitive ability of the child. For children under age 7, or in individuals with cognitive/emotional development below that of an average 7 year old, explaining the procedure, and asking the child if he/she wants to participate qualifies as verbal assent. For children over the age of 7, a simple statement to read and sign may be used.

C. Expedited Review: Research involving “human subjects” as defined in #5, but involving no more than “minimal risk” as defined in #1. Expedited review may also be applied to proposals that have been previously approved, but are making minor changes within the period for which the original proposal has been approved. The procedure for expedited review involves the researcher submitting a proposal with a request for expedited review to the HSIRB. The chair of the HSIRB will review the proposal, and if he/she concurs that the proposal qualifies for expedited review, he/she will review the proposal with one other committee member.

D. Full HSIRB Review: All proposals not qualifying for exempt or expedited review will be reviewed by the full HSIRB committee. At the discretion of the Chair of the HSIRB, expedited or exempt reviews may be forwarded to the committee for full review. These reviews will be made once each month.

III. Determining the Review Status of your proposal: The following guidelines may be helpful.

1. Age: Will subjects be at least 19 years old?

- a. **Yes:** Determine Informed Consent requirements. Proceed to Risk Assessment.
- b. **No:** Determine Parental consent, subject assent requirements. Then proceed to risk assessment:

2. Risk Assessment: Is there interaction/intervention with subjects:

- a. **Yes:** Does interaction/intervention expose subjects to “more than minimal risk”? (“not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations”):
 - i. **Yes:** Requires **Full HSIRB Review:** Proceed to privacy and risk management information. Submit a final proposal to the graduate office for review by the HSIRB committee at the next scheduled meeting.
 - ii. **No:** Your proposal probably qualifies for **Expedited Review.** Proceed to Privacy Information.
- b. **No - Adults:** Your proposal probably qualifies for **Exempt Review Status.** Review privacy requirements. Submit a proposal to the graduate office for review by the Chair of the HSIRB. The Chair will notify you of approval or need for more extensive review.
- c. **No – Minors:** Review the guidelines for parental consent, subject assent. Review privacy requirements. Your proposal probably qualifies for **Expedited Review Status.** Submit a proposal to the graduate office for review by the Chair of HSIRB and one other member.

3. Risk Management: When you expose subjects to the potential risk for physical or psychological harm you must address these questions:

- a. What is the likelihood (probability) for harm?
- b. What is the potential extent of the harm?
- c. What is the potential benefit resulting from this study? Does the benefit justify the risk of harm?
- d. What is being done to minimize the potential for harm?
- e. What is being done to respond to subjects experiencing adverse effects as a result of this study? (i.e. debriefing, medical treatment, etc.)

3. Privacy Assessment: Will any public report of this research will be done in such a way that individual subjects will not be identifiable.

- a. **Yes:** Indicate how the protection of individual privacy in public reporting will be maintained, and provide information for individual access to subject data following the study when appropriate. Indicate storage of data: It is recommended that data be kept in locked files for 7 years following a study, then shredded.
- b. **No:** Studies where privacy of subjects will not be protected must clearly state so with appropriate justification. Any study where privacy will not be protected must meet with a **Full HSIRB Review.**

WSC HSIRB Approval Process:

<http://www/wsc.edu/research/>

