

**Longwood University Human and Animal Subjects Research Review Committee
Research Proposal Submission Form**

I. Proposal

All Longwood University administration, faculty, and students conducting investigations involving human subjects, and all other researchers conducting investigations involving human subjects at Longwood University, must submit a research proposal to be reviewed and approved by the Human Subject Research Review Committee prior to the commencement of research. Research involving children should conform to the ethical standards found at <http://www.srce.org/ethicalstandards.html>. **Some types of human subjects research are exempt from the provisions of state and federal law, however, even research exempt from these provisions must be reviewed by the committee to determine that they are indeed exempt.** Research proposals submitted to the committee must follow the protocols contained in this form and include the following information. *Check those that are included.*

A description of the research, including:

- 1) A Title,
- 2) The purpose of the research, and
- 3) The methods or procedures to be employed including descriptions of:
 - a) The human subjects and the criteria for including them in the research,
 - b) What is to be done with or to them,
 - c) Any possible risks, stress, or requests for information subjects might consider personal or sensitive, or which may be illegal, and whether or not the only risk to the subjects is the harm resulting from a breach of confidentiality,
 - d) the steps that will be taken to ensure the anonymity and confidentiality of the subjects,
 - e) the permissions from other institutions, if required, that will be obtained.

A signed, completed copy of this submission form.

In addition, the research proposal may have to include the following documents. *Check those that are included.*

A copy of the test, survey, or questionnaire, if employed, and if it is not a standardized professional diagnostic tool otherwise specified in the proposal.

A copy of the written statement explaining the research indicating that participation is voluntary, if required. (See III. A. below.)

A copy of what will be said to subjects before and after the research is conducted, if the methodology requires that the subjects be misled in any way. (See III. B.)

A copy of the informed consent statement that will be used, if required. (See Sec. IV. below.) A model informed consent statement can be found at the end of this form.

II. Exemptions

If your research falls into any of the categories of research below, it is exempt from the requirement of obtaining written informed consent and being reviewed by the entire Committee, and only 1 copy of the proposal need be submitted. All others must submit 3 copies of their proposal. If your project conforms to any of the following descriptions, check those which apply:

- Research or student learning outcomes assessments conducted in educational settings involving regular or special education instructional strategies, the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods, or the use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research involving surveyor interview procedures unless responses are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects, and either (i) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or (ii) the research deals with sensitive aspects of the subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.
- Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.
- Research involving solely the observation of public behavior, including observation by participants, unless observations are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects, and either (i) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or (ii) the research deals with sensitive aspects of the subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.
- 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 a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.

III. Special Types of Research

A. In addition to the above types of research that are exempt from the requirement to obtain written informed consent and full committee review, the committee may waive the requirement that the investigator obtain written informed consent for some or all subjects for the following type of research. If your research conforms to the following description, indicate by checking.

- Research in which the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

In the forgoing type of research, the committee may require the investigator to provide the subjects with a written statement explaining the research and indicating that their participation is voluntary. In addition, each subject shall be asked whether s/he wants documentation linking him or her to the research, and the subject's wishes shall govern. In the case that the subject agrees to be identified in the research, her or his written permission to do so shall be obtained by the researcher.

B. Some research methodologies may require that the subjects be initially misled regarding the purpose of the research, and so require that the consent procedure omit or alter some or all of the basic elements of informed consent, or waive

the requirement to obtain informed consent. If your research conforms to the following description, indicate by checking.

- [] Research involves no more than "minimal risk" or risk of harm not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, research could not practicably be performed without the omission, alteration or waiver, and the omission, alteration or waiver will not adversely affect the rights and welfare of the subjects.

In the forgoing type of research, the committee requires the researcher to provide the subjects with an adequate post-investigative explanation of the purpose and methods of the research, or explanatory debriefing procedure to be undertaken immediately after the conclusion of each subject's participation. The committee requires investigators undertaking this sort of research to furnish the committee with copies of the information that will be supplied to the subject before and after the investigation.

IV. Written Informed Consent

Research engaged in all other types of research must obtain written informed consent from the research subjects. Informed consent means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice.

The basic elements of information necessary to such consent are:

- 1. A reasonable and comprehensible explanation to the person of the proposed procedures of protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;
- 2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person;
- 3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to her or him;
- 4. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and
- 5. An offer to answer and answers to any inquiries by the person concerning the procedures and protocols.

Informed consent must be obtained in the following manners for the following types of human subjects: (a) competent, then it shall be subscribed to in writing by the person and witnessed; (b) not competent at the time consent is required, then it shall be subscribed to in writing by the person's legally authorized representative and witnessed; or (c) a minor otherwise capable of rendering informed consent, then it shall be subscribed to in writing by both the minor and her or his legally authorized representative.

Legally authorized representative means (a) the parent or parents having custody of a prospective subject, (b) the legal guardian of a prospective subject, or (c) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research.

Any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney in fact shall not be employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

A legally authorized representative may not consent to nontherapeutic research, or research in which

there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject, unless it is determined by the human subject research review committee that such research will present no more than a minor increase over minimal risk to the human subject.

Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of rendering informed consent shall be forced to participate in any human research.

In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force.

No informed consent form shall include any language through which the person who is to be the human subject waives or appears to waive any of her or his legal rights, including any release of any individual, institution, or agency or any agents thereof from liability for negligence.

Human subject research investigators are responsible for obtaining written informed consent from research subjects in accordance with these specifications, and for obtaining permissions from any other institutions that may be involved in informed consent statement which conforms to these specifications.

The Longwood University Human Subjects Research Review Committee must be informed of any violation or alteration of the research protocol. Continuing research projects must be re-approved annually.

The undersigned researcher(s) indicate that the information provided to the committee is accurate and true to the best knowledge of the researcher(s), and that the researcher(s) have conformed to the above guidelines to the best abilities of the researcher(s).

Date: _____ Signed (legibly): _____

Date: _____ Signed (legibly): _____

Date: _____ Signed (legibly): _____

If this research is being completed in partial fulfillment of a Masters degree, the thesis committee must approve of your project prior to submission of these forms. The signature(s) of your committee chair/advisor on the appropriate form constitutes acknowledgement of this prior approval by your committee.

Please indicate the address where you would like the approval form sent (along with phone # and/or e-mail address):

Further information of the status of proposals may be found at the following:

Dr. Eric Laws
Department of Psychology
Phone: (434)395-2841; e-mail: lawsel@longwood.edu