

## Instruction Packet for Submitting EXEMPT Research Protocols Involving Human Subjects

The Institutional Review Board for the Protection of Human Subjects (IRB) has the authority to review any research project involving human subjects that is associated with Arkansas State University. Unless a study is clearly exempt from any level of IRB review, all research that utilizes human subjects must be approved by the IRB **before the research begins**. This satisfies a number of federal, state, and institutional regulations and, more importantly, assures protection of the rights and welfare of persons used in research. Your cooperation is essential in following the procedures outlined.

This packet contains the materials necessary for submission of Exempt Research for review by the IRB. This packet (including forms to be submitted) is available on disk in WordPerfect format. **Only projects that fall into one of the 6 categories listed on pages ii and iii of this packet may be submitted as Exempt Research. Research that does not fall into one of the 6 categories must be submitted as Expedited or Full Review proposals.**

### INSTRUCTIONS

#### **PLEASE READ INSTRUCTIONS CAREFULLY AND COMPLETE THE APPROPRIATE PACKET.**

1. A packet must be prepared for each research study using human subjects that is submitted to the IRB for review. Assistance in preparation of materials for IRB review is available. Contact the Chair or another member of the Committee. **Route the completed packet (one copy) to the IRB care of the Office of Research, ABI Room 116.** Please allow a minimum of one week for processing of Exempt reviews.

#### 2. DOCUMENTS

All documents must be neatly typed and legible. USE TYPE SIZE NO SMALLER THAN 10 POINT. INCOMPLETE INFORMATION OR USE OF SMALL TYPE SIZE WILL RESULT IN DELAYS.

Do not type on the reverse side of any form.

Documents must be submitted in the following order: (1) Documentation of Review and Approval, (2) Exempt Research Attachment, (3) Informed Consent form or statement, and (4) copies of research materials.

A. **DOCUMENTATION OF REVIEW AND APPROVAL.** (p. 1, required for all types of review.) A response must be provided for each blank. Project Duration dates would be when **data collection begins** (this should be after the submission date) and when **data collection will be completed**. List one Principal Investigator on this page. Other primary investigators can be listed in item G on the Exempt Research Attachment (p. 2). Signatures must be originals (no copies). **Page 1 must be on a single page; do not carry it over to a second sheet of paper.**

B. **EXEMPT RESEARCH ATTACHMENT.** On p. 2 of the submission forms, researchers should provide all information requested so that the IRB can determine the nature of the study and what subjects will experience. Of particular concern for any study is (a) equitable selection of subjects, (b) voluntary informed consent, (c) minimization of acceptable risk, and (d) confidentiality of data. The research proposal must make each of these issues clear to the IRB.

C. **INFORMED CONSENT STATEMENT, STUDY INFORMATION SHEET, or equivalent demonstration of how informed consent will be provided.** Some type of Informed consent statement or form must be used with this type of project (other than category 4 on page iii). The informed consent materials should contain the information listed on page iv. *A sample format is provided on page v.* Indicate how the information will be given (written or oral). Please note that if vulnerable populations are used, such as minors, signed permission of a parent, guardian, or equivalent is likely to be required. A sample parental permission form is provided on page iv of Appendix E. **Type size must be no smaller than 10 point.**

D. **INSTRUMENTS.** Include any instrument(s) (questionnaires, surveys, etc.) to be used in the research as one or more attachments or Appendixes. In the case of interviews, include a list (or representative sample) of the questions to be asked. If subjects will do a task, provide a sample copy or description of the task.

E. **COOPERATING INVESTIGATORS, DEPARTMENTS OR INSTITUTIONS.** If it is anticipated that another investigator or department may be involved in the research, include a coinvestigator from each cooperating department (see guidelines). If the study will be conducted with another institution, a letter of cooperation from that institution may be needed.

4. **AMENDMENTS.** Investigators are required to report any significant, proposed changes to their research study via a **Study Amendment** form, which lists those aspects of the study that are to be changed (send one copy with original signatures to the IRB chair). Be sure to reference the original title of the study and the principal investigator.

5. **FILE MAINTENANCE.** It is important for the investigator to **KEEP A COPY** of every document related to the research study which is submitted to the Committee. For audit purposes, these documents must be kept for at least three (3) years after terminating the study.

7. **ACTIONS.** Much of the detail in these forms is required by Federal regulation. The IRB recognizes that this process can be frustrating and is willing to help in whatever way we can. If immediate approval is not received, approval can be obtained with modifications of the original proposal in the vast majority of cases. The Committee will provide feedback on the appropriate changes which will result in acceptance of the proposal. Please refer to the principal investigator, and exact title when submitting any documents related to a particular study. **Please remember that research (or amendments to the research) may not begin until this written approval is secured.**

### EXEMPT RESEARCH CATEGORIES

This section should be consulted when the investigator plans a research project which, in the investigator's judgment, is exempt from expedited or full Committee review. *Research activities are exempt from regulations for the protection of human research subjects when the **only** involvement of human subjects falls within one or more of the categories below.* **Please report (on p. 2, item A) the appropriate category that applies to your research project.**

**STUDIES INVOLVING PRISONERS, FETUSES, PREGNANT WOMEN, OR HUMAN IN VITRO FERTILIZATION AS SUBJECTS WILL NOT BE ACCEPTED AS EXEMPT FROM COMMITTEE REVIEW.** STUDIES INVOLVING MINORS in categories 1, 3, 4, 5, & 6 **MAY** BE ACCEPTED AS EXEMPT FROM COMMITTEE REVIEW following submission to the chair of the IRB. (Please note that, in line with Federal guidelines, studies involving minors will generally require parental permission, and the IRB will require submission of the permission form for approval.) Researchers with category 2 studies involving **MINORS** should call the IRB chair for help in determining the type of review required.

THE SIX EXEMPTION CATEGORIES ARE AS FOLLOWS:

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, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (i) information obtained is recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects's financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2, **if:** (i) The human subjects are elected or appointed public officials or candidates for public office, **or** (ii) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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 by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs (e.g., social security, welfare, etc.); (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a 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.

## OUTLINE FOR INFORMED CONSENT STATEMENTS

As specified in the guidelines, each study requires an Informed Consent Statement (which is read and signed by a subject), an Informational Sheet (which is read by the subject), or verbal instructions (which are read to the subject). The following points should be used to construct such statements, sheets, or instructions.

- I. **PURPOSE OF THE STUDY.** Briefly describe the reason the research project is being conducted.
- II. **REQUIREMENT FOR PARTICIPATION.** Describe what subjects will be asked to do if they decide to participate (i.e., procedures to be followed, length of participation, etc.).
- III. **POTENTIAL RISK.** Fully describe any potential harm or discomfort subjects could experience and the likelihood such negative effects will occur. When necessary, state that unexpected risks may occur and/or any risks of voluntarily withdrawing from the study. Describe any compensation or treatment available if harm should occur.
- IV. **POTENTIAL BENEFITS.** Describe any potential benefits subjects could gain from participation (including monetary payments, extra course credit, etc.).
- V. **ALTERNATIVE TREATMENTS.** Describe any alternative therapies available and the potential risks and benefits of these therapies.
- VI. **WITHDRAWAL OF TREATMENT.** Describe the circumstances under which treatment may be withdrawn without the subjects' consent.
- VII. **VOLUNTARY CONSENT.** Indicate that participation is voluntary and that there will be no penalty for refusal to participate. Also indicate that the subject can withdraw consent at any time. When interview or questionnaire data are being collected, indicate that subjects can refuse to answer individual items on the survey.
- VIII. **CONFIDENTIALITY.** Indicate that all data collected will be kept confidential. When responses are anonymous, indicate this to the subjects.
- IX. **QUESTIONS.** Inform subjects that they can ask any questions they have about the research. Give the name of the person(s) to be contacted, and this person's address and/or telephone number. Include the investigator's name, address, and telephone number that the subject may use to ask questions and report any study related problems. **Include the Office of Research, ABI Room 116, P.O. Box 2760, State University, AR 72467, 972-2447 as the place to contact with questions about subjects' rights.**
- X. **SIGNATURE.** Studies using information sheets or verbal instructions do not require signed informed consent-- assent is implied by the subjects' participation. When subjects are provided with a formal informed consent statement, have subjects sign a statement that they have read and understand the informed consent information.

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Note. Parts III, IV, V, and VI may be omitted when they do not apply to the research project. A waiver of confidentiality can be included with Part VIII when approved by the IRB.

## Sample Informed Consent for Exempt Research

We are conducting a study of perceptions and reflections of stress. We would like to ask you to participate in the study by filling out a survey, in which we ask you about your background, such as your age, sex, and student classification. We are also asking questions about your experience of stress, and how such things as family support and optimism relate to your perceptions. Your participation is voluntary, and there is no penalty for not participating. Not filling out the survey will not affect your grade. You can stop at any time you want, and you can skip any questions you do not wish to answer. If you do not wish to complete the survey once you have started, feel free to rip up the answer sheet, or we will do that later once all surveys have been collected. This survey should take about 15 minutes. We want this to be an anonymous survey, so please do not put any identifying information on it. No one but those directly involved in coding or analyzing the survey will see the responses. If you have any questions about the study, please feel free to ask me now or after the survey, or to call Dr. xxxxxxxx in the Department of xxxxxxxx, 870-972-xxxx, or Julie Linnstaedter, Office of Research, 870-972-2447.