ARKANSAS STATE UNIVERSITY
GOVERNING PRINCIPLES AND PROCEDURES
HUMAN SUBJECTS RESEARCH

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1.0 INTRODUCTION

The Arkansas State University (ASU) Institutional Review Board Governing Principles details the policies that govern research with human subjects and the procedures for submitting research proposals for review. These policies and procedures apply to all research involving human subjects at ASU and include all faculty, staff, students, or campus facilities regardless of sponsorship and/ or performance site.

ASU is guided by the ethical principles regarding all research involving humans, as set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* (*National Commissions for the Protection of Human Subjects of Biomedical and Behavioral Research,* April 1979).

2.0 PURPOSE

The purpose of these Governing Principles is to facilitate adherence to all federal guidelines concerning the conduct of human subjects' research and to assurance the equitable treatment of all human subjects who participate in research studies at ASU.

3.0 DEFINITIONS

Ancillary Workers. Ancillary workers include those individuals who serve as investigators or co-investigators on ASU-sponsored programs who are not formally affiliated with the University as an employee or as a student.

Human Research. Unless specifically exempted by the federal government, human research is defined as any systematic activity involving the collection and/or analysis of data on human subjects (including field studies, masters' theses, dissertations, etc.) for the purpose of advancing general knowledge. These activities would in all likelihood eventually lead to publication or presentation of the findings.

Research is differentiated from educational, administrative, or therapeutic activities when a study involves working with a vulnerable subject population who exhibit sensitive behaviors (see #16 checklist for expedited or full review) and may risk social, psychological, or physical consequences as a result of their participation. Neither coursework assigned for the purpose of demonstrating established methodologies nor collection of information for routine educational or administrative purposes constitutes

human research. However, the moment these activities occur outside the administrative, therapeutic or pedagogic context, they become research.[1] **Human Subjects.** A "human subject" is a living individual about whom an investigator conducts research to obtain: (1) data through intervention or interaction with the individual, or (2) identifiable private information. S/he includes individuals, as well as human embryos, fetuses, cadavers, and human tissue or fluids about whom an investigator (professional or student) conducts scientific research to obtain: 1) data through intervention or interaction with the individual, or 2) identifiable private information. Thus, the scope of "subject" is interpreted very broadly.

Informed Consent. Informed consent is agreement to participate in a research protocol after known risks are explained in easy-to-understand language. Legally-competent adults (age 18 or over) can consent to participate without intervention; however, certain vulnerable populations usually require the oversight of a legal guardian or advocate.

Institutional Review Board. A Board appointed by the Vice Chancellor for Academic Affairs and Research that has responsibility for reviewing and approving research projects that involve human subjects.

Office of Research and Technology Transfer (ORTT). The office with primary responsibility for support of the University's Institutional Review Board**.**

Research. As defined in CFR Title 45, Part 46 (Department of Health and Human Services policy for Protection of Human Research Subjects), "research" is a "systematic investigation designed to develop or contribute to generalizable knowledge." It is systematic investigation that includes development, testing, and evaluation.
and
Prisoner. Prisoner refers to any person involuntarily confined or detained in a penal institution. The term also includes persons detained in other facilities (e.g., group homes, work release centers) by statute or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as persons detained pending arraignment, trial, or sentencing.

Risk. Risk is defined as social, psychological, and/or physical consequences as a result of participation in a research project. .

Vulnerable Populations. A vulnerable population is defined as a group of subjects who lack the full capacity to provide informed consent (e.g., children, the mentally retarded,

[1] For example, if a physician compares a patient's reactions to those of other patients who use a variety of experimental or clinically-approved drugs, s/he is conducting a research study. If the same physician tries a series of drugs on one patient to help minimize harmful side effects, s/he is providing a therapeutic service and is not conducting research.

the mentally ill) or who are in circumstances that may compromise the subjects' freedom to provide voluntary informed consent (e.g., prison inmates).

4.0 APPLICABILITY

Faculty, staff, students, and unaffiliated researchers who work on the ASU campus are subject to the provisions of these governing principles. Note that research conducted outside of the United States is subject to the same considerations and review as work within its boundaries. Investigators also must abide by the laws and values of other countries.

5.0 REGULATIONS

The National Research Act of 1974 requires institutional review, letters of assurance, and documentation for any research protocol that includes human subjects in any of the biomedical, social science, and behavioral research disciplines. The Federal Policy for the Protection of Human Subjects[2] (known as the Common Rule) went into effect on August 19, 1991 and was published in the Federal Register. Vol. 56, No.117, June 18, 1992 beginning on page 28001. It represents the latest federal regulations for protection of human subjects. The Office of Protection from Research Risks within the Department of Health and Human Services maintains general jurisdiction over these matters.

Sixteen federal departments and agencies have adopted these regulations including the Departments of Agriculture, Energy, Commerce, Defense, Education, Health and Human Services, Housing and Urban Development, Justice, Transportation, and Veterans; the Consumer Product Safety Commission, Food and Drug Administration, Environmental Protection Agency, International Development Cooperation Agency, National Science Foundation, National Aeronautics and Space Agency, and the Office of Science and Technology.

Under the regulations, all institutions that receive funds from any of the departments or agencies listed are required to establish institutional review boards to review and monitor all funded research involving humans. Institutions are further required to submit letters of assurance periodically that indicate compliance with the regulations. Arkansas State University (ASU) has submitted such a letter of assurance to the Department of Health and Human Services, committing the University to abide by the provisions contained in Title 45 CFR, part 46, subparts A-D.

To assure appropriate treatment of all human subjects, ASU has chosen to extend federal human subjects protections to all research and research-related activities which involve humans, funded or not.

Infractions of the regulations could have very serious consequences; not only could grant or contract support be withdrawn from a single offending project, but the host institution

[2] The regulations can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

could lose all federal funding. Consequently, ASU takes the protection of human subjects very seriously for both fiscal and ethical reasons.

6.0 GOVERNING PRINCIPLES

6.1 OVERVIEW

In 1974, the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify fundamental ethical principles in the conduct of research that involves human subjects. ASU is committed to upholding those standards in the conduct of human subjects' research and to providing assistance to its investigators or departments to facilitate compliance with minimal delays or disruptions of research programs.

6.2 INSTITUTIONAL REVIEW BOARD (IRB)

6.2.1 Board Development

Consistent with federal guidelines, an Institutional Review Board has been established to consider research protocols that involve human subjects. Its purpose and responsibility is to protect the rights and welfare of human subjects by reviewing and overseeing research to ensure that the research meets established ethical standards and complies with federal regulations specific to human subjects' research and protection.

The Vice Chancellor for Research and Academic Affairs has responsibility for appointing members to the Board in three-year staggered terms. Members include one community and nine faculty representatives with qualifications as follows:

- Regular member(s). The backgrounds of regular member(s) shall be varied to promote complete and adequate review of research activities.
- Non-affiliated member(s). The non-affiliated member(s), who can be either scientific or non-scientific reviewers, should have no affiliation with the institution or be immediate family of anyone affiliated with the institution. This member(s) should be knowledgeable about the local community and be willing to provide input based on his or her knowledge about the local community.
- Scientific member(s). Scientific members use scientific and statistical merits and standards of practice to evaluate each study. If the IRB reviews studies involving science beyond the expertise of the members, the IRB may retain a third-party consultant to assist in the review, as provided by 21 CFR 56.107(f).
- Non-scientific member(s). Non-scientific members are individuals whose education, work or interests or not solely in medical or scientific areas. They provide input in areas germane to their knowledge, expertise, and experience, professional and otherwise.
- Representatives of vulnerable populations groups. Consultants who are knowledgeable about certain vulnerable population groups may be required when certain types of research are reviewed.

- Special consultants. The IRB may rely on third-party consultants competent in specific areas to assist in the review of issues that require expertise beyond that available to the IRB. These individuals may not vote with the members of the IRB, and their presence/absence will not be used to establish a quorum. Consultants will be used at the Chair's discretion or when requested by the entire IRB. All consultants will be required to sign Confidentiality Agreements.

The membership shall be diverse, with consideration of race, gender, cultural backgrounds, clinical experience, and health care experience to assess the research submitted for review. The IRB members shall be qualified through experience and expertise to review research proposals, keeping in mind applicable regulations, laws, and standards of professional conduct and practice. Regular IRB members and chairpersons are expected to commit to a specified term, during which time they will fulfill specific duties that will be given prior to appointment.

6.2.2 Meetings

The IRB meets monthly to review projects, September through May, and in summer as necessary. Membership and procedures for the IRB's meetings are governed by the bylaws of the IRB.

With the exception of expedited reviews, the IRB shall review proposed research at convened meetings with a quorum present. Absent a quorum, the IRB will take no action until the quorum is restored. More than one-half of members must be present to establish a quorum. Of that number, one member whose expertise is in a scientific area, one member whose expertise is in a non-scientific area, and one member who is not otherwise affiliated with the institution must be present. An alternate member may attend in the place of an absent member in order to have a quorum. If a member is present but abstains from voting, that member may be used to establish a quorum. To document the continued existence of a quorum, vote totals for each action shall be recorded in the minutes by listing the number of members originally present, the number of members who were absent for each vote, and a breakdown of members voting for, against, and abstaining. .

6.2.3 Recordkeeping

IRB files are maintained in the Office of Research and Technology Transfer, located in the Arkansas Biosciences Institute, Room 114. These include:

1. Federal regulations and communications, as well as University memoranda and letters of assurance;

2. Written procedures and guidelines;

3. Committee rosters;

4. Minutes of the meetings;

5. All approved and non-approved protocols, consent forms, revisions, and amendments;

6. Records of continuing review activities;

7. Communications to and from the IRB;

8. Protocols not as yet reviewed.

9. Protocols from which approval has been withheld and suitable remedial action not yet taken.

10. Documentation of adverse events, continuing review, or significant new findings where applicable.

11. Correspondence.

All protocols shall be kept for three years after completion of the research.

6.2.4 Criteria for IRB Approval

The IRB will approve research only after it has determined that the following criteria, which are applied to all types and levels of review, are satisfied (45 CFR 46.111):

- The study design is sound, peer reviewed, and approved by management;
- Risks to subjects are minimized;
- Risks are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
- The selection of subjects is fair and equitable (in making this assessment, the IRB must take into account the purpose of the research and the setting in which the research will be conducted, and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, the mentally disabled, or economically or educationally disadvantaged persons);
- Recruitment and solicitation methods and materials are appropriate for the research being conducted;
- Compensation or payment for participation is fair and reasonable for the activities taking place and do not increase the possibility of coercion or unduly influence a potential subject's decision to participate, particularly children or the economically disadvantaged;
- Participation is voluntary and informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- Informed consent is appropriately documented in accordance with, and to the extend required by, 45 CFR 46.117;
- When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and

- Additional safeguards are included to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence.

6.2.5 IRBs within Units

Departments, institutes, and centers whose faculty or students do research with human subjects are encouraged to establish screening IRBs to examine its faculty and student research prior to submission to the IRB. If a department, institute, or center generates so few research projects that a standing IRB is not justified, the head of such a unit could appoint ad hoc IRBs as needed.

6.3 TRAINING

Training of IRB Committee members, investigators, IRB and research staff is critical to fulfilling the mandate to protect the rights and welfare of human subjects throughout the research community.
IRB members and their alternates should be provided with copies of the following documents:

- The IRB's Governing Principles and Procedures
- The Belmont Report[3]
- 45 CFR 46
- 21 CFR 50 and 56

They should likewise receive initial and ongoing training regarding review and oversight of Office of Research Governing Principles and Procedures. The IRB manager/chairperson will establish the educational and training requirements for IRB members, investigators, and staff. All initial and ongoing training should be documented.

7.0 RESPONSIBILITIES

7.1 INVESTIGATORS

Overview. Researchers are responsible for maintaining high ethical standards in their treatment of human subjects. All research procedures must be consistent with University policy and with any ethical standards established by the researcher's academic discipline.

A. Researchers are responsible for following current IRB guidelines for ethical review of human subjects' research. Whenever there is a question of whether or not a particular study needs to be approved by the IRB, researchers must seek clarification from the IRB Chair.

B. Researchers are responsible for using only those procedures approved by the IRB. Whenever researchers want to make significant modifications in approved procedures, or

[3]The Belmont Report is report of the ethical issues debated by the National Commission for the Protection of Human Subjects at its inception. The full report can be found at http://ohsr.od.nih.gov/guidelines/belmont.html.

whenever unanticipated risks to human subjects occur, researchers must suspend data collection and seek approval from the IRB. If suspending treatment could harm subjects, the researcher may seek approval from the IRB Chair to continue the treatment pending IRB action.

C. Researchers are responsible for procuring the consent of program participants unless specifically exempted. This means that the investigator must use easily-understood language and must disclose any risks associated with the research protocol to prospective participants. To obtain informed consent, the investigator must provide a statement[4] that includes the information listed on the "Outline for Informed Consent Statements" in Appendix A. It is desirable, but not mandatory, that the investigator, rather than an assistant, obtain the consent. Non-disclosure and duress to assure participation are specifically prohibited;[5] however, deception[6] may be employed for legitimate research purposes when there are no other viable alternatives.

D. Investigators may be able to use secondary data or materials without obtaining additional consent forms if the original researchers received consent appropriately and if: 1) the new project(s) is related to the original one[7], 2) the original research has made the subjects truly anonymous, or 3) the data was pooled in a form that ensured anonymity.

E. Federal regulations exempt certain types of human subjects' research (See Appendix C or visit http://researchoffice.astate.edu/IRB/documents/irb_exemption.doc) from regulations. Nevertheless, the IRB strongly encourages investigators to submit a "Request for Exemption" form for approval by the IRB chair prior to beginning any research. It is the IRB's practice not to require signed informed consent statements in these cases, but it usually requires that information about the research be given to subjects in either oral or written form.

F. Researchers are responsible for notifying the IRB when an approved study has been completed. When a study will not be completed within one tear of the date of approval, the researcher is responsible for notifying the IRB on an annual basis (or more frequently if required by the IRB) that the approved procedures are still being employed. In both

[4] A sample informed consent statement is also included on the IRB website (http://researchoffice.astate.edu/IRB). The sample reflects both requirements of the federal regulations and customary language adopted by the IRB. Using the sample format will facilitate IRB review.

[5] The prohibition on duress is important in academic circumstances because it is easy for an instructor to call upon students to volunteer as subjects. It must be made clear that the decision to participate will have no effect on grades.

[6] For example, participants may be told that researchers will administer a specific drug to them, when in fact, they are receiving placebos. The research team would then analyze the psychological effect the placebo has upon the participant group. In cases such as this, investigators are urged to obtain preliminary consents, even though the experiment cannot be fully described in advance. After the experiment has been conducted, the subject should be informed of the deception. There are rare instances in which no consent can be obtained or briefing done (e.g., if the researcher pretended to lie unconscious on a sidewalk and noted how many and what sorts of persons stopped, attempted assistance, or simply hurried past).

[7] If a participant consented to have his/her blood sample available to persons studying blood diseases, his/her sample could be shared with other researchers without additional consent. However, when secondary use of samples or data is distinctly different from the original project, it is likely that consent must be obtained.

cases, the IRB will send a form to be used for notification. Notification is not necessary for research which falls into the "exempt" category.

7.2 INSTRUCTORS AND STUDENTS

General. Class assignments (including research practica that are usually in the form of course-related research projects and/or directed studies) that are intended primarily for educational purposes (e.g., to demonstrate how research is conducted) are not subject to IRB review as long as such assignments do not involve physically or psychologically invasive, intrusive, or stressful procedures; and in the judgment of the instructor, do not have the potential for placing the subjects at more than minimal risk. However, student research, including classroom and independent study projects, theses and dissertations, that may place the subjects at more than minimal risk are subject to IRB review. In clinical courses, subjects will be considered to be at risk if the procedures used and/or the questions asked do not fall under what is construed to be ordinary practice. Likewise, studies involving special populations (pregnant women, fetuses, abortuses, prisoners, mentally disabled, economically or educationally disadvantaged, or minors) are subject to IRB review.

1. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project may fall in the category of research as explained above, thus requiring IRB review.

2. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge or that it may involve risk, the project must be reported on the appropriate forms provided by the IRB for its review and approval prior to initiating the research. Forms and guidelines may be obtained through the graduate school, IRB office, Dean B. Ellis library.

3. If there is any doubt as to whether the project should be reviewed by the IRB, the IRB Office must be contracted. If the IRB chairman or representative believes that a particular project is subject to regular IRB review, the proposed project must receive IRB review.

4. In the event IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Instructors and students are reminded of the substantial penalties and risk of liability for failure to comply with federal policy governing the use of human subjects in research. Consequently, the researchers should adhere to ethical standards and use informed consent where appropriate.

5. If there is reasonable expectation on the part of the instructor and the student that the study will be funded (regardless of source) and/or published or offered for public performance, regular IRB guidelines should be followed.

6. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that IRB approval is required, the instructor shall present an “umbrella” form on behalf of all students enrolled in the class that describes: 1) the types of research to be undertaken by the students, 2) the nature of the subjects to be used, and 3) the procedures to be used. Any

research not within the described parameters would require separate approval. All student research submitted must include the instructor's signature and must identify the students conducting the study.

7.3 INSTITUTIONAL REVIEW BOARD

Overview. The IRB has primary responsibility for ensuring adherence to federal and University regulations concerning the conduct of human subjects' research. In its review of research protocols, the IRB is responsible for ensuring that the following requirements have been satisfied.

1. **Equitable Selection of Subjects**. No individual or group should be pressured to participate in a research program. When risk is involved, the potential benefits that justify this risk should be generally available to the subject population selected for the study. Members of vulnerable populations should not be used as subjects unless they are the specific focus of the investigation.

2. **Voluntary, Informed Consent.** Unless the IRB waives one or more aspects of informed consent, human subjects must voluntarily give their full informed consent prior to their research participation. No aspect of informed consent will be waived unless there is no more than minimal risk involved and the study could not be practically carried out without the waiver. If deception is involved, or if information must be withheld prior to participation, full disclosure must be provided at the earliest reasonable opportunity.

    a. When members of vulnerable groups are used as subjects, they should be allowed to give their informed consent to the extent that they are able. However, full informed consent should also be obtained from appropriate persons who are responsible for the subjects' welfare.

    b. Researchers must have subjects sign a written, informed consent statement if the research involves more than minimal risk, or if subjects will receive therapy and/or drugs. Researchers typically will be required to obtain signed informed consent statements from those persons who represent the interests of subjects from vulnerable populations. When data are collected using questionnaires, informed consent information can be included as part of the instructions for completing the questionnaire. Oral informed consent can be obtained in most other types of research.

    c. No informed consent statements may include exculpatory language through which subjects waive or appear to waive any of their legal rights. In addition, informed consent statements may not include language that releases the researcher or the institution from liability due to negligence.

3. **Risk Analysis.** Some risk is inevitable, but the IRB's task is to ascertain whether the proposed research increases risks beyond the normal level.[8] To do so, the IRB must address three questions:

[8] For example, breach of confidentiality might result in a child being labeled the "stupidest" in an entire school, or a family could be upset if their neighbors learned that a family member was suffering from a

a. Is the risk minimal? Minimal risk is defined as the level of risk, considering both magnitude and probability, encountered in the course of normal daily living, including routine physical exercise or psychological examination or tests. Because people often try to avoid situations in their daily lives that produce strong negative emotional states (e.g., anxiety, guilt, depression) research on topics likely to evoke such reactions in some people (e.g., death and dying) may involve more than minimal risk.
b. Could the research objective be attained through procedures bearing less risk? Researchers must demonstrate that a) alternative procedures involving only minimal risk are not available, b) the risk is justified by the anticipated benefits of the research, c) every effort has been made to reduce the level of possible risk, and d) reasonable efforts will be made to remove any injury or harm incurred by subjects.[9]
c. Do the benefits justify the risks involved? Although the regulations do not ordinarily require institutional review boards to evaluate the merit of a proposal, they must determine whether the value of the research is sufficient to justify it. The risk/benefit analysis must conclude that the benefit clearly offsets the risk to participants.

4. **Minimization of Acceptable Risk.** When the study involves more than minimal risk the IRB may require researchers to provide a copy of the signed informed consent statement to subjects or their guardian and to report on the status of the research more often than annually, and may also require independent verification that the approved procedures are being followed.

5. **Confidentiality of Data.** All data collected from human subjects must be kept confidential. Only persons actively involved in conducting the research project should have access to information that would allow identification of individual subjects or their responses. If appropriate, the IRB may approve subjects to VOLUNTARILY sign statements waiving their rights to confidentiality. The waiver statement must inform subjects of the circumstances under which their identity could be revealed and the purpose of doing so. Information must be released in such a way that it can be used only under the specific conditions to which the subjects have agreed.

7.4 CHAIRS

The IRB Chair should be capable of managing the IRB with fairness and objectivity and should ensure that the IRB carries out its responsibilities. In addition to the duties of all IRB members, the chairperson has the following responsibilities:

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particular disease. Or, psychological damage may result if a researcher gives a specific subset of children a number of insoluble problems and psychometric tests which "reveal" various mental and emotional deficiencies.

[9] For example, could an aversive electric shock be given by batteries rather than by a transformer plugged into a 110-volt wall socket? Could anonymous numbers be used instead of names?

- Leads IRB meetings;
- Assures that expedited reviews are conducted in a timely manner;
- Keeps institutional officials informed regarding issues related to human subjects research;
- Educates IRB members and investigators;
- Signs off on all Full Board Review Approval letters as well as Unanticipated Problems and Noncompliance.
- Suspends the conduct of research if an investigator is not following IRB requirements.

7.5 VICE CHAIR'S RESPONSIBILITIES

The Vice Chair is delegated to act in the Chair's absence. In this event, the Vice Chair has signatory authory for any documents that must be processed or approved during that time.

7.6 IRB MANAGER

The IRB Manager is responsible for the day-to-day operations of the IRB Office and is accountable to the IRB Chair for the timeliness and accuracy of the IRB's administrative tasks, including providing ongoing oversight and evaluating the following administrative processes:

- Organizing all applicable files;
- Taking minutes and creating meeting agendas;
- Providing timelines and accuracy of letters to investigators;
- Managing and overseeing IRB member appointments;
- Managing IRB-related activities and communications;
- Ensuring timeliness and accuracy of processing protocols and IRB submissions; and
- Other administrative duties as assigned.

8.0 PROCEDURES

8.1 APPLICABILITY

If the study in question is a research project (a systematic investigation designed to develop or contribute to generalizable knowledge), the results of which are to be published or made public in some other manner, and humans are/were involved now or in the past, then the study most likely needs to be reviewed, and the IRB should be consulted. Even in those cases where the research may be exempted from IRB review, investigators are strongly encouraged to contact the Chair of the IRB to determine whether a full IRB review is required.

IRB Meetings. Projects are considered by the IRB at regular meetings on the second Monday afternoon of each month, September through May, and as needed during the summer. Studies are rarely disapproved by the IRB; however, its members may require additional information

8.2 SUBMISSION OF APPLICATIONS

The first step in the process is for the researcher to determine whether to submit an application for exemption[10] or an application for expedited/full review. The chair of the IRB will determine whether the proposal is eligible for expedited review based on the criteria in the Request for Review (http://researchoffice.astate.edu/IRB/documents/review_request.doc). Forms must be completed according to the instructions provided. To ensure review, requests should be submitted one full week before a scheduled meeting and well in advance of the onset of the project.

8.2.1 Letters of Exception/Expedited Review

If a proposal poses only minimal risk to participants, investigators may request an expedited review. In theses cases, the Chair or his/her designee will consider and review the case. The Chair and/or designee, however, reserve the right to refer the project to the full Board if s/he deems it necessary.

Written requests for letters of exemption must be submitted to the Chair (please see Appendix C). When the IRB Chair determines that the research is exempt from IRB review, s/he will provide the researcher with a letter of exemption. If the Chair believes the research is not exempt, s/he will submit the request to the Board for review. Please refer to the Website as follows http://researchoffice.astate.edu/IRB/document/review_request.doc or see Appendix __ of this document..

8.2.2 Full Review

Researchers must submit one copy of their request for approval to the Chair of the IRB. After reviewing the proposed research, the IRB will take one of the following actions:

1. **Full Approval**. Researchers may proceed with the research.

2. **Conditional Approval**. Researchers may proceed with the research only after making modifications required by the IRB.

3. **Non-Approval**. Researchers may not proceed with the research.

The IRB Chair will notify the researcher and the Department (if appropriate) in writing of the reasons for either denying or conditionally approving an application,. Researchers who believe this action is inappropriate can have the IRB reconsider its decision by writing the IRB Chair to request a second review. The letter should contain the researcher's rationale for suggesting that the IRB's decision was is in error. The researcher may also request to appear before the IRB to explain his/ her position. The decision of the IRB following the second review will be final.

8.2.3 Duration. IRB Approval is granted for one year. Studies which undergo expedited or full review that are continuing for a longer period must apply for an updated approval each

[10] Exempt research involves no more than minimal risk AND meets the criteria listed in the Request for Exemption (http://researchoffice.astate.edu/IRB/documents/irb_exception.doc).

year the study is active. If the initial application indicates a multi-year study, the investigator will be notified by the IRB when it is time to apply for an updated approval. If the initial application indicates less than a one-year approval period, the investigator will be contacted to indicate whether the project has been completed or is continuing.

8.3 DELAYS IN PROCESS

Common problems that may cause delays in the review and approval include:

- Failure to complete the appropriate forms (e.g., Documentation of Review and Approval page, with dates, address, signatures, etc.).
- Lack of, or lack of an adequate, informed consent statement.
- Lack of IRB ability to ascertain risk without consulting experts.
- Lack of clarity in how confidentiality will be protected.
- Unacceptable risk involved. (These are generally few in number and, typically, can be modified to meet concerns of the IRB.)

APPENDIX A
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.

X. **Include the Office of Research and Technology Transfer, ABI Room 116, P.O. Box 2760, State University, AR 72467, 972-2447 as the place to contact with questions about subjects' rights**.

XI. **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.

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.

APPENDIX B
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 filing 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-xxxx.

APPENDIX C
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 federal, state, and institutional regulations and, more importantly, assures protection of the rights and welfare of research participants. 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 in 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 IRB. **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
.
2. 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. Additionally:
    a. Do not type on the reverse side of any form.
    b. Documents must be submitted in the following order:
        i. Documentation of Review and Approval,
        ii. Exempt Research Attachment,
        iii. Informed Consent form or statement, and
        iv. Copies of research materials.

DOCUMENTATION OF REVIEW AND APPROVAL

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 is required for all types of review and must be on a single page; do not carry it over to a second sheet of paper.**

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.

INFORMED CONSENT STATEMENT, STUDY INFORMATION SHEET

An Informed Consent Statement, Study Information Sheet or equivalent to demonstrate 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.**

INSTRUMENTS

Include any instrument(s) (questionnaires, surveys, etc.) to be used in the research as one or more attachments or appendices. 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.

COOPERATING INVESTIGATORS, DEPARTMENTS OR INSTITUTIONS

If it is anticipated that another investigator or department may be involved in the research, include a co-investigator 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.

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.

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 IRB. For audit purposes, these documents must be kept for at least three (3) years after terminating the study.

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 IRB 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 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 IRB 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 will not be accepted as exempt from IRB review. Studies involving minors in categories 1, 3, 4, 5, & 6 **may** be accepted as exempt from IRB review after submission to the Chair. (Please note that, consistent 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: a) research on regular and special education instructional strategies, or b) 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**: a) information obtained is recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subjects; **and** b) 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' 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**: a) the human subjects are elected or appointed public officials or candidates for public office, **or** b) federal statutes require without exception that the confidentiality of the personally identifiable information must 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: a) Public benefit or service programs (e.g., social security, welfare, etc.); b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible chances in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies if: a) wholesome foods without additives are consumed or b) 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.

APPENDIX D
POPULATION SUBSETS

Legally-Competent Adults. Any legally competent adult, aged 18 and older, may assent to participation in a research study unless s/he is under the influence of alcohol or drugs.

Minors. The consent of at least one parent or guardian is required for participants aged 17 and under. In addition, the aims and general nature of the project must be described in language a child can comprehend, and the child's assent must be obtained verbally. If biomedical research on infants is planned, the drugs or procedures must tried first on animals, adults, and older children. In certain cases where there is no risk and where it would be unreasonable to require parental permission, the IRB may waive the requirement (*under what circumstances??*). Research on minors which involves more than minimal risk will be approved only if it is of direct benefit to the subject or yields useful knowledge about a subject's problem or disorder. If a child is a ward of the state, the IRB must require that an advocate function as a guardian in the child's behalf.

Mentally Disabled. Persons with mental disabilities require special consideration. Depending upon the severity of their disabilities, they may or may not be able to give consent. If a person is capable of understanding the nature of the project, consent should be obtained from both the subject and a parent or guardian. In instances where the person is not competent to consent, parental or guardian consent is needed, along with assent from the person him/herself. If the disability is very severe, such that assent is not possible, parental or guardian consent is sufficient.

Prisoners. The use of prisoners as subjects is severely limited because such subjects' ability to consent voluntarily is limited by the "coercive nature of the environment." Funded research involving prisoners must be approved by both the local IRB and the department/agency head. The research must be limited to: 1) "minimal risk" studies of criminal behavior and incarceration, penal institutions, and prisoners as a social class; 2) research on conditions affecting prisoners - including social and psychological problems - only if approved by the department/agency head after expert consultation; and 3) therapeutic research, with control groups also requiring the department/agency head's approval.

Any researcher planning research involving prisoners is encouraged to review the current regulations for other requirements before submitting the IRB application for review.