The Handbook for Ensuring Protection of Human Research Subjects

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GENERAL POLICY STATEMENT

ULM POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

All research projects, involving human subjects, conducted by The University of Louisiana at Monroe (ULM) faculty, students, or staff (including collaborative projects with other institutions and agencies) must be reviewed and approved by the ULM Institutional Review Board (IRB). Before submitting a project for review, investigators are urged to obtain a copy of the ULM Policy for the Protection of Human Subjects from the ULM Office of Sponsored Programs and Research (OSPR).

Introduction

Biomedical and Behavioral Research may be accompanied by a variety of risks to human volunteers. Such risks may be physical, psychological, or financial in nature. For this reason, the justification for such activities must be carefully weighed against ethical, moral and legal considerations – some of which are not always self-evident. Justification must include consideration of the potential value of the research activity in relation to all possible risks, the scientific merit of the investigative approach, the adequacy of the experimental design in minimizing risks, the protection of the individual rights of the subjects involved, and the adequacy of informed consent measures as well as the potential legal liability incurred by the sponsoring institution. Careful attention must be given to security of informed consent from the volunteer subject.

While the fundamental safeguard for the proper conduct of research rests on the moral integrity and sound professional judgment of the investigator, the responsibility for establishing high standards in research is shared by his/her professional colleagues, department head and institution. Accordingly, it is necessary to establish a consistent institutional policy, which both safeguards the health and welfare of volunteer subjects and provides investigators an opportunity to pursue meaningful research involving human subjects. The ethical principles and guidelines embodied in the Report of the National Commission for the protection of Human Subjects of Biomedical and Behavioral Research, commonly known as "The Belmont Report," are believed to be a suitable basis of such a policy and are accepted by The University of Louisiana at Monroe. All investigators are expected to be familiar with this report (See Appendix A).

I. Procedure for Submitting Projects for Review

A. **TIMING OF SUBMISSIONS**: All project proposals requiring IRB approval must be received by OSPR at least five working days prior to the meeting at which the project is to be reviewed. The intent of this requirement is to ensure the individual board members will have an opportunity to adequately study the proposal prior to a meeting of the full board. This five working day requirement is in addition to all other on campus administrative review procedures, which may be applicable to an individual proposal.

   Proposals, which are to be forwarded to an off-campus-funding agency, must be submitted well in advance of any deadlines established by the funding agency. Investigators are reminded that a minimum of one week is required for completion of the on-campus administrative review process for grant proposals, which do not require IRB approval.

B. All submissions must be in the form of a final project proposal and include the following information:

   1. Purpose of the project and its significance.

2. Justification for using humans as experimental subjects in the project.

3. Identification of possible risks to the subject and specific measures designed to minimize such risks.

4. Experimental plan including a detailed explanation of how subjects will be recruited and selected for the project.

5. Informed consent measures including a sample of all written documents to be furnished to volunteer subjects (see Part V).

C. At the time request for review is submitted, OSPR will verify training requirement for each individual listed on the project. Per ULM's Human Subject Protections Policy, all individuals, faculty, staff and students included, working in human research must take training before commencing any research on human subjects. Training is valid for two years, after which time, individuals are required to take refresher courses. ULM IRB Committee will not review the protocol until all individuals listed on the request for review have successfully passed the training requirement.

D. A completed IRB Request for Review must be attached as the cover sheet for all project proposals and must be approved by the department head having administrative authority over the investigator. (Copies of IRB forms may be obtained from OSPR's website)

E. Within one week of the committee's review of the protocol, OSPR will notify the lead investigator of the IRB's decision and recommendations.

II. ULM Institutional Review Board Review Process

A. The Board is responsible for ensuring that all research projects conducted by individuals representing themselves as members of the University and involving human subjects are conducted in compliance with the ULM policies established for the protection of human subjects. The Board shall review and have authority to approve, require modifications in, or disapprove all research activities covered by these policies.

B. The Board shall require that information given to subjects as part of informed consent is in accordance with Parts V and VI of this policy. The Board may require that information, in addition to that specifically mentioned in Part V, be given to the subjects when in the Committee's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

C. The Board shall require documentation of informed consent or may waive documentation in accordance with Part VI, Section C.

D. The Board shall notify (in writing) OSPR of its decision to approve or disapprove the proposed research activity, or of modifications required to secure Board's approval of the research activity. If the Board decides to disapprove a research activity, a statement of the reasons for disapproval shall be provided in its written notification and the investigator will be given an opportunity to respond in person or in writing. OSPR will in turn notify investigators of the Board's decisions and recommendations.

E. The Board shall be responsible for conducting continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

III. Projects for Which this Policy Applies

A. Except as provided in Section B of this part, this policy applies to all research involving human subjects conducted by or under the supervision of University employees whether funded in whole or in part by an intramural or extramural grant, contract, cooperative agreement or fellowship.

B. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy. However, these projects must meet basic ethical standards, and must be reviewed by the IRB and found to meet federal criteria for exemption:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (i) research on regular and special educational 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), 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, except where all the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonable place the subject at risk of criminal or civil liability or

be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4. Research involving the observation (including observation by participation) of public behavior, except where all the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonable place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or of the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6. Each subpart of this policy statement contains a separate section describing to what the subpart applies. Research, which is covered by more than one subpart, shall comply with all applicable subparts.

IV. Criteria for Board's Approval of Research

A. Before approving research covered by this policy, the Board shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Board will consider only those risks and benefits that may result form the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

3. Selection of subjects is equitable. In making this assessment the Board will take into account the purposes of the research and the setting in which the research will be conducted.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Part V. of this policy.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by Part VI.

6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

V. General Requirements for Informed Consent

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these guidelines unless the investigator has obtained legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include an exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the University or its agents from liability for negligence.

A. Basic elements of informed consent.

Except as provided in Section C of this part, in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be

followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedure or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A subject that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequence of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

C. The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the Board finds and can document that the research could not be practically carried out without the waiver or alteration.

VI. Documentation of Informed Consent

A. Except as provided in Section C of this part, informed consent shall be documented by the use of a written consent form approved by the Board and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

B. Except as provided in Section C of this part, the consent may be either of the following:

1. A written consent document that embodies the elements of informed consent specified in Section V of this policy. This form may be read to the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A "short form" written consent document stating that the elements of informed consent specified in Section V have been presented orally to the subject or the subject's legally authorized representative. When this method is used there shall be a witness to the oral presentation. Also, the Board shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person obtaining consent shall sign both the short form and a copy of the summary, and the person obtaining consent shall sign a copy of the

summary. A copy of the summary shall be given to subject or the representative, in addition to a copy of the "short form."

C. The Board may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In cases where the documentation requirement is waived, the Board may require the investigators to provide subjects with a written statement regarding the research.

VII. Additional Protections Applicable to Specially Defined Subject Populations and Research Projects

Certain subject populations and research projects possess characteristics, which necessitate specific additional protections and/or considerations. These are defined in The Code of Federal Regulations Title 45 Part 46 as revised January 15, 2009 – Protection of Human Subjects – and are included in this policy by reference (See Appendix B):

Subpart B, Sections 46.201 – 46.207 Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research .

Subpart C, Sections 46.301 – 46.306 Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

Subpart D, Sections 46.401 – 46.409 Additional Protections for Children Involved as Subjects in Research.

VIII. Expedited Review Procedures

Research projects deemed to involve only minimal risk or minor changes in previously approved projects may be reviewed on an expedited basis. Such reviews shall be carried out by the Board Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the Committee. In reviewing the research, the reviewers shall exercise all of the authorities of the Board except that the reviewers may not disapprove the research. Board members shall receive written notification of all projects subjected to an expedited review and shall be apprised of the outcomes of all such reviews.

Examples of projects, which may qualify as minimal risk activities, include:

A. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

B. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.

C. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

D. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

E. Collection of both supra-and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

F. Voice recordings made for research purposes such as investigations of speech defects.

G. Moderate exercise by health volunteers.

H. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

I. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subject's behavior and the research will not involve stress to subjects.

IX. Definitions

A. Board means the ULM Institutional Review Board.

B. Institution means any public entity or agency (including federal, state, and other agencies).

C. Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

D. Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

    1. Activities, which meet this definition, constitute "research" for purposes of this policy, whether or not they are supported or funded under a program, which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

E. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention and interaction, or (2) identifiable private information.

F. 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.

G. Interaction includes communication or interpersonal contact between investigator and subject.

H. Private information includes information about behavior that occurs in a context in which an individual can reasonable 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 reasonable 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 be readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

I. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

APPENDIX A

THE BELMONT REPORT

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

APPENDIX B: Code of Federal Regulations

TITLE 45 – PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46

PROTECTION OF HUMAN SUBJECTS

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Revised January 15, 2009

Effective July 14, 2009

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

APPENDIX C: Institutional Review Board Form

REQUEST FOR REVIEW

http://ulm.edu/research/irbrequest.xls

APPENDIX D: Internal Review Board

Tips on Informed Consent

http://www.hhs.gov/ohrp/policy/ictips.html

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Informed Consent Checklist

http://www.hhs.gov/ohrp/policy/consentckls.html