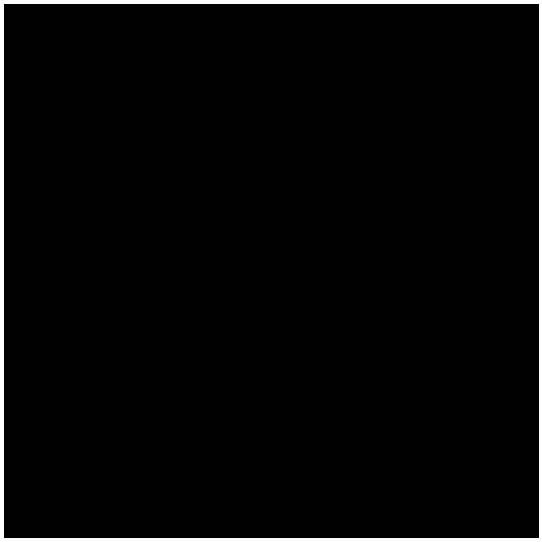

The Handbook for Ensuring Protection of Human Research Subjects

January, 2011 (revised)

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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

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

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,

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

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

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.

B. Institution

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