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1. INTRODUCTION

All research projects with human subjects conducted by faculty, staff and students associated with Lamar University must receive approval from the Institutional Review Board (IRB). This document describes human subject studies and the procedure to obtain IRB approval. Additional information on ethical questions in the conduct of human subject research can be found in the Belmont Report. This material contains information that assists Lamar University researchers in the preparation of IRB applications for review.

1.1 A Brief History on Codes of Research Ethics

Codes of research ethics have been developed to address the disregard for human safety and dignity reflected first and foremost in the scientific experiments by Nazi doctors during WWII, but also with regard to other unethical projects such as the Tuskegee experiment in Alabama between 1932 and 1972 in which treatment for syphilis was withheld from

1.2 Federal Administration of Research Ethics

The Office for Human Research Protections (OHRP) is the federal office responsible for the oversight of research

2. THE IRB AT LAMAR UNIVERSITY

2.1 The IRBôs Charge

The scope of the IRB's charge is broad. Generally, any university research that involves humans, human tissue, surveys of human subjects, or human subjects' records requires IRB review and approval, regardless of funding source. This purview extends to all student research projects. The specific charge to the IRB includes:

- potential risks to the subjects;
- anticipated benefits to the subjects and others;
- importance of the knowledge that may reasonably be expected to result; and
- informed consent process to be employed.

The basis for the board's charge is found in the Code of Federal Regulations (CFR). Although protection of human subjects is a concern of all agencies that sponsor research, regulatory leadership is vested in the federal Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). The OHRP has general responsibility for the protections of humans as subjects in research, and the FDA regulates the use of drugs and medical devices in experiments. The OHRP regulates compliance of institutions primarily through "assurances." The university's assurance outlines our responsibilities and explains the steps the university will take to meet the federal regulations for research on human subjects.

2.2 Membership and Structure of the IRB

a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influen ! ' "

Board members need to successfully complete

information that could cause harm to persons unless this jeopardizes the rights and welfare of the research participants.

The IRBs will consider on a case-by-case basis the circumstances under which third parties should be considered research subjects. In reaching this determination, the IRB will consider the following factors: (1) the amount of private information collected about third parties; (2) the sensitivity of that information; (3) the ability of investigators to maintain the confidentiality of third parties; (4) the welfare of the originally designated research subjects; and (5) the right of the originally designated research subjects to provide information on their personal life experiences. Third parties normally are not considered research subjects from whom consent must be obtained unless information obtained

A copy of IRB approval from the other institution, as well as the Lamar University IRB site permission letter is required

subject to full review, in keeping with federal guidelines. Additionally, any survey or interview that is likely to be stressful for the subject may require full committee review. The IRB administrator will make this determination.

The administrative staff screens all applications before they are assigned to the IRB. *If incomplete, the application is returned to the investigator*. The IRB reviews only complete applications (see 4.1). After review, the IRB will act on the application. Possible committee decisions include:

- approved as submitted;
- approved with minor requests for minor changes;
- approved with contingencies (conditions that must be met before final approval is granted) – most common decision;
- deferred pending receipt of additional information or major revisions; or
- disapproved.

4.5 Expedited Review

research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and additional risks have been identified.

particular research project is reviewed by more than one Board only one Board need satisfy this requirement [45 CFR 46.304].

5. THE PROCESS OF CONSENT

5.1 A Consent Process ï Not a Form

Since subjects/participants retain the right to withdraw from a study, consent is an ongoing process. Informed consent starts well before any forms are signed and continues until participation is complete. The informed consent process is different from the consent form. The consent process involves meeting with a potential subject, determining whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation with that subject. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed.

If consent is to be informed, the subjects must genuinely understand the study. Hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to demonstrate their understanding of the procedures, risks, and benefits of the study in which they are agreeing to particid re

Conflict of Interest

The university IRB requires that researchers inform their subjects of any conflicts of interest in the research. For example, researchers should disclose any personal stake in companies that might be affected by the research.

Finder's Fees

Companies sometimes offer researchers incentives for recruiting subjects or conducting research on an investigati r

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5.12 Consent and Language Barriers

When planning research that will include non-English speaking subjects, researchers should prepare consent forms in English and in the other relevant language(s). The IRB may consult with language experts or require a "back-translation" into English. As an alternative to translated consent forms, the IRB may approve a process consisting of an oral presentation of informed consent information in conjunction with a short form document stating that the elements of consent have been presented orally and a written summary of what is presented orally. A witness to the oral presentation

7.5 Investigation Purpose and Process of Non-compliance

Purpose

The purpose of the investigation is to explore the allegations by assembling and examining relevant information. The investigation panel's charge is to generate a report that summarizes the information it considered, its conclusions as to whether there was non-compliance with human subjects' regulations and recommendations for action. During an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The researcher shall be informed if new and different allegations are discovered during the course of the investigation.

Process

Research's decisions under certain limited circumstances. Grounds for appeal are limited to: 1) new information not reasonably available during the investigation; 2) material failure to follow these policies and procedures; and 3) sanction exceeds the severity of the violation. No other grounds will be considered.

Process

8. CONTINUING REVIEW

The IRB review is an ongoing process – not a one-time step. Regular re-evaluation ensures that research is conducted responsibly. Even in responsibly conducted studies, a one-time review ~~in~~ is inadequate, since some risks can really be understood only after research has begun, and since the regulations for human subjects' research are constantly being refined as the risks and benefits are better understood. Unexpected developments in a project can raise questions about the conduct of the research, and new findings can raise questions about the project.

8.1 Continuing Review

"Continuing review" refers to regularly scheduled complete reappraisals of a project. The goals of continuing review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard subjects are adequate, that

8.2

Death of a Research Subject

Researchers should alert the IRB immediately to the death of any study subject, whether the death is believed to be related to the study or not.

New Risk/Benefit Findings

As a study progresses and the risks and benefits of participating in the study are better understood, researchers may find that the study must be stopped. For example, in some placebo-controlled trials, preliminary findings may give compelling evidence that a new treatment is efficacious. It then becomes unethical to continue giving placebos. (This occurs most frequently in multicenter trials in which a central statistical center receives and processes large volumes of data from several sites.)

In such cases, the investigator should write to the Lamar University IRB, describe the findings and the need to suspend the placebo portion of the study. If the IRB agrees, the researcher should identify all subjecm x]l srt l' T]e e ʊ fy Y i d

- If the original title is to remain active but funding is sought from another agency for a different title, the investigator should write to the IRB office and request approval of an additional title. This request should certify that the study with the new title is identical to the student study under the original title. The request should include a revised consent form as well as a copy of the grant application associated with the new title. This procedure may be used only when the research procedures are genuinely identical to those approved previously.

Several cautions apply to the second procedure:

- If the project does not receive funding and the investigator does not intend to use the title for another submission, the investigator should notify the IRB that the title will be "retired."

- The IRB does not want research titles to proliferate. Investigators who overuse the procedures may be prevented from employing them in the future.

Researchers must file for these changes **at least 30 days** before the grant submission date. In all cases investigator must provide a copy of the grant proposal**.**

9.4 Unfunded Proposals

If a proposal is not funded, the investigator should inform the IRB whether or not the work will be conducted in the absence of external funding.

GLOSSARY

Assent