2.10 Policies and Procedures Related to the Use of Human Subjects in Research

2.10.1 Policies on Research Involving Human Subjects

2.10.1.1 Intent of These Policies

These policies are intended to protect the rights and well-being of persons who are subjects of research that is sponsored, funded, conducted, or supervised by the University of Dallas and its faculty. They seek to assure such privacy as may be reasonably expected by those who are survey participants or otherwise subjects of observation, and to secure confidentiality and other rights of persons who are the subjects of research that seeks to alter significantly the behavior or state of health of the subjects, or that poses more than minimal risk that participation in the research may significantly affect the physical or emotional well-being of the subjects.

2.10.1.2 Policy to Secure Confidentiality for Subjects of Surveys and Other Observational Research

No researcher may include in the publication of the results of a survey or other observational technique such data or other information by which the identity of an individual participant in the survey, or the identity of an individual observational subject, may be directly discovered, unless the participant or subject has given express, informed, and deliberate consent to such identification. The researcher is responsible for maintaining written records of any such consent, in such form that the consent is not merely implied but reasonably demonstrated. Such records shall be maintained for a period of seven years from the date of publication of the research results and shall be open to inspection at any time within that period by the Institutional Review Board hereinafter established (established at 2.10.2, below, and hereinafter "IRB).

2.10.1.3 Policy Requiring Prior Approval of Research Involving Human Subjects

Research on human subjects which poses more than a minimal risk to the physical or emotional well-being of the subjects, or research using participants from vulnerable populations, such as children or individuals with limited cognitive abilities, or that seeks to alter significantly and beyond a short term their behavior or state of health, shall require prior review and approval by the IRB without regard to the source of sponsorship or funding of the research.

2.10.1.4 General Exemptions from Prior Approval

Research involving human subjects is specifically exempt from the prior approval of the IRB if any of the following conditions apply:

1. Only observational or survey techniques are used, in public settings or in settings in which in ordinary life outside the research protocol there is no reasonable expectation of privacy or confidentiality.

2. The research uses only testing or other techniques ordinarily used in an educational setting.

3. The anticipated probability and magnitude of harm or discomfort to the subjects or participants in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.10.1.5. Condition for exemption of class research projects

A faculty member who requires students to undertake research on human subjects, which research is believed to fall under the provisions for general exemption from prior review specified in the preceding section 2.10.1.4, shall provide to every research student a written protocol establishing parameters for the research that will ensure that the research shall be and remain within the provisions for exemption. The faculty member shall provide a copy of this protocol to the IRB before the research begins. A faculty member making such a research assignment assumes full responsibility for ensuring that all research carried out by a student meets the parameters described in the protocol submitted to the IRB, and that any research outside the scope of that protocol is submitted for separate review by the IRB.

2.10.1.6 Saving of Other Policies

The policy set forth in this section 2.10.1 is in addition to, and not prejudicial to, any other policies and regulations of the University.

2.10.2 Institutional Review Board

2.10.2.1 Purpose

The Institutional Review Board is established to assist researchers in the protection of the rights and welfare of human subjects involved in research.

2.10.2.2 Scope of Responsibilities

The IRB is responsible for prior approval of research involving human subjects that is conducted, sponsored, or funded by the University of Dallas or its faculty, in those instances in which prior approval is required by the provisions of this section 2.10. Prior approval by the IRB may be countermanded by the President of the University, but its disapproval is not subject to review.

For the University of Dallas, the IRB is the “Institutional Review Board” required by the applicable regulations of the U.S. Department of Health and Human Services in respect of

research involving human subjects that is (1) conducted or supported by a federal department or agency (45CFR46 §101), or (2) which a federal department or agency has specific responsibility for regulating as a research activity (45CFR46 §102 (e)).

The IRB functions as a Board of Inquiry into allegations that a researcher has not adhered to the policies and procedures set forth herein for research involving human subjects. In such instances, its findings and recommendations are made to the Dean of the faculty of which the chief investigator is a member, and to the President of the University.

2.10.2.3 Membership of the Institutional Review Board

1. The IRB consists of at least five voting members who have a variety of backgrounds and interests.

2. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. At least one member shall have expertise in ethics as a professional discipline. The IRB shall also include at least one member who is not otherwise affiliated with the University of Dallas and who is not part of the immediate family of a person who is affiliated with the University of Dallas.

3. Members of the IRB are appointed by the President of the University for staggered two-year terms.

4. Regular terms of office of members of the IRB begin on September 1st of the year of appointment. In the event of a vacancy before the end of the term for which the person was appointed, the President may appoint another person to serve the remainder of the unexpired term.

2.10.2.4 General Procedures of the Institutional Review Board

1. The IRB shall meet in person at least annually, to review University policies and procedures concerning research involving human subjects, and to review changes in applicable laws, and to take up such other business as may be pending.

2. The members of the IRB shall elect their own chairman at the beginning of each academic year. A Secretary shall be selected to keep minutes of the meetings of the IRB.

3. A majority of the IRB is a quorum for conducting all business. Any formal act of the IRB, in particular any prior approval of research, must be pursuant to a motion duly made and seconded and agreed to by a simple majority of the members present.

4. Meetings are called by the Chairman of the IRB or by any two members acting in

concert. All members must be afforded ample notice of any meeting.

5. Meetings may be conducted by telephone conference provided that no objection to this procedure is made by more than one member of the IRB in any particular instance.

2.10.2.5 Procedures for Prior Approval of Research

1. An investigator who plans research which falls within the scope of section 2.10.1.3, above ("Policy requiring prior approval of research involving human subjects") shall make application to the IRB, through the President's Office, for approval of the research before beginning the actual research work. The IRB may not approve such research begun without its approval.

2. The application for prior approval must include, at a minimum, all of the following:

A. The names of the investigators and their affiliations

B. The identities of sponsors and sources of funding

C. The objective(s) of the research

D. The plan of the research, including at a minimum the following:

I. Dates when the research is proposed to begin and end

II. Scope of concrete activities

III. General identification of the subjects of the research

IV. Specific investigational techniques to be used

V. How the results of the research are expected to be published or otherwise disseminated or used

E. A statement justifying the involvement of human subjects in the proposed research

F. Specific concrete measures to be taken to safeguard the rights and welfare ofthe human subjects

G. The printed name, departmental affiliation, and signature of the person making the application, and the date of the application

3. The Chairman of the IRB shall provide a copy of the application to every member of the IRB. The members shall consider the application and meet to vote on the application.

The IRB may approve the application, disapprove the application, or require modification of the research proposal.

4. The IRB must vote on the application and notify the applicant of the vote within thirty days of receiving the application, except, however, the IRB may extend its consideration for an additional thirty days if the complex or unusual nature of the proposed research requires more extended consideration or assistance from one or more outside experts. Any further extension may be appealed by the applicant to the President of the University, who must act within ten days either to approve or disapprove such further extension, which must be to a date certain.

5. A faculty member who is not certain that a particular research project, of his own or of one or more of his students, is exempt from prior review under the provisions for general exemption in section 2.10.1.4 above shall make an application for prior approval as specified in this section 2.10.2.5 and request an advisory opinion as to whether the research is exempt. Such an application may be eligible for expedited review by the Chairman of the IRB or by a single voting member of the IRB designated for such purpose by the IRB. If the faculty member requests such expedited review, an opinion shall be rendered not later than the end of the second business day following the calendar day on which the request is made. Should the IRB or its designee issue an opinion that a particular research project is exempt from prior approval, that opinion may be relied upon, but only by that faculty member and only for the particular research project specified by the applicant in the application.

6. Should an application be disapproved, the reasons therefore must be given in writing to the applicant. If the IRB requires modification of the research proposal, the required modification(s) must be specifically enumerated and the grounds for each modification must be stated.

2.10.2.6 Periodic Review of Approved Research

Every investigator who has secured from the IRB prior approval of a research project shall annually report to the IRB on the progress of the investigation, specifically discussing the operation of the safeguards for the rights and welfare of the human subjects involved in the research, with special mention of any complaints or problems that have arisen in that regard.

The IRB shall have authority to oversee any research for which it has granted prior approval, and shall have power to require special reports of the investigators, and to stop the research work if it finds compelling evidence of damage to the rights or welfare of human subjects of the research, or failure to implement fully the safeguards of rights and welfare stated in the application for approval, even if there is no evidence of specific instances of damage or abuse. Researchers are required to notify immediately the IRB of any situation where there is an injury, harm, or complaint of a participant.

2.10.2.7 Special Procedures in Respect of Research Falling under Federal Regulations

Research conducted or supported by a federal department or agency (45CFR46 §101), or which a federal department or agency has specific responsibility for regulating as a research activity (45CFR46 §102 (e)), shall be governed by the applicable regulations adopted by the U.S. Department of Health and Human Services and codified in Title 45, Subtitle A, Part 46 of the Code of Federal Regulations as revised. If, as, when, and where the provisions of this section 2.10 are deemed not to meet the minimum requirements of the federal regulations, such additional policies and procedures as are needed to conform to the minimum requirements of the regulations shall be formulated and proposed by the IRB for consideration and adoption in the usual channels as elsewhere specified in the policies and procedures of the University of Dallas.

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