

The University of Tulsa Institutional Review Board Policies and Procedures

1.0 Introduction

To implement the principles of the Code of Federal Regulations: Title 45 CFR Part 46; Protection of Human Subjects (revised June 23, 2005), The University of Tulsa at Tulsa, Oklahoma, has developed a systematic policy and a set of procedures to be followed in all investigations involving human subjects, whether or not the project is federally funded. Every application for financial support of research projects which involves the use of human subjects must be reviewed first by a Department Chair or Chair designate appointed by the Chairperson of the academic department from which the application emanates. Second, the application must be reviewed by the Institutional Review Board (IRB) either by the full membership of the IRB or by an exempt or expedited review conducted by the Chairperson of the IRB. The reviews by the IRB are conducted to ensure that research activities involving human subjects safeguard the rights and welfare of human subjects as provided for in 45 CFR 46.

General Policy

It is the policy of The University of Tulsa (TU) to require that all applications for support of research, training, or demonstration, which involve the use of human subjects, must follow the procedures and guidelines established by any sponsoring agency, and in the exact form to be used for submission. Regardless of the nature or degree of risk anticipated, the applicant must present in writing, and be prepared to defend in person before the IRB, detailed information on the following points:

1. The possible risks to the rights and welfare of human subjects, including the rights of privacy, freedom from undue harassment, and confidentiality of data, and a description of the provisions made to minimize these risks.
2. Methods used to acquire informed consent, with special emphasis on their appropriateness to the particular situation inherent in the study plan.
3. The relative risks of the project as compared to the probable benefits to the subjects and to society.

Every application for support of research which involves human subjects must include a completed application form and an informed consent form. The informed consent form should adhere to the guidelines of Sections 46.116 and 46.117 of 45 CFR 46 which can be obtained from the Office of Research and Sponsored Programs or by visiting the website at www.utulsa.edu/research. The Principal Investigator is required to keep on file the signed informed consent forms for at least three years. Reviews by the IRB will be used by the Administration as a basis for determining whether The University of Tulsa will approve the project. Data collected during periodic reviews of each ongoing investigation involving human subjects will be used as a basis for determining whether approval by the IRB shall continue.

Detailed procedural guidelines have been prepared by the IRB. These guidelines, as well as 45 CFR 46, are available in the Office of Research and Sponsored Programs.

1.1 The Belmont Principles

The use of human subjects in research is extremely important to the development of new knowledge in many areas. However, careful attention must be given to the questions of ethics and human dignity whenever human subjects participate in research. In 1978, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broad ethical principles to provide a basis on which specific rules could be developed.

These principles are discussed in *The Belmont Report*. Three basic principles are relevant to the ethics of research involving human subjects:

Respect for Persons: Respect for persons incorporates two basic ethical tenets: first, individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. In most cases of research involving human subjects, respect for persons demands that subjects enter the research voluntarily and on the basis of adequate information about the research situation and possible consequences.

Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as complementary expressions of beneficent actions in this sense. First, do not harm. Second, maximize possible benefits and minimize possible harms. Learning what will, in fact, benefit may require exposing persons to risk. The problem posed by these imperatives is how to decide when it is justifiable to seek certain benefits, despite the risks involved, and when the possible benefits should be foregone because of the risks.

The obligations of beneficence affect investigators because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risks that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of medical, psychotherapeutic, and social procedures.

Justice: Who ought to receive the benefits of research and bear its burdens? This is a question of justice – in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The selection of research subjects needs to be scrutinized in order to determine whether some groups (e.g. welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Especially when research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

1.2 Application of this policy

The Federal Policy for the Protection of Human Subjects (56 FR 28003) requires each institution engaged in research to have a written assurance of compliance that includes a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. Although the federal government (CFR.103.(b)(1)) does not regulate research with human subjects that it does not fund, it requires that institutions that receive funding for any human subjects research to be responsible for regulating all human subjects research conducted at or by the institution.

All research projects involving human subjects require prior review and formal approval by an Institutional Review Board. The purpose of this review is to determine whether subjects are at risk, that potential risks are minimized as much as possible, whether the potential benefits of the research outweigh the risks, that adequate provision has been made to obtain informed consent, and that participation is voluntary.

Some projects assigned to students in class may have a research component or constitute training in research methodology. If such projects contribute to general knowledge (e.g. through publication or dissemination of the findings), they are subject to the regulations and must undergo review. If a project is conducted as a student project and does not undergo IRB approval and then the student later decides they want to publish their findings, the IRB will not give approval after the fact. Approval must be obtained before data is collected.

Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB; however, instructors and students are encouraged to follow federal and university regulations when designing and conducting class projects with human participants. The University of Tulsa IRB policy on Undergraduate Student Course-Related Research Projects can be found on the Office of Research and Sponsored Programs website located at www.utulsa.edu/research in the Human Subjects Compliance section and is completely contained in this document as Appendix A.

The University of Tulsa recognizes its basic responsibility to ensure the protection of human subjects. The University has adopted this policy applicable to all research involving human subjects that is conducted at or sponsored by the University.

1.3 Assuring Compliance

In accordance with the Federal Policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46, Code of Federal Regulations Common Rule, Federal Policy for the Protection of Human Subjects, rev. June 23, 2005 implementing Public Law 93-348, July 12, 1974) establishing institutional review boards and an ethics guidance program, The University of Tulsa assumes the responsibility for the protection of the rights and welfare of human subjects who participate in research and other activity projects conducted by, or under the supervision of faculty, staff, or students, hereinafter called **investigators**.

To conduct this responsibility effectively, the University has an Institutional Review Board competent to review research, training, and other activity protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRB to (1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set by DHHS regarding the health, welfare, safety, rights and privileges of human subjects; and (2) assist the investigator in complying with DHHS regulations in a way that permits accomplishment of the research activity.

1.4 All Investigators Must

- Adhere to the principles of Respect for Persons, Beneficence, and Justice embodied in the *Belmont Report*.
- Adhere to the policies and procedures set forth in the University's *Policy for Protection of Human Subjects in Research*.
- Assure that the decision to participate in research governed by this policy meets the standards of informed consent. The decision must be: (a) voluntary – it must occur as the result of free choice, without compulsion or obligation; (b) based on full disclosure of the information needed to make an informed decision about whether or not to participate; and (c) based on the subject's comprehension of the information provided. If children are involved as subjects and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.
- Assure that the selection of research subjects is fair. Subjects should not be selected for potentially beneficial research on the basis of favoritism, nor should risky research be targeted to subjects who are less powerful.
- Assure that the procedures for recruiting subjects protect their privacy and be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Any payment made to subjects should not be so large as to constitute excessive inducement for

participation. When access to subjects is gained through cooperating institutions or individuals, the subject will be afforded the level of protection required by this document.

- Assure that risks to subjects are minimized and that they are justified by the anticipated benefits to the subject or society.
- Assure that adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.
- Assure that approval for conducting research with human subjects is obtained prior to any involvement of subjects. All such research must either be reviewed or designated as exempt from review by the IRB. All approved projects must be periodically reevaluated.

This policy does not apply to routine courses, workshops, or curriculum development using accepted educational practices sponsored by The University of Tulsa, unless the activity meets the definition of research in section 5.0 below.

2.0 Definitions

A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information (Title 45, Code of Federal Regulations, Part 46.102).

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably 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 reasonably 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 readily be ascertained by the investigator or associated with the information) to be of concern in research involving human subjects.

As defined in the federal policy [45CFR46.102(f)], **research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

People **not considered to be subjects** are individuals receiving services that are not experimental and which are intended to benefit only the recipient of the service; such services include most therapeutic treatments, counseling, and academic instruction. The definition of "**subjects**" excludes all accepted and established service relationships,

students to instructors, and other clients to professionals in which the student, or client is receiving aid or services consistent with accepted and established practice, that is intended only to meet his/her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. The normal employer-employee relationship is also excluded from the definition of subject. Payment of research subjects for their time as participants does not alter their status as subjects and does not change the relationship to one of employer-employee.

The rights of some subjects require special attention. These include: (1) children, because of their vulnerability, diminished autonomy, and incomplete understanding (In Oklahoma, a subject can't give consent without a parent's consent until they reach majority age, which is 18.), (2) subjects with limited civil freedom, such as prisoners and persons subject to military discipline, (3) people with limited capacities or mental disabilities, such as the mentally retarded or the mentally ill, and (4) pregnant women and the viable fetus, both in utero and ex utero.

IRB means Institutional Review Board.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at TU within the constraints set forth by the IRB, The University of Tulsa and Federal Requirements.

The Office of Human Research Protection (OHRP) considers the term **investigator** to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide coded information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research.

Obtains. In its guidance for use of coded specimens, OHRP has determined that under the definition of human subject, *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Individually Identifiable Private Information. According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be *individually identifiable* as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, OHRP considers private information or specimens not to be

individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

With respect to private information or human biological specimens, **coded** means that:

1. Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e. the code); **and**
2. A key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

Research that involves only coded private information/data or coded human biological specimens may not constitute human subjects research under the HHS human subjects regulations (45 CFR Part 46) if:

- The specimens and/or information/data are not obtained from an interaction/intervention with the subject specifically for the research; and
- The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the investigator's access to subject identities is prohibited).

3.0 Institutional Review Board

Campus policies and federal requirements regarding research with human subjects are implemented by the Institutional Review Board (IRB).

3.1 IRB Charge

The Human Subjects Institutional Review Board is appointed to review research involving human subjects for compliance with applicable federal and state regulations.

3.2 IRB Membership

The TU IRB includes a Chair, as appointed by the President of The University of Tulsa, and at least five additional members, appointed by the Vice Provost for Research, which includes one non-scientist member and one member from outside the university. Additional members to provide adequate attention to special expertise or to the risks of certain research subject populations will be brought in as necessary.

4.0 Scope of the Review

The **investigator** is faculty, staff or students of TU and is responsible for ensuring that his/her work is conducted in full compliance with all applicable laws, regulations, guidelines, and policies. It is his/her responsibility to refer to the Compliance sections of the Human Subjects Policy on any questions related to compliance or to seek clarification from the IRB.

The **department chair** has responsibilities related to all investigators in his/her unit and/or using facilities charged to the department. It is the department chair/chair designates' responsibility to be knowledgeable concerning all relevant aspects of compliance requirements; to ensure that all activities conducted in the department meet with compliance requirements; and to consult with the IRB Chair on any questions related to compliance. All department chairs or chair designates (the person the chair has designated to approve IRB protocols) must complete the online Collaborative Institutional Training Initiative (CITI) within 45 days from February 13, 2009 or within 45 days of their appointment, or protocols from the department will not be reviewed until training has been completed.

The University meets its responsibilities with respect to complying with applicable laws, regulations, guidelines, and policies. Among those responsibilities are:

- Developing and maintaining a coordinated system of compliance that includes activity review and approval, monitoring, reporting, and enforcement;
- Developing and maintaining a system of auditable files and information for the benefit of TU, and external oversight;
- Providing administrative and consultation services for offices, departments, review bodies and individuals to assist the process of establishing compliance;
- Providing educational services to faculty, staff, and students so that they can better meet compliance requirements;
- Coordinating activities with other units of TU so that the institution can meet its obligations in the most uniform, effective, and efficient way possible;
- Providing a communications link between agencies promulgating compliance requirements and TU personnel; and
- Submitting assurances, reports and/or other required communications to the appropriate federal and state agencies.

The University of Tulsa affiliated investigators are afforded the normal legal protection by the University, provided their activities have IRB approval and if they are working within the scope of their employment or University association. It is important to recognize that unless these conditions have been met, the University will not be in a position to protect TU affiliated investigators performing research with human subjects.

4.1 Whose Research must be Reviewed?

Human subject research conducted and/or sponsored by the University includes that conducted and/or sponsored by University employees, auxiliary employees, and/or students (including student/faculty collaborative research). All studies that utilize The University of Tulsa time, facilities, resources, students, faculty, or personnel must be reviewed.

Investigators affiliated with other institutions wishing to use The University of Tulsa subjects or work in any capacity under the auspices of the university, must submit a copy of their institution's federal assurance of the protection of human subjects, and documentation of the favorable review of their protocol by the IRB of their own institution, as well as the documentation required by this policy.

4.2 Extramural Support

Investigators requesting extramural support and planning to perform activities involving human subjects under the auspices of the University are required to submit an application for funds through the Office of Research and Sponsored Programs. All extramural research support requests involving human subjects should be submitted to the IRB a reasonable time in advance of deadline, receipt or submission dates specified by the operating agencies. Completed IRB review can under no circumstances be expected in less than 30 working days from receipt of a correctly completed application.

If external funding is requested, the protocol should be submitted to the Institutional Review Board in time to complete the review process and have approval prior to the beginning of the award or in accordance with agency/sponsor guidelines; otherwise, if it is not a sponsored project, the protocol should be submitted in time to complete the review before the start date of the research activity that involves the use of humans. If a sponsored project has "just in time" language in the request for proposals, then the protocol must be submitted and approved before the contract can be executed.

4.3 Student Research Activities

All student-initiated research involving human subjects must be supervised by a faculty or staff member to assure that human subjects are protected. The signature of the faculty advisor and the department chair (or the chair designate) is required for all student protocols. The faculty signature on student research attests that the research procedures comply with federal and university policies with regard to the protection of human subjects. The faculty sponsor is expected to monitor the research to ensure that the approved protocol with human subjects is followed.

Before any investigator can manipulate or collect data on human subjects proof of having completed human subjects training must be submitted to the IRB.

A final report is expected before a student departs the University for all protocols that are approved under expedited or full board review. It is the faculty sponsors' responsibility to ensure that this report is filed with the IRB. Sponsoring faculty are responsible for informing student investigators of human subject procedures.

Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB; however, instructors and students are encouraged to follow federal and university regulations when designing and conducting class projects with human participants. The University of Tulsa IRB policy on Undergraduate Student Course-Related Research Projects can be found on the Office of Research and Sponsored Programs website located at www.utulsa.edu/research in the Human Subjects Compliance section and is completely contained in this document as Appendix A.

5.0 Research as Federally Defined

The University of Tulsa IRB will review research involving human subjects conducted at or sponsored by the University in order to protect the rights of human subjects of such research. Activities which are not research but which nevertheless involve people, are not covered by this policy, but rather by other appropriate codes of conduct. Research is defined by the Federal Policy (CFR Pt. 46, Sect. 102 (d)) as: *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.*

As used in this document, the word research is defined as any systematic gathering and analysis of information, usually made under conditions determined by the investigator that aims to test a hypothesis, to discover some unknown principle, or effect, or to re-examine some known or suggested principle. The term research includes: (a) studies in which any substance or stimulus is administered to a subject by any means; (b) studies that involve changes in physical or psychological state or environment or major changes in diet; (c) interviews, surveys, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups; and (d) studies of existing public or privately held records where the identity of individuals is known. Activities that meet this definition constitute research even if they are supported or funded under a program that serves other purposes.

The term research is not intended to apply to:

- Routine course, workshop, or curriculum development using accepted educational practices sponsored by The University of Tulsa, including evaluation to determine participant satisfaction, attitude change, and /or knowledge gain during the educational experience; or to

- Aid or services provided by professionals to their clients that are consistent with accepted and established practice, and intended only to meet the clients' own personal needs.

These judgments and others in this section will ordinarily be made by the TU IRB.

Administrative surveys, questionnaires, and interviews not supported by federal funds and designed for use in the internal management and operation of The University of Tulsa do not constitute research within the meaning of this policy if the information or conclusions of the surveys are not intended for scholarly publication or for dissemination to persons outside the administrative organization of the University. A survey which is not research need not be submitted to the IRB for review. However, administrative personnel are encouraged to seek review by IRB in circumstances where there is potential in the future for scholarly publication or dissemination outside the administrative organization of the University, or where the survey involves information of a sensitive personal nature.

Classroom curriculum projects, workshop evaluations, and administrative review projects need not be reviewed by the IRB if they are not research, results will not be distributed outside the classroom or institutional setting, or are used to evaluate or review a program in order to build a better program. If however, the results of the project will be published or otherwise distributed, the project must be reviewed by the IRB. If in doubt, have the project reviewed.

Occasionally there are numbers of undergraduate and graduate students involved in behavioral research using human subjects. There is a wide range in types of student research that occur, everything from course related research exercises to master thesis studies. Departments offer courses that require students to undertake small projects in which other people are interviewed, observed, or otherwise serve as human subjects. The purpose of the course projects is to provide students a closer view of social, educational, or psychological processes, and/or with an opportunity to practice the same methods of observation customary to the various disciplines. Before making the decision to treat any project as a classroom study please refer to Appendix A of this document.

The following guidelines provide recommended methodologies for implementing the ethical principles for protection of human subjects:

- Services performed strictly for the benefit of the subject do not require review unless they place the subject at risk. For example, classroom instruction is a service and does not require review; however, the use of unconventional or experimental techniques such as blindfolding or hypnosis should be submitted for review. Research surveys and questionnaires utilizing human subjects are covered by this policy and may, or may not, be exempt from IRB review.

- Submissions proposing the use of class time for research should include an explanation of the beneficence of the research to the students. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class. The submission should also outline the precautions that will be taken by the investigator to ensure that student participation is voluntary and free of coercion.
- Signed parental consent is routinely required for any involvement of a subject who is a minor. School officials cannot grant consent for the use of students for research without signed parental consent; signed parental consent is required in addition to any administrative approvals.
- In addition to obtaining parental consent for a minor to participate in research, the minor should also be asked for his/her assent to participate.
- A training program does not constitute human subjects research if no data are collected. However, training programs that collect individual data through questionnaires, surveys, or direct physical involvement do constitute the use of human subjects and do require consideration. Instruments classified as exempt must be filed with the IRB.
- Anonymous questionnaires and surveys may not require signed Informed Consent, but the subjects should always receive the Explanation of Study. In addition, a non-anonymous instrument may not require signed Informed Consent if the information being collected by the questionnaire or survey could in no way be damaging to the subject. Signed Informed Consent is required when coding or demographics preclude anonymity, except if the consent document itself could lead to loss of anonymity; and if the collected information could be damaging to the subject.
- Long-term projects, especially large grants and contracts, may require preliminary approval before all human subjects involvement has been completely defined. Such projects should be submitted for review before funding is received and the project is initiated. A preliminary submission should contain all currently available information on the proposed use of human subjects. If possible, the proposed subject pool should be described and all currently foreseen risks should be outlined.
- Standard medical or psychiatric evaluations are services; however, the use of such records for any purpose other than the patient's own treatment constitutes research and requires IRB review.
- Methods of subject recruitment should comply with all federal, state, and local laws.
- If individuals in the proposed subject pool are in a position of diminished autonomy for any reason, the submission should identify safeguards that will be implemented to ensure that individuals in the subject pool are not at risk of negative repercussions from either their agreement or refusal to participate in the research. Subject pools including persons with diminished autonomy are pools that may include students, employees, prisoners, or patients.
- Consent of a guardian is needed for any adult subject who is not autonomous or is not capable of giving fully informed consent.

For formal research, federal regulations require institutions to take formal responsibility through human subjects review. In the case of under-graduate class projects, the course instructor is considered to be responsible. It is also the instructor's responsibility to disseminate this information to any teaching assistants or research assistants who may be under his/her direction.

Any student-initiated and/or student conducted research that does not fall under the heading of a research practicum which is defined by Webster's New Collegiate Dictionary as a course of study that involves the supervised practical application of previously studied theories of research method, and which uses human subjects, requires clearance by the IRB. This includes the graduate thesis and the senior project/thesis. Student research projects are reviewed using the same principles and guidelines for the protection of human subjects in general. Since responsibility for obtaining the human subjects committee approval for student research resides equally with the student and the faculty advisor, the signatures of both are required on the review protocol.

6.0 Categories of Research

Research involving human subjects is divided into three categories, depending on the type of research to be performed. These categories are: (a) research that is **exempt** from full board review; (b) research that is eligible for **expedited** review; and (c) research that requires **full board** review. The IRB Chair or the Coordinator of Research Compliance determines which research protocols are exempt from review. The IRB Chair or the IRB Chair's designate performs the review of projects which qualify for expedited review. The Chair calls upon members of the IRB when necessary to aid in decisions requiring special expertise. The IRB reviews all protocols whether the review is by the full board or the chair.

Approval certifications from the Board for the Protection of Human Subjects in Research are in force for no more than one year, after which any ongoing project must undergo another review cycle.

6.1 Minimal Risk

Research involving no more than minimal risk to human subjects *means that the probability of harm or discomfort anticipated 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 examination or tests* (CFR 102.I). Protocols at variance with this principle will be prepared for full IRB review.

- Minimal risk is to be determined with regard to the state of vulnerability of the particular subject or subjects, especially if special populations are used as subjects.
- Research in this category may receive expedited review as specified in CFR.220.a-d of the uniform federal regulations as described in this policy.

Investigators should submit protocols in the same manner as for protocols involving more than minimal risk.

6.2 Exempt Review

The IRB chair or the Coordinator of Research Compliance can approve exempt protocols: full board review is not necessary. The protocol is reviewed by the Coordinator of Research Compliance who communicates with the investigator any necessary changes. The Chairperson or the Coordinator of Research Compliance then reviews the protocol and either approves or requests additional changes or clarification. There are times when a subject matter expert will be requested to review a protocol.

6.2.1 Categories of Exempt Research

Federal regulations allow some human subject research of minimal risk to be exempted from review by the full IRB (**45 CFR 46.101 (b)**). However, the University of Tulsa does not authorize investigators to make this determination. Application for exempt status does not absolve the investigator(s) from ensuring that the welfare of the subject is protected and the methods used to gain subjects' informed and voluntary consent are appropriate. To be considered exempt status, the research activities must qualify as one or more of the following categories listed below:

- **45 CFR 46.101 (b)(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.
- **45 CFR 46.101 (b)(2)**: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior unless: (a) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' 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.
- **45 CFR 46.101 (b)(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) of this section if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statutes requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter, excluding pediatric subjects.
- **45 CFR 46.101 (b)(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 subjects (retrospective).

- **45 CFR 46.101 (b)(5)** Research and demonstration projects which are conducted by or subject to the approval of department of agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- **45 CFR 46.101 (b)(6)** Taste and food quality evaluation and consumer acceptance studies (a) if wholesome foods without additives are consumed or (b) if 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.

6.3 Expedited Review

Research involving no more than minimal risk can qualify for Expedited Review. The protocol is reviewed by the Coordinator of Research Compliance who communicates with the investigator any necessary changes. The Chairperson or Chair's designee then reviews the protocol and either approves or requests additional changes or clarification. There are times when a subject matter expert will be requested to review a protocol.

The review performed by the IRB Chair or designee will verify that subjects will be placed at no more than minimal risk. The policy criterion for determining risk whether a subject is "at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his/her needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

The IRB may use the expedited review procedure to review either or both of the following: (1) some or all of the research appearing on the list below and found by the reviewer(s) to involve no more than minimal risk. (2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 108.b.

6.3.1 Categories of Expedited Review

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review,

including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
8. 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.
9. 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 no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).

6.4 Full Committee Review

Projects not qualified for exemption or expedited review are considered as full review projects. Federal law requires that research involving human subjects be reviewed once a year at a minimum, even if expedited.

- Approval for these projects is granted for one year only.
- Investigators of projects that last more than one year must file each year for renewal of a project, and also upon completion of a project.
- The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- The IRB shall require that information given to subjects as part of informed consent is in accordance with CFR.116. The IRB may require that information, in addition to that specifically mentioned in CFR.116., be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- The IRB shall require documentation of informed consent or may waive documentation in accordance with CFR.117.
- The IRB shall notify investigators and the institution (TU) in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- The IRB shall conduct 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.

7.0 Risk-Related Questions

If risk is involved, the answers to the following three questions will be weighed:

- Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks?
- Are the rights and welfare of any such subjects adequately protected?
- Is legally effective informed consent obtained by adequate and appropriate methods in accordance with the provisions of the Federal Policy?

7.1 Protection from Undue Risks

The protection of human subjects from undue risks and deprivation of personal rights and dignity can best be achieved through consideration of three issues, that (1) subject participation is voluntary, indicated by free and informed consent (the subject is free to withdraw at any time without jeopardy, and may request that his/her data be destroyed), (2) the degree, nature, and management of risk to the subject and the investigator have been delineated explicitly by the investigator, and (3) appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subjects. The IRB has the ultimate responsibility to determine risk with regard to human subject research, and to approve or not approve such research under the sponsorship of the University.

Federal mandate (45 CFR 46) requires that the IRB review and approve any biomedical or behavioral research involving human subjects or organs, fluids, or tissues and assure that legally effective informed consent is obtained from study subjects. Risks to subjects are minimized by (1) using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; and (2) whenever appropriate using procedures already being performed on the subjects for diagnostic or therapeutic purposes. Appropriate safeguards to protect potentially vulnerable populations (e.g. pregnant women, fetuses, children, the mentally disabled, prisoners) are required. The Board must include persons whose primary concern is the welfare of these study subjects. The IRB examines and approves all proposed informed consent forms to ensure that subjects are provided with a clear and complete explanation of the study and its potential benefits and risks.

Investigators have many obligations, including designing the study so that the incidence of risk and stress are minimized to the greatest degree possible and that these risks are accurately described in the protocol. The Investigator bears responsibility for terminating the study when hazards or risks to the subject become apparent or may be incompatible with the benefits of the study; further, investigators must report any adverse reactions associated with the study to the IRB.

8.0 Application Procedures

The IRB requires three documents for each new study involving human subjects: (1) an application form, (2) a complete protocol, and (3) a copy of the consent form. These documents must be prepared using the headings indicated in the paragraphs which follow.

Full Board protocols must be submitted by the 1st working day of the month in which they are to be reviewed. Meeting dates of the Full Board are subject to change without notice.

8.1.1 Protocol

Investigators are required to submit a protocol describing the research or activity to the IRB. All protocols are submitted directly to the IRB. The IRB, or its designee, then reviews the protocol and takes action regarding approval.

All procedures related to the preparation of appropriate protocols as well as processes leading to their submission to the IRB are the responsibility of the University departments and investigators.

8.1.2 Contents of the Protocol

The **protocol** is a statement of the investigator's responsibilities toward the human subjects involved in the proposed research, and contains the information described below. A protocol is the investigator's plan of a scientific experiment or treatment. A full review protocol consists of an application form, an informed consent form, survey instrument(s) or questionnaire(s), and a grant proposal, thesis or prospectus (if available), so as to provide complete information regarding activities involving human subjects. The protocol provides the IRB with the information that it needs to approve the proposed research.

When preparing and reviewing a protocol, it is the responsibility of the investigator and the IRB to consider, among other issues, the following: the benefits and risks of the investigation, confidentiality of subject data, and the procedure for obtaining informed consent from all subjects.

Purpose and Background. The protocol must contain information pertaining to the background of a particular discipline. This section should state the relation of the proposed research to previous scientific investigations in the field including relevant laboratory and animal studies. Clear justification for the participation of human subjects at this stage of the investigation must be given. Investigators should keep in mind that most members of the IRB are not experts in the research being reviewed. **Adequate lay language explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the potential results, as well as the conditions and risks to which human subjects will be exposed.** The specific aims and hypotheses of the investigation should be discussed, including a definition of the area of the problem, the contribution the research is expected to make, and the relevance of the hypothesis to be tested. If specific hypotheses are not being tested, then the questions to be answered or the information hoped to be gained should be discussed. Also, if the investigation is a pilot or exploratory one, then a discussion of the way in which the information obtained will be used in future studies should be included.

Methods Section. A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with their subjects and the means of observation to be used. When questionnaires are to be administered, a copy

should be included. Standard psychological tests should be identified. Special attention will be given to issues of confidentiality in behavioral studies. In cases where information provided to subjects regarding procedures and purposes of the study would invalidate the objectives, the investigator should report to the IRB reasons for not informing subjects of the procedures. Devices or activities that are not customarily encountered by the subjects in their daily living or unusual applications of such devices or activities must be described in detail. Any special procedures involving unusual electrical devices, radioisotopes, or investigational new drugs (IND's) must also be described. If the study is to be administered off campus, approval must be obtained from the agency before IRB approval can be granted. If the study is to be administered on campus with a particular group (i.e. athletes, fraternity, sorority, etc.) approval must be granted (for example the Athletic Director must give approval for any studies with athletes, the president of the fraternity or sorority, etc.) before IRB approval can be granted. A tentative time schedule for the various procedures (or flow-chart where appropriate) should be provided showing how long each aspect of the study will take, the frequency and timing of ancillary procedures, the nature and duration of human discomfort, and the precise location in which the study is to be conducted. Frequency, duration, and location of interviews or observations should be indicated in behavioral or social science studies.

Subjects. Effects of sample size on the magnitude of risk and problems of risk management will be considered by the IRB. Justification must be provided for the use of subject groups that are members of a population whose capability of providing informed consent is or may be absent or limited. These include children, persons with diminished mental capacity, the senile who are confined to institutions (whether by voluntary or involuntary commitment), the unborn child or fetus, and pregnant women. A pregnant woman's ability to provide consent is limited insofar as they can participate only in activities whose purpose is to (1) meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

A detailed and specific discussion of potential problems involving the subject groups must be given.

Potential Benefits. This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the benefits to individuals and/or society with respect to the risks involved in the study. Please note that incentives such as cash payments, gift certificates, or extra credit are not considered a benefit of the proposed study. Incentives should be included in the subject compensation section of the informed consent.

Potential Risks. A discussion of the risks, if any, to the subject is required. Such harmful effects may be physical, psychological or social. Some research involves neither risks nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

Management of Risk. A Discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described (including confidentiality safeguards). An assessment of their likely effectiveness should be discussed also. Management of risk procedures ranges from those applicable to a group (such as the exclusion of pregnant or potentially pregnant women from a study involving a new drug) to those applicable to an individual subject.

Procedures for Risk Management.

- Obtain informed consent.
- Maintain anonymity or a high degree of confidentiality through secured data and research records.
- Debrief human subjects after their participation in the experiment is concluded. Information should be appropriate for the individual (i.e., based on experimental situation and performance). Subjects should be supplied with a summary of the project when it is completed.
- All possible alternative methods should be explored prior to the selection of a procedure which would place a human subject at risk. Procedures selected should result from an attempt to minimize stress while maximizing the usefulness of the information obtained.
- Investigators should concern themselves with how the information obtained from the experiment will affect individual human subjects as well as the community in general.
- Adequate access to first aid must be available in any study involving even minimal physical risks.
- Ready access to medical personnel, services and emergency care must be provided in any study involving significant potential physical risk.
- Adequate access by referral to psychological treatment must be available in any study involving psychological risk.

Personnel. Identify all personnel who will participate in or assist in the conduct of this research. Identify each individual by name, title, and responsibility in the research project. Briefly outline each individual's qualification. For procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or background of the investigators qualifying them for the performance of these procedures should be indicated. All personnel must complete an IRB training course. If the principal investigator is a student, the student's faculty advisor must also complete an IRB training course.

Other. The IRB relies on the expertise of the investigators to provide insight about any peripheral benefits or potentially harmful effects of the conduct of the research. Based on your past experience and knowledge, please identify any extraordinary moral, legal, or ethical concerns, either beneficial or harmful, which may have been linked to this type of research.

When the proposed project is submitted to the appropriate human subjects officer, a preliminary review of the protocol is done to determine whether (a) the project is exempt under the regulations or is to be reviewed under the expedited or full review process (b) the protocol meets the general requirements for review under the regulations; and (c) the informed consent form contains the required elements and is in satisfactory form for review.

Anonymity exists when there are no identifiers whatsoever on project materials which could link the data with individual subjects. Even the research investigator cannot know the identity of participants.

Confidentiality is the right of privacy and of non-release of disclosed personal information. The investigator should protect subjects against invasion of privacy and loss of confidentiality. Lack of secure handling of completed personality tests, questionnaires, interview protocols or data, and recorded materials, arguments risk and must be avoided.

8.2 The Consent Form

Any project proposing to place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

If the subjects are minors or are not capable of giving consent, parental, guardian or other legal representative consent is required. Use of written consent form that includes all the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative.

A consent form documents informed consent and is designed to protect the investigator and the institution against legal liability.

The consent form should be a statement addressed to the subject and should read as such. It must be in language the subject can understand. Avoid or define technical terminology, adjust for educational background and ages, and provide translations in other languages when subjects do not understand English.

8.3.1 Informed Consent

Research investigators are responsible for obtaining informed consent and for insuring that no human subjects will be involved in the research prior to obtaining their consent. In obtaining informed consent, investigators must avoid the possibility of coercion or undue influence. Unless otherwise authorized by the IRB, investigators are responsible for insuring that legally effective informed consent shall:

- Be obtained from the subject or the subject's legally authorized representative;
- Be in language understandable to the subject or the representative;
- Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
- Not include exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

8.3.2 Required Elements for Informed Consent Forms

The written consent form must include the following items. In addition, special provisions are required when subjects are from special populations.

- A statement that the study involves research;
- An explanation of the purposes of the research
- A Description of the procedures to be followed;
- The expected duration of the subject's participation;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A statement describing how confidentiality of records identifying the subject will be maintained;
- An explanation of whom to contact for answers to questions about the research (investigator's name and phone/address, and that of the faculty advisor if investigator is a student); regarding research subjects right; and in the event of a research related injury to the subject;
- Statement that: participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; that the

subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and an indication that the subject may keep a copy of the consent form.

8.3.3 Additional Elements (as appropriate)

- For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and who is responsible for payment of medical expenses;
- For research projects that involve videotaping, a videotape release must be included in the written consent form (if the investigator anticipates use of the tapes beyond the scope of the initial research project, the written consent form must indicate (a) who will view the tapes, (b) for what purpose, and (c) when the tapes will be destroyed);
- If subjects will be paid, all information concerning payment, including amount and schedule of payment;
- A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
- Identification of any procedures which are experimental;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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
- The approximate number of subjects involved in the study.

8.3.4 Documentation of Informed Consent

The consent form is a written document that contains the required elements of informed consent, to be read by the subject or the subject's representative or by the investigator to the subject. Investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form and signed by the subject or, the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. Each person signing the written consent form must be given a copy of that form.

8.3.5 Waiver of Documentation of Informed Consent

Under certain conditions, the IRB can waive the requirement that the subject sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if one of the following conditions exists:

- The consent document is the only record linking the subject and the research and the principle risk would be potential harm resulting from a break of confidentiality. (Subjects will be asked whether or not they want documentation linking them to the research, and their wishes will prevail);
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- Projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in a introductory letter attached to the instrument, which includes a statement that completion and return of the questionnaire will constitute consent to participate.

8.3.6 Verbal Consent

Only in special and/or unusual circumstances can the consent of the subjects be obtained orally. Waiver of prior written informed consent must be approved by the IRB. A waiver of prior written informed consent might be granted in the case where: (a) the risk to the subject is minimal; (b) use of primary procedures for obtaining consent would invalidate important research objectives; or (c) alternative means would be less advantageous to the subjects. Oral presentation of the elements of informed consent should be used only when it is the most appropriate means of conveying relevant information to the subject, thus adapting the presentation to the subject's capacities.

The presentation maybe made in either of two ways. A written consent document that sets forth the required basic components of informed consent may be read to the subject or the subject's representative and the investigator will allow the subject or representative ample time to read and consider the document before it is signed. Or the IRB may approve a short written form describing the particulars of required informed consent that are to be presented orally to the subject or representative. Where oral consent is allowable, investigators shall insure that: a witness is present at the oral presentation; the short form is signed by the subject or the representative; the witness signs both the short form and a copy of the written summary of the oral presentation; the person obtaining consent signs a copy of the summary; a copy of both the short form and summary is given to the subject or the representative; and the written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

8.3.7 Waiver of Alteration of Informed Consent

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided one of the following sets of conditions exists and is documented:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (a) programs under the Social Security Act or other public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.
- The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

9.0 Review Outcomes

After review and discussion of the protocol and application, the IRB may take one of the following four actions: (1) approve, (2) approval after modification, (3) disapproval, or (4) the suspension/termination of a previously approved protocol. These actions may only be taken at convened meetings at which a majority of the members are present.

9.1 Approval of Research

In any review, the reviewers will determine that:

- Participation of human subjects in the project is justified.
- Risks to subjects are minimized by using appropriate procedures.
- Risks are justified in view of anticipated benefits.
- Selection of subjects is equitable. Justification is required if the subject population is restricted to one gender or ethnic group. (In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.)
- Adequate provision is made for confidentiality of data and anonymity of participants in any published record.
- Adequate provision is made for the rights and welfare of participants who are mentally, physically, economically or educationally disadvantaged.

- Adequate provision is made for obtaining informed consent of the subjects, including those for who English is not their first language.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by CFR.117.
- When appropriate, the research plan makes adequate provision 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.

9.2 Requires Modifications

This action involves major or minor modifications to some part of the proposed study. The modifications or conditions set by the IRB include such items as revising the consent form to explain the procedures more clearly, adding a Spanish version of a consent form, restrictions on the use of certain procedures or subject groups or necessary for the protection of human subjects. The IRB may request the investigator to discuss problems with the IRB directly or through a selected member. The IRB may require significant modifications in the research protocol. This occurs when the IRB feels that it has insufficient information to take action, or when it feels that the research design contains significant risks and should be revised to minimize those risks to human subjects. The IRB may request the investigator to discuss problems with the IRB directly or through a selected member. Modified research protocols must be resubmitted for approval. The IRB may choose to use expedited review for resubmissions involving minor modifications.

9.3 Disapproval

In this case the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject.

9.4 Suspension or Termination

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. (CFR.113.)

9.5 Disposition of Decisions

Approvals, recommendations, restrictions, conditions, or disapprovals are communicated to the investigator through the office of the appropriate administrator, as appointed by the Vice Provost for Research. At the time of transmittal of approval, the IRB will also inform the investigator of the expiration date of the approval.

If an application is not approved as conforming with the Federal Policy for the Protection of Human Subjects and the University, the IRB shall forward to the investigator a statement setting forth in detail the reasons for the non-conformity and the recommendations of the IRB for modification of the research protocol. (CFR.109.(d))

9.6 Documentation

Investigators. Investigators are required to make and keep written records of the IRB reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent of the subjects or their legally authorized representative. Such forms must be retained on file by the responsible individual for a minimum of five years after termination of the project.

In compliance with Federal Policy of the Protection of Human Subjects, investigators will maintain records of research data for at least three years after the research is concluded.

The investigators must periodically review research results to assure (1) that harm has not occurred and (2) that the ongoing research protocol is producing adequate results such that benefits of the research continue to balance risks to human subjects. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefit, the investigator must report immediately to the IRB.

The IRB. The IRB is required to keep copies of all documents presented or required for initial and continuing review by the Board. The records of the IRB pertaining to individual research activities are not accessible to persons outside the Board and the individual investigator, except for purposes of audit or inspection by federal agencies and appropriate University administrators to assure compliance with the uniform federal policy.

The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

- Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members in the same detail as described in CFR 103.(b)(4) and CFR 103.(b)(5).

- Statements of significant new findings provided to subjects, as required by CFR 116.(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

The Institution. It is the responsibility of TU through the appropriate administrator or administrative office, as appointed by the Vice Provost for Research, to assure compliance with and provide documentation of compliance with the Federal Policy for the Protection of Human Subjects.

Research that is covered by this policy and that is conducted or supported by a federal department or agency must provide written assurance satisfactory to the federal department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office of Human Research Protections, DHHS, and approved for federal wide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports, (except certification) required by this policy to be made to department and agency heads shall also be made to the Office of Human Research Protections, DHHS.

Federal Departments and agencies will conduct or support research covered by this policy only if TU has an approved assurance and only if TU has certified to the federal department or agency head that the research has been reviewed and approved by the IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

- A statement of principles governing TU in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by TU, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by TU itself. This requirement need not be applicable to any research exempted or waived under CFR 101.(b) or (I).
- Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping duties.
- A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB membership shall be reported to the department of agency head, unless in accord

with CFR. 103.(1) of this policy the existence of an DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office of Human Research Protections, DHHS.

- Written procedures which the IRB will follow for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of TU the obligations imposed by this policy and shall be filed in such form and manner as the federal department or agency head prescribes.

Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under CFR 101.(b) or (I). TU shall certify that each application or protocol for research covered by the assurance and by CFR 103. of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. If TU is without an approved assurance covering the research, TU shall certify within 30 days after receipt of a request for such a certification from the federal department or agency, that the application or protocol has been approved by the IRB. If the certification is not submitted within these time limits, the application or protocol may be returned to TU.

9.7 Duration of Approval and Renewal Applications

Federal policy requires that the IRB conduct at least an annual review of approved research activities, (CFR 109.(e)). Investigators should indicate the expected overall duration of the research when submitting an initial protocol. Renewal applications should be made before the date of expiration of IRB approval, bearing in mind the time needed for review and that research activity must cease at expiration date if renewal has not been obtained.

The IRB will determine the term of approval and will notify the investigator of the date of expiration of approval at the date of approval. As a courtesy, notice of expiration of

approval will also be sent to the principal investigator by the administrator of the IRB approximately four weeks before the expiration date of any currently approved protocol.

Approval of a protocol is granted to the principal investigator. If the principal investigator ceases to be responsible for the study, approval automatically ceases. Should a new principal investigator desire to continue the study, reapplication (as for a renewal, see below) to the IRB is required.

10.0 Renewal Applications and Modifications for Protocols

Renewal of approved protocols is required annually and is also required if the principal investigator changes. If during the course of any research, training, or demonstration, a change in plans is made so that human subjects are now to be used, or that the research methods or techniques are significantly different, or new hazards are evident, a statement of such change in plans must be submitted to the IRB, and an approval of modification of the existing protocol must be obtained. In general, any change which alters the risk/benefit balance or which modifies the informed consent in some way requires approval.

Renewal applications require a copy of the current or new consent form and (1) a **summary** of the previous (approved) protocol, or copy of the previous protocol; (2) **progress report**. This should be a brief discussion of the work accomplished to date, including particularly:

- The number of subjects enrolled this year and the number enrolled to date;
- A synopsis of activities to date, including the progress of the study as compared to the hypothesis;
- A discussion of any grievances or complaints received about the study, if any;
- A discussion of any adverse events occurring to any subjects during the conduct of the study (if no adverse event has occurred, it should be stated, rather than omitting this item altogether);
- A discussion of any information (i.e. publications, presentations, etc.) that have become available since starting the study that indicate a need to modify the study; and
- A summary of any anticipated revisions not yet reviewed by the IRB. (Separate approval is required for revisions and approval of the progress report does not indicate an approval of revisions.)

Progress reports should not be photocopies of papers either published or submitted for publication. The papers primarily inform their readership of scientific advances. It is necessary to inform the IRB, in as concise a manner as possible, of the results only as they influence the balance of benefit to risk to human subjects. Published papers may be appended as evidence of benefits of the research.

Modification applications require a copy of the current or new consent form and: (1) a **summary** of the previously approved protocol, or a copy of the previous protocol itself, (2) a **description** of any modifications which are desired and (3) a complete protocol with changes highlighted.

The investigator must submit a new protocol at the beginning of the project's fourth year. This submission should include the original protocol, any revisions, the current informed consent, and any other pertinent documents.

11.0 Unanticipated Problems

Any unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices must be reported immediately to the IRB and to any federal agency sponsoring the project by the investigator.

Reports should include:

- Identification of individual(s) involved;
- Identification of principal investigator, title of project and project number;
- A description of adverse reactions and any possible association with the experimental procedures, drugs, medical devices, etc.;
- Any relevant information on the subjects (previous exposure to drugs, therapy, case history, background information, etc.).

12.0 Violations of Policies and Procedures

Noncompliance with these policies and procedures is subject to University disciplinary action. Violations of these policies and procedures should be reported to the IRB immediately.

The IRB will review allegations of violations of these policies and procedures, and will follow the policies and procedures as set forth in The University of Tulsa Policy for Ethical Conduct in Academic Research and Scholarship, and other regulations governing faculty, staff, and student ethical conduct as appropriate.

If any research which is federally funded is found to be in violation of any of the federally mandated portions of this policy, or of appropriate federal regulations regarding the protection of human subjects, the IRB shall report to the appropriate agency on behalf of the investigator, if the investigator fails to report.

In any instance where IRB requirements are not being followed, the IRB shall inform the principal investigator and also the appropriate administrator, as appointed by the Vice Provost for Research, who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the appropriate administrator will terminate

the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action.

13.0 Advice and Consultation

Investigators and departments may call upon the IRB for informational consultation. Any consultation extended is informational in nature. It is neither interpretative nor decisional, as these are solely the prerogatives of the IRB in its review function.

14.0 Omissions

In the event that issues related to the use of human subjects in research at TU are not covered by this policy, the IRB will rely on the Federal Policy.

15.0 Amendments

Any amendments to this policy require the approval of the majority of the membership of the IRB, as well as approval of the Vice Provost for Research and the President of The University of Tulsa.

New campus or changes in state or federal laws shall be incorporated in this document by the appropriate administrator without further review.

The final authority for amendment of these policies and procedures and for the adoption of a new revision rests with the President.

For current information on the Policy for Protection of Human Subjects, refer to the federal website: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

Appendix A

The University of Tulsa-Institutional Review Board Policy and Procedure

Undergraduate Student Course-Related Research Projects*

Federal regulations require that research protocols involving human subjects be reviewed by an Institutional Review Board for the Protection of Human Subjects in Research (IRB). These regulations also allow certain types of studies to be exempted from IRB review. The University of Tulsa (TU) abides by an approved "Federal Wide Assurance" (FWA00006580) assuring the Office for Human Research Protections (OHRP) the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the university are adequately protected.

In the case of a student course-related research project assignment, it may be difficult at times to distinguish between that which would require IRB review and that which is designed simply to provide an experience in research methodology. In some courses, students collect data by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. Some of the methods involve human subjects and, in some instances, subjects may be placed at risk.

In an effort to clarify the matter, the TU- IRB has drafted the following guidelines for determining when institutional review and approval is necessary for projects that are part of an academic course:

Student projects that are solely classroom directed exercises (purpose of the student investigation is solely for the fulfillment of a course requirement) do not require IRB review if they meet all of the following criteria:

- (a) involves the learning of research techniques; AND
- (b) involves no more than minimal risk; AND
- (c) the data is recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names, or the recorded data will not identify the subject through their behavior); AND
- (d) the data will not be used beyond the classroom environment (**i.e. will not be published, orally presented, presented at a conference, colloquium, departmental colloquium, poster presentation or used in further research by the student, other class members or the instructor**); AND
- (e) the research review category would normally fall under the exempt or expedited review categories (defined by CFR 45 Part 46 available at the

following website:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>).

If protocols/projects meet ALL of the above criteria, these projects shall be deemed to be "classroom exercises" and are not subject to review by the IRB.

In these cases, the primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor in accordance with Attachment A. The faculty member/instructor shall take responsibility for communicating to students ethical principals of research, review/approve student research protocols prior to initiation of the research project, monitor students' research activities and reports of findings, and assure that the students' own work does not violate human subjects' protection.

If the instructor is not certain that all of the criteria above have been met, they should contact the Coordinator of Research Compliance. If the instructor/student has reason to believe they may wish to present the results of this research in an activity such as a poster presentation or colloquium, the protocol must go before the Board for approval.

* This policy does not apply to master's theses or doctoral dissertations. Those protocols must follow standard IRB review policies and procedures.

**The University of Tulsa-Institutional Review Board
Policy and Procedure**

Undergraduate Student Course-Related Research Projects*

ATTACHMENT A

1. Ethical Principles for the Protection of Human Subjects of Research
 - 1.1. Every person has the right to determine what shall be done to him or her, what activities he or she shall engage in and what risks he or she will take. Consequently, research on human subjects cannot be carried out without the subjects' competent, voluntary and informed consent.
 - 1.2. No person should be placed at risk as a subject of research unless the risks are reasonable in relation to the anticipated benefits of the research.
 - 1.3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and should not impose inequitable risks and burdens on any segment of society.
 - 1.4. Special consideration and protection should be given in research to persons who may lack full capacity to secure their own rights and interests, due to age, mental capacity, involuntary custody, cultural barriers or other special circumstances.
2. Definitions
 - 2.1. "Student Research" means any observation or intervention by a student as part of a course which is designed to develop or contribute to student learning or to general knowledge, and for which publication of findings outside class will not take place.
 - 2.2. "Human Subject" means an individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the person, or (2) personally identifiable information.
 - 2.3. "Student Researcher" means any student enrolled in a course at The University of Tulsa who conducts research on human subjects as an assignment or project in the course (excluding masters' or doctoral theses research which are not designated as classroom projects).

- 2.4. "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals. Minimal risk does not involve data that, if made public, could place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing.
3. Responsibility of Instructors
 - 3.1. Instructors of courses in which students do research involving human subjects must complete the TU-IRB required training program prior to review/approval of any student project.
 - 3.2. Instructors of courses in which students do research involving human subjects are responsible for informing students of the ethical principles for the protection of the human subjects of research and applicable policies and procedures.
 - 3.3. Instructors of courses in which students do research involving human subjects are responsible for prior review of that research in accordance with these policies and procedures.
4. Instructor Review of Student Research
 - 4.1. If student research involves passive observation of public behavior, poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, instructors shall review and approve the research. Informed consent of subjects is not required. Examples of such research are:
 - a) observation of public behavior except where it is recorded in such a way that the subject can be identified directly or by identifiers linked to the subject and the subject's responses, if they became known, could place the subject at risk of legal liability or financial loss, or deals with sensitive aspects of behavior or use of alcohol;
 - b) research involving the collection or study of existing data, documents, records or specimens, if they are publicly available or if they are recorded in such a manner that subjects cannot be identified; or
 - c) observation in established or commonly accepted educational settings.

- 4.2. If student research involves intervention but poses no more than minimal risk, the course instructor will be responsible for the review and approval of the research. Informed consent of subjects is required. If the research involves more than minimal risk, it must be reviewed by the IRB as described in Section 5.
- a). The instructor is responsible to assess whether risk is more than minimal as defined in 2.4. If there is any question or doubt about the degree of risk posed by the research and if there is any possibility of more than minimal risk, the protocol must be reviewed under Section 5 below.
 - b). The instructor must review and approve the procedures for obtaining informed consent and assure that they meet the requirements of The University of Tulsa, Institutional Review Board prior to their use by student researchers.
 - c). The instructor must review and approve the instruments, methods and procedures of the research protocol in their final form prior to their use by student researchers.
 - d). The instructor must keep a record for at least one calendar year of research protocols which includes the research project title, the student researchers' names and the date of the instructors' review and approval.
 - e). Examples of research which may be approved by the procedures of this section are:
 - i) research conducted in established or commonly accepted educational settings involving normal educational practices;
 - ii) research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information is recorded in such a manner that the subjects cannot be identified directly or through identifiers linked to the subject;
 - iii) research on individual or group behavior or characteristics or individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not stress the subjects;
 - iv) research involving survey or interview procedures except where responses are recorded in such a way that the subjects can be identified directly or through identifiers linked to the subject AND the subject's responses, if they

became known, could place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing;

- v) moderate exercise by health volunteers;
- vi) recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.

5. IRB Review of Student Research

- 5.1. If student research involves more than minimal risk, the research protocol must be submitted to and approved by the IRB prior to any data collection activity.
- 5.2. If the research protocol is generic (i.e., all student researchers will use the same instruments, methods and consent procedures), the course instructor will submit a regular IRB application form. Once approved by the IRB, the generic protocol may continue to be used by student researchers without further review by the IRB unless:
 - a) the protocol is changed;
 - b) there is a complaint from a subject;
 - c) there is an adverse reaction by a subject; or
 - d) there is a change in the research environment or new information that would indicate greater risk to human subjects than that assumed when the protocol was initially reviewed and approved.
- 5.3. By law, IRB approval is only valid for up to one calendar year. Renewed approval must be sought for projects extending beyond one year.