Tulsa Community College Institutional Review Board Policy

1.0 Introduction

To implement the principles of the Code of Federal Regulations: Title 45 CFR Part 46; Protection of Human Subjects, Tulsa Community College 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. The application must be reviewed by the Institutional Review Board (IRB) either by the full membership of the IRB or by an expedited review conducted by at least two reviewers assigned by a co-chair of the IRB or their designee.

The TCC IRB includes typically two co-chairs (and may operate with only one as college needs dictate), and at least five additional members. Co-chairs and members may be nominated by the members of the IRB and/or the Council Effectiveness Committee and are subject to approval by the Chair(s) of the Institutional Effectiveness Council. The membership must include one non-scientist member and one member from outside the college.

Additional members to provide adequate attention to special expertise or to the risks of certain research subject populations will be brought in as necessary. The reviews by the IRB are conducted to ensure that research activities involving human subjects safeguard the rights and welfare of human subjects.

1.1 General Policy

It is the policy of Tulsa Community College (TCC) to require that all applications for support of research, training, or demonstration, that involve the use of human subjects or their data or biospecimens, 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:

- 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.

- Methods used to acquire informed consent, with special emphasis on their appropriateness to the particular situation inherent in the study plan.

- The relative risks of the project as compared to the probable benefits to the subjects and to society.

Every application for support of research that 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 .116 and .117 of 45 CFR 46 which can viewed by visiting the TCC IRB Website. The Principal Investigator is required to keep on file the signed informed consent forms for at least three years after completion or termination of the research. 45 C.F.R.____.115. Reviews by the IRB are limited to the ethical treatment of human subjects and do not necessarily

constitute approval to conduct the study at TCC.

If a researcher would like to continue to conduct a study after the approval date (i.e., 1 year) he/she is required to complete the *Annual Renewal Form* (https://www.tulsacc.edu/about-us/administration/offices/academic-affairs/institutional-review-board-irb/irb-policies-forms). The primary investigator will be notified 4 weeks before the expiration date of approval. In addition, if minor changes are made to the protocol, participants, etc. the researcher is required to complete the Research Modification Form that can be found in the IRB website (http://www.tulsacc.edu/irb).

1.2 The Belmont Principles

The use of human subjects in research is extremely important to the development of new knowledge in many areas. 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:

1.2.1 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.

1.2.2 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.

1.2.3 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.

1.3 Application of this policy

The Federal Policy for the Protection of Human Subjects 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. The federal government does not regulate research with human subjects that it does not fund. It requires that institutions that receive funding for any human subjects research be responsible for regulating *all* human subjects research conducted at or by the institution.

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

If a project contributes to general knowledge (e.g., through publication or dissemination of the findings), they are subject to the regulations and must undergo IRB review. If a project is conducted and did not undergo IRB approval and then the researcher 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.

Before any investigator can manipulate or collect data on human subjects proof of having

completed human subjects training must be submitted to the IRB. The following are accepted human subjects training: NIH, CITI training, or TCC's online modules.

1.4 Student Research Activities

Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB. Classroom projects include assignments not intended for dissemination or that do not involve data gathering outside of the classroom. Instructors and students should follow federal and college regulations when designing and conducting class projects with human participants whether or not they are intended for scholarly presentation (e.g., participation in Oklahoma Research Day, submitted to a peer review journal, poster presentation).Tulsa Community College IRB policy on Undergraduate Student Course- Related Research Projects can be found in Appendix A.

All student-initiated research involving human subjects must be supervised by a TCC faculty or staff member to assure that human subjects are protected. An alternate class assignment must be provided to students who opt out of participation in the research. The signature of the faculty sponsor is required for all student protocols. The faculty signature on student research attests that the research procedures comply with federal and college policies with regard to the protection of human subjects.

2.0 Definitions

The following are definitions for the purpose of this policy.

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

Archival Research is a method of collecting data from sources that already exist. Common examples are student data (e.g., GPA, course grades, data from IR&A) or survey data that was collected in the past. This method differs from empirical research in which a hypothesis and areas of interest are determined before data collection occurs. Data does not include artifacts collected prior to IRB application approval. For example, using course writing assignments, lab assignments, journals, etc. from a previous course in which the researcher did not receive permission from students to use their work.

Biospecimen is blood and other body fluids, tissues, nucleic acids, and other direct derivatives from **human** tissues. Subsets of human materials and derivatives of the biospecimens, such as extracted DNA, or derived cell lines that are traceable to a human subject.

Broad Consent is when the researcher is seeking prospective consent to unspecified future research.

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.

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 (45 C.F.R. 46.102). 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 or diminished cognitive capacities, (4) pregnant women and the viable fetus, both in utero and ex utero, and (5)people that are economically, educationally disadvantaged.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may be ascertained by the investigator or associated with the biospecimen.

Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (45 CFR 46.102. (e) (5))

Informed Consent is the process by which a volunteer confirms his or her willingness to participate in the research after having been informed of all aspects of the trial that are relevant to the volunteer's decision to participate.

Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102. (e) (3))

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (45 CFR .102. (e) (2).

Institution means any public or private entity, or department or agency (including federal, state, and other agencies). (45 CFR .102. (f)).

IRB (Institutional Review Board) means an institutional review board established in accord with and for the purposes expressed in this policy. (45 CFR .102. (g)). The IRB determines and certifies that all projects conform to the regulations and policies set by DHHS regarding the health, welfare, safety, rights, and privileges of human subjects; and assists the investigator in complying with DHHS regulations in a way that permits accomplishment of the research activity.

IRB Approval is the determination of the IRB that the proposed research has been reviewed and that it does not violate the ethical standards of human subjects research. However, IRB approval does NOT grant approval to conduct research on TCC employees and/or students. Further approvals are necessary for collecting information on or from TCC employees and/or students.

Investigator includes anyone involved in conducting the research. The IRB 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. If the individuals who provided coded information or specimens also collaborated 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 investigators in the conduct of the research.

Legally Authorized Representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. (45 CFR .102. (i)).

Minimal Risk the probability and magnitude of harm or discomfort anticipated in research are no greater in and of themselves than is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental, or psychological examination, participation in questionnaires, surveys or interviews 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 (45 CFR .102.(j)).

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).

Protocol is synonymous with TCC's IRB Application.

Research is defined by the Federal Policy (CFR Pt., Sect. 102 (l)) as: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research.

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

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 Tulsa

Community College, including evaluation to determine participant satisfaction, attitude change, and /or knowledge gained during the educational experience unless you might want to disseminate the results of the evaluation; 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 be made by the TCC IRB, not the investigator.

Administrative surveys, questionnaires, and interviews not supported by federal funds and designed for use in the internal management and operation of Tulsa Community College 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 College. A survey, which is not research need not be submitted to the IRB for review. However, administrative personnel are should seek review by IRB in circumstances where there is potential in the future for scholarly publication or dissemination outside the administrative organization of the College, or where the survey involves information of a sensitive personal nature. All surveys administered to TCC employees and/or students must adhere to the TCC Survey Guidelines.

Sponsor is a TCC faculty, staff, or administrator that has advocated for the proposed research study.

3.0 Scope of Responsibilities

The **investigator** 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:

- 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 College's *Institutional Review Board Policy.*
- 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 or legally authorized representative.
- 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 the research protocol provided and approved by the IRB.
- 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 or collection of data. All such research must be reviewed by the IRB.
- All approved projects must be annually reevaluated by completion of the *Annual Renewal Form* (available on TCC's IRB Website).
- When changes to the protocol need to be made before the annual review, the *Modification form* (available on TCC's IRB Website) must be completed.

The College IRB meets its responsibilities with respect to complying with applicable laws, regulations, guidelines, and policies. Among those responsibilities are:
- Developing and maintaining a coordinated system or 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 TCC, 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; and
- Submitting assurances, reports, and/or other required communications to the appropriate federal and state agencies.

A Sponsor must:
- be a full-time employee at Tulsa Community College
- be familiar with the protection of human subjects,
- review IRB application before submission,
- have the authority to speak on behalf of the human subjects being used in the proposed study, and
- complete the *Research Sponsor Form* (available on TCC's IRB Website) to be submitted with the IRB application

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

4.0 Categories of Research

Research involving human subjects is divided into two categories, depending on the type of research to be performed. These categories are: (a) research that is eligible for **expedited** review;

and (b) research that requires **full board** review. At least two members will review protocols that are under expedited categories of research.

4.1 Expedited Review

IRB Co-chairs or their designees can approve expedited protocols based upon recommendation from at least two IRB members: full board review is not necessary. The IRB co-chair or their designee communicates with the investigator any necessary changes. The IRB co-chair or their designee then reviews the protocol and either approves or requests additional changes or clarification. There are times when additional subject matter expert will be requested to review a protocol.

In conducting expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b).

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, and (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

4.1.1 Categories of Expedited Research

Federal regulations allow some human subject research of minimal risk to be expedited from review by the full IRB however, TCC does not authorize investigators to make this determination. Application for expedited 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 expedited status, the research activities must qualify as one or more of the following categories listed below:

a. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.45 CFR____.104 (d)(1)

b. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability,

educational advancement, or reputation
§___.111(a)(7). 45 CFR____.104 (d)(2)

c. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. 45 CFR_____.104 (d)(3)

d. Archival research for which consent is not required: Archival research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* 45 CFR____.104 (d)(4)

e. 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_____.104 (d)(5)

f. 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. 45 CFR_____.104 (d)(6)

g. Storage or maintenance for Archival research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential Archival research use.

h. Archival research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for Archival research use, if the following criteria are met: Broad consent for the storage, maintenance, and Archival research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §_____.116(a)(1) through (4), (a)(6), and (d); Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §ll.117; *and* the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. 45 CFR_____.104 (d)(9)

i. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (IND) 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 (IDE) is not required; or (ii) the medical device is approved (cleared) for marketing and the medical device is being used in accordance with its approved (cleared) labeling.

j. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) Collected from healthy, non-pregnant 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) Collected from other adults and children, 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.

k. 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 gum base 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.

l. 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.

m. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing in this document refers only to research that is not expedited.

n. Collection of data from voice, video, digital, or image recordings made for research purposes.

o. 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.

p. 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.

q. Continuing review of research, not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) where categories (j) through (p) above 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.

4.2 Full Board Review

Protocols that do not qualify for expedited review are considered as full board review projects. Full board review requires that all members of the IRB review the protocol and vote on whether or not the project can be approved. Voting can be conducted electronically. Any IRB action to approve, require modifications in (to secure approval), or disapprove proposed research activities that occurs at a convened meeting must be documented in the minutes. Minutes should include names of all attendees, including those on the roster, and any guests not listed on the membership roster. Minutes should also include the location of the meeting (virtual meetings are acceptable); if attendees were present via a different method (call, video, etc.), it should be reflected in the minutes. Minutes should document changes in attendance (ie: arrivals/departures) as they may affect quorum. For research to be approved, it must receive the approval of the majority of members. If quorum is lost during the meeting, the IRB may not vote on proposed research. Individual names do not need to be documented with each vote, but the number of individuals voting for, against, or abstaining should be recorded.

When there is a "no" vote by the majority of members, the co-chairs will provide the final determination to the researcher, as well as provide comments regarding the rationale behind the decision or suggestions on methodology so that the researcher may consider altering their research to resubmit their request. In some cases, even when the research is approved, the IRB may make recommendations or provide comments to the researcher or the Institutional Research Department as it pertains to the research. The IRB application in its entirety, is subject to the review of the Institutional Research Department, as well administrative leadership included in the approval process.

4.3 IRB Authority

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 College. The IRB also has the authority to:

- Approve protocol for only one year. 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.

- Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- 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.
- Require documentation of informed consent or may waive documentation in accordance with CFR.117.
- Notify investigators 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 writing.
- 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 observe or have a third party observe the consent process and the research.

5.0 IRB Application

The IRB requires the following documents for each new study involving human subjects: (1) a completed IRB application form, (2) a copy of the informed consent form, and (3) any additional documents.

Expedited reviews can take up to a month (or longer if changes are required) to be completed. Full Board review may take up to 2 months (or longer if changes are required) to be completed. Meeting dates of the Full Board are subject to change without notice.

Investigators are required to submit a completed TCC IRB Application. All applications are submitted directly to the IRB through the online submission link. The IRB then reviews the application and acts regarding approval.

All procedures related to the preparation of a complete application as well as processes leading to their submission to the IRB are the responsibility of the investigator(s).

5.1 Contents of the Application

An application is the researcher's plan of a scientific experiment or treatment. The application provides the IRB with the information that it needs to approve the proposed research. The following describes each section of the application.

5.1.1 Personnel

Identify all personnel who will assist in the conduct of or sponsor the research project. Identify each individual by name, contact information, institutional affiliation, and personnel type

(student, faculty, staff, administrator, or other).

If the principal investigator is not a full-time employee or student of Tulsa Community College, the PI must gain sponsorship from a full-time TCC employee who is affiliated with the human subjects of focus in the study. If the PI is a TCC student, the PI must gain sponsorship from a full-time TCC employee for the research project who is affiliated with the human subjects of focus in the study.

All personnel must complete a human subjects protection training course. If the principal investigator is a student, the student's faculty sponsor must also complete a human subjects protection training course. Trainings are available through, TCC, CITI, or NIH. Training certificates must be submitted along with the IRB application. Any training completed within the past three calendar years will be accepted.

5.1.2 Project Overview

5.1.2.1 Project Title

The Project Title should be brief and reflect the subject and scope of the proposed research study.

5.1.2.2 Project Abstract

Provide a summary of the protocol, including the potential benefits, potential risks, and risk management procedures.

5.1.2.3 Project Type

Identify the appropriate type of project (e.g., thesis/dissertation, pilot, faculty research, class project, etc.)

5.1.3 Research Protocol

5.1.3.1 Research Questions

Provide the research question(s) to be addressed by the proposed study.

5.1.3.2 Purpose and Background

Provide information pertaining to the background of the study. This section should explain the relation of the proposed research to previous scientific investigations in the field including relevant human, laboratory, and/or animal studies. 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 purpose, hypotheses, and/or any other relevant information.** If the investigation is a pilot or exploratory study, then a discussion of the way in which the information obtained will be used in future studies should be included.

5.1.3.3 Methodology

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 must be included. Standard psychological tests should be identified, with a link or a copy provided.

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.

Note: If the study is to be administered off campus, approval must be obtained from the site before IRB approval can be granted. If the study is to be administered on campus with a particular group (e.g., student organization) approval must be granted (e.g., faculty advisor must give approval for any studies of students within a student organization) 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 subsidiary 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.

5.1.3.4 Study Sites

Identify the location(s) that human subjects will participate in the study. If the study site(s) is/are not listed on the application, choose other and specify the study sites. If the study is being conducted somewhere other than through a Tulsa Community College location, permission to use human subjects at the other site(s) must be gained in writing and submitted with the IRB application.

5.1.3.5 Instruments and Materials

Describe all instruments to be used in the proposed study. Indicate the number and type of items, the time necessary to complete the instruments, and the frequency and method of administration (telephone, online, face-to-face, etc.) If the study is an archival study, the archival data must be described. A copy of all instruments must be submitted with the IRB application. This includes copies of the informed consent forms.

5.1.3.6 Subjects

Identify who the research subjects will include. If participants will be excluded from a study based on gender, ethnicity, demographic information, or any other criterion, a description along with the rationale must be provided. A detailed and specific discussion of potential problems involving the subject groups must be given including those who are considered "at risk;" and students as subjects (see definitions section for details on these populations). The magnitude of risk and problems of risk management will be considered by the IRB.

5.1.3.7 Recruitment Procedures

Describe the recruitment procedures to be used in the study. A copy of any recruitment material or language must be submitted with the IRB application. If participation in the study will occur through a course, program, or organization, permission must be obtained from the designated authority. A letter of support from the authority must be submitted with the IRB application.

5.1.3.8 Compensation of Human Subjects

Tulsa Community College has a responsibility and a requirement to maintain a specified level of confidentiality and, in some instances, total anonymity in research involving the use of human subjects. In addition, it is important to maintain appropriate business practices in payment to these subjects. The College has set practices for handling various types of payments and the IRS requires reporting of certain payments. Payment is defined as compensation in the form of cash, check, gift certificates, or any other item of value. The procedure for handling payments to human research subjects should follow any policies and regulations set forth by the TCC Controller's office.

Compensation to subjects should never be such as to constitute coercive inducement. If course credit of extra credit will be given as compensation for the study, you must provide the students with an alternative method by which to earn the credit if they choose not to participate in the study. This option must be equivalent in type, effort, and resources necessary to complete.

5.1.3.9 Potential Risks

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

Certain groups are protected populations and if the focus of a research study, require a full board review. The protected populations are: elderly (65 and older), psychologically and/or cognitively impaired, prisoners, Native American Tribes and/or Tribal Organizations, educationally disadvantaged persons, economically disadvantaged persons, and any persons under the age of 18.

5.1.3.10 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 also be discussed. 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.

The following are some procedures that can help control possible risks.

- 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.

5.1.3.11 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.

5.1.3.12 Impact of Research on TCC

This section must describe how the findings from the study will positively impact Tulsa Community College, its students, faculty, and/or staff, and/or the community it serves. The dissemination of the results of the study upon its conclusion to TCC stakeholders who will be affected by the research must also be discussed.

5.1.3.13 Privacy Procedures

Special attention should be given to issues of confidentiality. If it is important to collect

identifiable information about subjects, the rationale should be provided in the protocol and the mechanism for maintaining confidentiality must be specified, including coding and reporting procedures, storage and access of identifiable data, and approximate date identifying data will be destroyed. If confidentiality has been promised and case histories or anecdotes will be reported, explanation should be given on how narratives will avoid identifying subjects through description of unique information about them.

6.0 Informed Consent

Investigators are responsible for obtaining not only consent to participate, but informed consent for ensuring that no human subjects will be involved in the research prior to obtaining their consent and the subject understands the benefits and risks of participation. 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, avoiding or defining technical terminology, adjusting for educational background and ages, and providing translations in other languages when subjects do not understand English;
- 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 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, or the institution or its agents from liability for negligence.

6.1 Required Elements for Informed Consent Forms

The written consent form must include the following items.

- 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, data, information, identifying the subject will be maintained
- A statement describing when and how records, data, information, biospecimens will be destroyed
- 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 rights (TCC IRB contact information); and who to contact and what to do in the event of a research related injury to the subject

- The following statements:
    - Participation in the study is voluntary.
    - Refusal to participate will not result in penalty or loss of benefits to which the subject is otherwise entitled.
    - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
    - The subject may keep a copy of the consent form.

In addition, special provisions are required when subjects are from special populations.

6.2 Additional Elements of Informed Consent

There may be conditions under which more information is necessary in the informed consent form. The following elements are required when 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 audio, pictorial, or video recording, a 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 (see Human Subjects Compensation section - 5.1.3.8)
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus)
- 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
- Any possible consequences of the subject's decision to withdraw from the research (e.g., lack of benefits from continued participation)
- A statement that if there are significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, they will be given the opportunity to withdraw from the study
- The approximate number of subjects involved in the study if there is a threat to anonymity or confidentiality due to the sample size

6.1.3 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 to the subject by the investigator. Investigators shall be responsible for ensuring 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. TCC has created an informed consent form template that researchers can use. This template is available on the IRB website (http://www.tulsacc.edu/irb).

6.1.3.1 Waiver of Documentation of Informed Consent

Under certain conditions, the IRB, and only 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. Each subject (or legally authorized representative) must be asked whether the subject wants documentation linking the subject with the research, and the subject wishes will govern; or,
- 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.

6.1.3.2 Oral Informed 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. Permission for oral informed consent might be granted in the case where the subjects or legally authorized representative are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk of harm to subjects. Oral informed consent will only be approved provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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. In this situation, a written consent document that sets forth the required components of informed consent may be read to the subject and/or the subject's representative. Where oral consent is allowable, investigators shall insure that:

- a witness is present at the oral presentation;
- the witness and researcher sign a copy of the written document; and
- the subject is provided a copy of the signed document.

6.1.3.3 Archival research for which broad consent is required

Broad consent can be obtained as an alternative to traditional informed consent for the storage, maintenance, and secondary research use of identifiable private information, coursework, or

identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes). If broad consent is obtained, any subsequent storage, maintenance, and secondary research uses of the individual's identifiable biospecimens and data consistent with the broad consent would not require additional consent, so long as additional conditions are met, including limited review by an IRB.

The following elements should be included for broad consent:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- When appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
- A general description of the types of research that may be conducted with the identifiable private information, coursework, or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the Broad Consent would permit the types of research conducted;
- A description of the identifiable private information, coursework, or identifiable biospecimens that might be used in research, whether sharing of identifiable private information, coursework, or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information, coursework, or identifiable biospecimens;
- A description of the period of time that the identifiable private information, coursework, or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information, coursework, or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information, coursework, or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results

may not be disclosed to the subject; and
- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information, coursework, or identifiable biospecimens, and whom to contact in the event of a research-related harm.

6.1.3.4 Alteration of Informed Consent

The IRB may approve an informed consent procedure that does not include, or that alters, some or all of the elements of informed consent provided one of the following sets of conditions exists and is documented in the IRB application:

- 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.

7.0 IRB Review Outcomes

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

7.1 Approval of Research

The IRB may approve research as submitted by the recommendation of at least two IRB members. Approval by the IRB does not necessarily mean that the study may proceed. If the research involves collecting data, information, etc. from or about TCC students and/or employees, there may be additional approval processes that must be followed (e.g., TCC Survey Guidelines and Procedures). Researchers should be aware of all regulations that must be followed to collect such data or information.

To receive approval by the IRB, 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 consider 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 whom English is not their first language.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by local, state, and federal regulations.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7.2 Approval after Required 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, or changes in research personnel.

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 discuss problems with the IRB directly or through a selected member.

Modified research protocols must be re-submitted for approval. The revised application should include a cover letter addressing all required modifications as well as highlighting throughout the application where changes were made.

7.3 Disapproval of Research

In this case the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject. This decision can only be made by a full board review. This decision means that the researcher(s) may NOT proceed with any part of the research. If the researcher(s) do proceed with any part of the research, they will be subject to appropriate disciplinary actions.

The IRB is required to provide a written explanation outlining specific reasons for the disapproval of the research. If a research protocol has been disapproved, the researcher(s) have three options.

1. Accept the decision as it stands.
2. Appeal the decision by submitting a written appeal to the IRB explaining why they are appealing. The researcher will then need to attend the next convened meeting of the IRB to plead their case. The full board will then reevaluate their decision and provide a final decision.
3. Reevaluate their project and submit a new application for review.

7.4 Suspension or Termination of Previously Approved Research

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 and Senior Vice President/Chief Academic Officer's designee, and, if federally funded, the department or agency head of the funding organization. This decision can only be made by a full board review. This decision means that the researcher(s) may NOT proceed with any part of the research. If the researcher(s) do proceed with any part of the research, they will be subject to appropriate disciplinary actions.

7.5 Disposition of Decisions

Approvals, modifications, restrictions, conditions, or disapprovals are communicated to the investigator by a co-chair of the IRB or their designee. At the time of transmittal of approval, the IRB will also inform the investigator of the expiration date of the approval, which will be no more than one year from the approval date.

If an application is not approved as conforming with the Federal Policy for the Protection of Human Subjects and the College, a co-chair of 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))

7.6 Duration of Approval of Research

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.

7.6.1 Annual Renewal of Research

IRB approval to conduct research expires within one year of the approval date. Each year that researcher(s) plan to continue the research, they must apply for renewal. Renewal of approved protocols is required annually. The Research Renewal Form should be completed to continue research that has NO changes, including personnel changes. This form can be found on the IRB website (https://www.tulsacc.edu/about-us/administration/offices/academic-affairs/institutional-review-board-irb/irb-policies-forms).

Research may not continue after the expiration date without additional approval from the IRB. If the researcher(s) do proceed with any part of the research, they will be subject to appropriate disciplinary actions.

7.6.2 Modifications of Research

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, that the research methods or techniques are different, new hazards are evident, or there are personnel changes, an approval of modification of the existing protocol must be obtained from the IRB. In general, any change that alters the risk/benefit balance or modifies the informed consent in some way requires approval. Thus, if there are any changes to the study, the researcher must submit a Research Modification Form.

Research may not continue with any changes or modifications without additional approval from the IRB. If the researcher(s) do proceed with any part of the research, they will be subject to appropriate disciplinary actions.

8.0 Documentation required of Investigators, IRB, and the Institution

The following outlines the documentary responsibilities for Investigators, IRB, and the Institution.

8.1 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 three years after conclusion of the research and/or 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 conclusion of the

research and/or termination of the project.

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.

8.2 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 College 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 three years, and records relating to research that is conducted shall be retained for at least three 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.

8.3 The Institution

It is the responsibility of TCC through the appropriate administrator or administrative office 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 of

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 TCC has an approved assurance and only if TCC 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 TCC in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by TCC, 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 TCC itself. This requirement need not be applicable to any research expedited or waived under 45 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 45 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 TCC 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 45 CFR .101(b) or (I). TCC shall certify that each application or protocol for research covered by the assurance and by 45 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 TCC is without an approved assurance covering the research, TCC 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 TCC.

9.0 Unanticipated Problems

Any unanticipated problems involving risk to subjects or others, including any adverse psychological, biological, or physical reactions to the research must be reported by the investigator to the IRB, the Office of Risk Management, and to any federal agency sponsoring the project. **If there is a medical emergency as a result of the research, the investigator must contact 911 immediately,** and then report the incident to the offices listed above.

Reports must 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.; and,
- Any relevant information on the subjects (previous exposure to drugs, therapy, case history, background information, etc.).

10.0 Violations of Policies and Procedures

Noncompliance with these policies and procedures is subject to College 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 TCC, state, and federal 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 their supervisor who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the principal investigator will be required to terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the termination, and possible disciplinary action.

11.0 Advice and Consultation

Investigators and departments may call upon the IRB for advice or informational consultation. Any advice or 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.

12.0 Omissions

In the event that issues related to the use of human subjects in research at TCC are not covered by this policy, the IRB will rely on the Federal Policy 45 CFR Part 690 and Part 46.

13.0 Amendments

Any amendments to this policy require the approval of the majority of the membership of the IRB, as well as approval through the appropriate channels set forth in TCC policy approval guidelines.

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 and TCC Board of Regents.

For additional 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
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 expedited from IRB review. Tulsa Community College (TCC) 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 college 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 TCC 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:

- involves the learning of research techniques; AND
- involves no more than minimal risk; AND
- 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
- involves no subjects from protected groups, including minors under the age of 18; AND
- involves only students enrolled in the class as subjects in the research; AND
- 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
- the research review category would normally fall under the 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 are "classroom exercises" and are not subject to review by the IRB.

Responsibility of Instructors

Instructors of courses in which students do research involving human subjects must complete the

TCC IRB required training program prior to review/approval of any student project.

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. The faculty member/instructor is responsible for communicating to students ethical principles 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 a chair of the IRB. 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 IRB for approval prior to conducting the research.

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

Appendix B
Scholarship of Teaching and Learning & Action Research

This appendix provides a brief introduction to some of the ethical considerations involved in conducting Scholarship of Teaching and Learning, and particularly course-related action research at Tulsa Community College.

Hutchings and Shulman (1999) define the **Scholarship of Teaching and Learning** (SoTL) as the systematic investigation or inquiry into student learning that advances the practice of teaching by making findings public. Two methods of SoTL include course-related action research and instructor inquiry. While the general purpose of SoTL is generalized research, action research is, "more systematic and data-based than personal reflection, but it is more informal and personal than formal education research" (Mettetal, 2001, p.7).

All TCC employees planning to do any action project or SoTL research project is required to complete the Human Subjects Protection training provided by TCC's Institutional Review Board (IRB) via Blackboard, unless the employee has completed similar training within the past three years. Certification through Blackboard is good for three years from the date completed. This training must be completed whether or not your project needs to go through the IRB approval process.

As stated in the TCC Action Research Guidebook, employees wishing to conduct a SoTL research project, more specifically a course-related action research project (whether for promotion in rank or other purposes), should submit the project to the TCC IRB if *any* of the following are true about the project:

1. The employee plans to present or publish the findings to an audience or venue outside of TCC.
2. The employee plans to use data collection methods that are not typical educational measurement tools or interventions that would not fall under the federal definition of "Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction" (Common Rule, §46.104.d.1).
3. If the study will include participants under the age of 18.

If you are unsure if your project falls within any of these options, please contact a co-chair for the IRB.

This Appendix does not apply to any research related to work on a master's thesis or doctoral dissertation. Those research studies must follow standard IRB review policies and procedures.

Roles as Researcher and Instructor

A significant concern is the "two-hat" problem in which a researcher is also an instructor with potential coercive power or undue influence over students who are also potential research subjects. Students may feel pressured to participate in such projects because they are worried about the

impact on their grade of not participating, wish to help out an instructor who they like, and so forth. Such a situation does not automatically qualify a project for required IRB review, but the researcher-instructor should be cognizant of the problems such an arrangement might create.

Strategies for decreasing potential for coercion of students while conducting SoTL research:

- Use subjects not currently enrolled in your class.
- Have someone, unaffiliated with the class or the data analyses, collect the data so that whether or not a student participated will be unknown to the instructor.
- Make it clear to students that data will not be analyzed until after the semester is completed and grades have been submitted.
- Offer an alternative assignment for those students who do not wish to participate in the study (this is required if students receive either class credit or extra credit for their participation).
- Contact a co-chair of IRB to discuss alternate approaches or models that colleagues are currently using in their classes.

Receiving IRB approval to conduct your SoTL research

Information about Tulsa Community Colleges' IRB and application materials are available at https://www.tulsacc.edu/irb.

You are required to complete the TCC Human Subjects Protection on-line research ethics training made available to all TCC faculty, staff, and students (or other official human subject training course) prior to starting your research study. Certification is required to have been completed within the three years prior to conducting the research project. TCC training is available in Blackboard.

The IRB application and consent form templates are Microsoft Word documents with spaces left for you to fill in specific information about your project. The templates ensure that applicants provide all information necessary for an IRB review; some modifications can be made to tailor the application to your project, but be cautious about making major changes without consulting an IRB expert.

Frequently Asked Questions about ethical collection of SoTL data

Faculty are encouraged to carefully consider the following questions in preparation for conducting ethical SoTL research:

- **How will I receive truly voluntary informed consent from my students?** Many faculty worry about whether participation in SoTL research can ever be truly voluntary given the inherent power imbalance between faculty members and students. Can students really be fully informed about the nature of their participation in the research project at the beginning of class? Informed consent is a process, not a one-time event. You are encouraged at minimum to use the "Opt-In" syllabus attachment available on the TCC IRB forms website.

- **How does grading relate to my SoTL research?**

  Often researchers use the same criteria to evaluate student work for research purposes that

they use for grading purposes. This is certainly the most efficient approach. You could expand your usual grading rubric to include research-specific items and assign those items relatively few points compared to the items most closely tied to your learning outcomes. Sometimes learning outcomes and research objectives are not the same; in this case consider whether you should make copies of student work to be evaluated for research purposes after all coursework is completed and graded, so as to minimize the risk that you are scrutinizing student work unfairly (through a researcher's lens rather than a instructor's).

- **How might I collect informal or ungraded student work?**

  In-class and out-of-class activities often create useful data for research on student learning. However, the use of informal materials and student-student or student-instructor communication requires careful consideration. If you are using informal or ungraded work, are you confident that those materials accurately capture student understanding? If you will be using journals, blog entries, or other forms of informal writing, do students need to be reminded that this writing is part of your research? If you are using informal student work in your research, you might consider collecting and saving only specific activities (such as responses to certain writing prompts that link to your research), rather than collecting all informal student work.

- **How might I collect audio or video-recordings of students working, focus groups, or interviews?**

  The use of audio, video or other recording requires special consideration, because of the difficulty of ensuring the anonymity of your participants. It is important to allow students to indicate whether or not they agree to the use of their image or recording. Only tapes in which all potentially identifiable students have consented to the use of their recorded voice or image may be used for research. Consider having someone else collect any potentially sensitive data from students. For example, in a study of students' critical thinking about course content, an undergraduate research assistant interviewed students at multiple points during the semester. The interviews were transcribed and not viewed by the professor until after the course was completed. In the interviews students frequently expressed frustration, confusion, and disagreement with the professor – crucial information that she could not have collected as effectively herself.

- **Should responses to surveys or questionnaires be anonymous?**

  Not all survey data needs to be associated with a specific student's identity, and you might receive different responses (see audio/video above) if you collect anonymous data. Also, consider if there are ways to make completing a survey a learning or reflective experience for students. Our students spend a lot of time completing various surveys outside of class, so be wary of "survey fatigue" unless yours is clearly linked to learning, reflection, or course goals.

- **How should I analyze my data and report my conclusions to ensure my students are not identifiable?**

  You should strive to avoid associating data with the identity of any particular student. There are many ways in which data can be "de-identified." For example, you can assign each participant a random id (not their t-number) which you then use to label all data or student work that you will treat as data, avoiding or removing students' names. Ask a colleague to do this if you want to provide an extra layer of anonymity. Privacy and confidentiality are especially problematic when class size is small or work is highly personal. Be mindful that even though students may turn in work for evaluative purposes, it is still their work and students' rights must be considered. Ask students' permission to quote from their work or to use an audio or visual image of them or their work in any kind of public report or presentation. Consider that in some cases, as when student work is creative or exemplary, students may wish that any use of their work retain their identity.

- **Might your SoTL research be improved by collaborating with students?**

  Some faculty members believe that many of these ethical issues are mitigated when their students are also involved in the SoTL research as researchers. For example, Bloch-Schulman, Flannery, and Felten (2009) use a "multivoiced" technique in order to share perspectives of students and faculty members in an Elon SoTL project. Consider whether an examination of student learning might fit in with the objectives of the course you are teaching. Of course, you will need to pay extra attention to privacy and coercion issues if peers are evaluating student work.

Additional SoTL Resources

The above suggestions are not meant to be prescriptive or exhaustive; they are meant to give new SoTL researchers a sense of the scope of ethical issues they will likely encounter as they plan their research projects. The work of Hutchings (2002; 2003) and Gurung and Schwartz (2009) provide more information about SoTL research in general, and Vanderbilt's Center for Teaching has prepared an excellent guidebook for SoTL projects (which includes specific information about ethical guidelines and the IRB).

Zeni (2001) discusses classroom research as self-study in education which challenges both the theory-practice dichotomy and the insider-outsider dichotomy typical of university research. Discipline-specific models for conducting pedagogical research can often be found in journals published by disciplinary societies (see Kennesaw State University's CETL website for a searchable Teaching Journals Directory).

References

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Note: Material for this policy was taken or adapted from SOTL and classroom-based research information from Elon University, Vanderbilt University, and Stonehill Community College, SOTL Center.