

**ADMINISTRATIVE PROCEDURES
FOR
RESEARCH WITH HUMAN SUBJECTS**

**INSTITUTIONAL REVIEW BOARD
JANUARY 2020**



TJCTM

CHARGE OF TYLER JUNIOR COLLEGE INSTITUTIONAL REVIEW BOARD

The Tyler Junior College Institutional Review Board (hereafter referred to as the IRB) process assures, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. To accomplish this purpose, the IRB uses a group process to review research proposals and related materials (e.g. informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research. The IRB follows FDA regulations and is authorized to approve, require modifications in (to secure approval), or disapprove research.

RESEARCH WITH HUMAN SUBJECTS

All research and experimental activities in which human beings participate as subjects must be approved by the Institutional Review Board (IRB) of Tyler Junior College. Approval must be obtained prior to involving subjects and prior to distributing any information or written materials to subjects that would require approval. This applies to all research sponsored by external funding agencies, to unsponsored research, and to continuing education and instructional projects and activities conducted by College students, staff, and faculty. This applies to all research conducted under College auspices or as a part of an investigator's professional activities as an employee of the College. It does not apply to research entirely unrelated to the College or to an employee's professional activities (e.g., conducting research for an external agency) unrelated to his or her College responsibilities, though employees may choose to submit such research for IRB review.

Tyler Junior College's human subjects' policy was developed in accordance with the Federal Policy for the Protection of Human Subjects, published in the Federal Register on June 18, 1991, as a final common rule for participating federal agencies. The policy is designed to safeguard the rights and well being of human subjects, and to ensure that the principles of respect for persons, beneficence, and justice are met by proposed activities involving human subjects.

MEMBERSHIP

The IRB shall be comprised of seven standing members: six representatives of the College and one chair. The College representatives are selected for three-year terms.

A member may not serve longer than six (6) consecutive years. At the end of a member's three-year term, the member will be given the opportunity to continue to serve on the Board before a replacement is considered. If a member decides to no longer serve, then an alternate member would have the first opportunity to be appointed and become a voting member. The Chief Academic Officer (CAO) would appoint an alternate member to fill the vacancy. Once filled the CAO would then appoint a replacement for the alternate member's vacancy. This would allow the new alternate member to become

familiar with the Institutional Review Board process and that of reviewing protocols. The members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the College. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, including fetuses, pregnant women, prisoners, children, handicapped or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects. The IRB may not consist entirely of men, women, or of members of one profession or College department.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

SCOPE OF AUTHORITY

All research covered by the College's Human Subjects Research Policy shall be reviewed by the IRB prior to the involvement of the subjects. The IRB shall have authority to approve or disapprove the research protocol, and to conduct continuing review of the research protocol at intervals appropriate to the degree or risk. In certain exempt cases, an annual review may be conducted.

The IRB shall have authority to require that information given to subjects as part of informed consent is in accordance with the requirements for informed consent lists below and to observe or have a third party observe the consent process and the research.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with 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 actions and shall be reported promptly to the investigator, appropriate institutional officials, and the appropriate granting agency official.

DECISION RULE

The Institutional Review Board is designed to protect human subjects of research by making decisions on the ethics of proposed research. It is not to offer an opinion on the merits of a research proposal's design or execution apart from this narrow question of the effect on human subjects. The board should consider the rights of subjects not to be harmed or have risks they are willing to accept. Since the decisions of the Institutional Review Board are not to reflect members' possibly divergent interests or opinions regarding research methods or topics, decisions should normally be made by consensus.

The Institutional Review Board should strive for consensus rather than a simple majority. The board should function as a jury ascertaining facts and applying standards rather than as a legislature representing diverse interests and creating policy. Not all faculty interests can be represented on the review board or in the appeals process. A consensus decision-making rule is therefore important because it both reflects and promotes a unitary community where equal respect obviates the need for equal protection of interests. The decision-making rule is protection of interests. The decision-making process will optimally entail reasoned deliberation and consensus regarding the ethics of proposed research.

CRITERIA FOR APPROVAL OF RESEARCH

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- A. Risks to subjects are minimized:
 - 1. by using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk, and
 - 2. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.) The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of research on public policy) as among those research risks that fall within the purview of its responsibility.

- C. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with the requirements for informed consent listed below.

There are two possible exceptions to the requirement for informed consent:

1. In the instance of ethnographic fieldwork which relies principally on participant observation as a method, it is recognized that the complex, continuing interaction between the researcher and hosts cannot always be reduced to an informed consent form. However, in those cases where the protocol of informed consent might be waived, the researcher should explain why it would not be appropriate to follow this procedure and what steps he or she plans to take to eliminate the possibility of doing any harm to individuals or groups.
 2. In the instance of covert observation of non-public behavior in which there are no apparent risks and the research project would be seriously compromised by disclosure of the research in progress, the IRB may waive the informed consent requirement (For example, if the only risk involved disclosure of information, appropriate safeguards could be established to negate this risk.) Approval for covert research methods would be granted only after full board review and guidelines are established by the board.
- E. Informed consent will be appropriately documented, in accordance with the requirements for informed consent listed below.
- F. Where appropriate, there are adequate provisions for monitoring the data collected to ensure the safety of subjects.
- G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- H. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as fetuses, pregnant women, children, prisoners, handicapped or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline, appropriate additional safeguards are required in the study to protect the rights and welfare of these subjects.

DEFINITIONS (as defined in the federal policy)

“**Research**” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. In addition, research includes activities that are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions).

“Human Participant” means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

“Intervention” includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

“Interaction” includes communication or interpersonal contact between investigator and subject.

“Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable when the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

PRINCIPLES

- A. Research serves to advance the study of human thought, behavior, and physical make up and ultimately the knowledge base of science. This positive outcome of research is defined as beneficence. However, research also has potential risks and hazards to human subjects. The purpose of the Institutional Review Board is to evaluate all research proposals, to determine what risks may be present for subjects, and to assess how these balance against benefits to subjects and the advancement of knowledge.
- B. The IRB requires that research recognize and practice the principle of respect for persons upholding their choice about whether to participate in any proposed research and their right to be properly informed about the nature and conduct of such research. Potential subjects must be given the opportunity to indicate their assent by signing an informed consent document; this signals their awareness of the research to be performed and their understanding of the potential risk to them. In the case of minors or others not capable of determining this, their legal representative must be consulted for informed consent. The IRB will review all proposals to ensure that the participation of subjects is voluntary, and their consent is based on adequate information about the project.

- C. Both the benefits and burdens of participation in research must be distributed fairly across all populations to ensure justice. Researchers must take care not to overburden vulnerable populations who, by virtue of their status, may be coerced to participate. These populations include fetuses, pregnant women, children, prisoners, handicapped or mentally disabled persons, person with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline. The IRB will assure that the subjects are selected fairly, and appropriate selection procedures are followed so that no one group is disproportionately burdened.
- D. The College's policy places primary responsibility for the protection of human subjects with the principal investigator. This responsibility is shared by Tyler Junior College, by any sponsoring agency where outside support is provided, and by any faculty member involved in supervising student-conducted research.

RESPONSIBILITY

The individual investigator has the responsibility to bring research proposals that involve human subjects to the IRB. In accordance with federal regulations, approval of a project extends one full year from the anticipated start time. If the project extends beyond that date, the proposal must be reviewed 30 days prior to the end of the first and any subsequent years. If the project changes in any way, the investigator should apprise the IRB of those changes. The IRB reserves the right during the review process to seek clarification from the investigator and/or require alternation and resubmission.

All funded research and certain other types of research, e.g. course related, student generated, and unfunded faculty research, normally require IRB approval. Certain categories of institutional and internal research about the students, faculty, and staff of Tyler Junior College that involves data collection on the opinions and preferences of the College community or surveys about ways to improve College services would not usually require approval. (For example: Course Evaluation, Faculty Evaluation - by students, by faculty, by peers.) The exception to this would be research on certain disclosure of the responses outside the research context could put individuals at risk of civil or criminal liability or be damaging to their reputation or social and economic standing. Information deemed as sensitive includes that about subject's drug use, alcohol use, sexual behavior, medical condition, or possible illegal conduct. Research of this nature must receive IRB approval.

CATEGORIES OF RESEARCH REVIEW

All research involving human subjects must be submitted to the IRB. There are four categories of review: Exempt, Expedited, Limited Review, and Full. The Exempt review determines whether or not the proposed research meets the requirements for Exempt status, or whether the project should be submitted for review under another category. Exempt category does not apply to any research with children. The Expedited

review is applicable in instances of minor changes in previously reviewed research and in special cases of limited human involvement with minimal risk. The limited review can be conducted if the research includes adequate provisions to protect the privacy of the subjects and to maintain confidentiality. The full review is required for all new research proposals that do not meet the requirements for Exempt status or Expedited review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive full committee review if they are not eligible for Expedited review.

Sections A to E below provide further information related to the types of review. Research that is conducted while fulfilling the requirements of a course would normally be determined as Exempt (see A). In the interest of facilitating these types of course-related research projects involving human subjects, a slightly modified procedure is recommended in these cases. Part D below gives further information related to the handling of course-related research. Research that has already been reviewed by the IRB of another institution is also normally determined to be Exempt. Part E provides further information for these cases.

A. Exempt Review

Review for Exempt Status: All research proposals involving human subjects must be submitted to the chair of the IRB. If the research is found to be Exempt, the investigators must still ensure confidentiality, inform the participants of the requirements of the research, and inform participants that participation is voluntary and that they may withdraw from the study without penalty. Subjects must be exposed to no more than minimal risk, which is defined as risk of harm no greater than those encountered in daily life or during performance of routine physical or psychological tests. Proposals are exempt from more detailed review if the research described poses minimal risks to subjects and proper procedures are used to implement ethical principles for the protection of human subjects. The following types of research (conducted by both faculty and/or students) may fall into the Exempt review category:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and

- b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial and academic standing or employability or cause social or psychological harm. Examples include sensitive aspects of subjects' behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol. **Note:** Research involving children under 18 is not eligible for Exempt review under this category. Please see Special Consideration: Children as subjects in Research.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2) of this section if:
 - a. the human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner in which subjects cannot be identified, directly or through identifiers linked to subjects.
5. Sponsored research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads must be publicly posted, 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;
 - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies;
 - a. if wholesome foods without additives are consumed or
 - b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.
7. Storage or Maintenance of Identifiable Biospecimens with Broad Consent
45 CFR 46.104(d)(7): This is a new exemption in the revised Common Rule that covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for

non-research purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

8. Use of Identifiable Data or Biospecimens Obtained with Broad Consent 45 CFR 46.104(d)(8): Secondary research use of identifiable private information or identifiable biospecimens originally obtained for non-research purposes or for research other than the current proposal, if:
 - a. broad consent must be obtained from the subjects for the secondary research use of their identifiable materials;
 - b. documentation or waiver of documentation of informed consent must be obtained;
 - c. an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent;
 - d. investigators cannot include the return of individual research results to subjects in the study plan.

B. Limited Review

Limited review is a process that is required only for certain exemptions and does not require an IRB to consider all of the IRB approval criteria. In Limited IRB review, the IRB must determine the certain conditions, which are specific in the regulations and can follow the expedited review. The IRB chair can approve the limited review or designate an IRB committee member to review.

C. Expedited Review

Expedited review procedures may be used for certain types of research involving no more than minimal risk and for minor changes in approved research. The review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the chair from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the Full review procedure set forth below. (See p. 10, Part C) Reviewers may refer the proposal to full committee. The principal investigator will be informed in writing whether the proposed research has been approved or referred for full committee review. All members of the IRB will receive written notification from the chair of research activities that have been approved by Expedited review. Expedited review can be used for minor changes in previously approved research, during the period for which approval has been authorized, and for the following categories of research:

1. Collection of: hair and nail clippings, in a no disfiguring manner; deciduous teeth; and permanent teeth if patient care indicated a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays, microwaves).
4. Collection of blood samples by venipuncture; in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and sub gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individuals, such as studies of perception, cognition, game theory, or test development where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

D. Full Review

Any research not covered under the Exempt or Expedited review categories is referred to the IRB for Full committee review. The investigator may be invited to attend the review. The research is either approved, approved pending modifications which must be verified by committee members, or not approved. Investigators will be notified in writing about the committee's decision.

E. Course Requirement Review

Many of our courses require students to engage in research as part of the regular academic experience. While the majority of student research falls into categories which in no way may be construed as exposing subjects to more than minimal risk, Tyler Junior College wants to insure that all student researchers are

cognizant of the need to obtain informed consent and to protect those subjects from risk. We ask that faculty who allow or require research projects from their students (when such projects involve the use of human subjects) follow the procedure in item “4” under “Procedures for Submitting a Research Project for Review.” In addition, student learning outcomes for the course should be tied to the research requesting IRB approval.

F. Certification by another Institution’s IRB

If a Tyler Junior College student, faculty member, or staff member is conducting research in another institutional setting, Tyler Junior College’s requirement for research ethics review will be met by a certification, signed by the principal investigator of the other institution, verifying that the research project has been reviewed and approved. That certification and a copy of the letter notifying the Principal Investigator that the research has received institutional approval must be submitted to the IRB Chair. Review of research funded by or conducted at Tyler Junior College, or for which a member of the Tyler Junior College academic community has primary responsibility, must follow the procedures outlined in other sections of this document.

SPECIAL CONSIDERATION

A. Children as Subjects in Research

The range of activities that may be approved by Exempt or Expedited review is reduced when children are involved as subjects in research. Specifically, research involving survey or interview procedures and research involving the observation of public behavior where the investigator is a participant in the activities being observed may not receive Exempt or Expedited review when these research activities involve persons under the age of 18 (hereinafter, “child” or “children”).

Written permission is required of both parents or the child’s guardian(s) for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the review committee where it is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Assent: In addition to the written permission required of parents, it is necessary to acquire the assent of children, when they are capable of providing assent. “Assent” means a child’s affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 14 years and older, written assent is required. For children under 14, verbal assent

may be obtained. The Principal Investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented. Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background experience to act in the best interests of the children for the duration of their participation in the research. It is suggested that the principal investigator identify a suitable advocate and secure his or her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or research presenting the prospect of direct benefits to the individual children.

B. Research involving Fetuses, Pregnant Women, or Human in Vitro Fertilization

Additional protection and limitations are placed on research involving pregnant women, fetuses in utero or fetuses ex utero. The Chair of the IRB should be contacted for additional information.

C. Research Involving Prisoners

Additional protection and limitations are placed on research on prisoners. The Chair of the IRB should be contacted for additional information.

D. Fieldwork or Ethnographic Research

The foregoing fall into the category of special populations that requires additional protection and oversight by the IRB. By the same token, there may be circumstances that imply less rather than more oversight. The IRB Guidebook developed by the National Institute of Health (Section 5.5) recognizes that fieldwork or ethnographic research commonly conducted in the field of anthropology is a type of method in which the use of consent forms may not be appropriate. The IRB should keep in mind the possibility of granting a waiver of informed consent.

INFORMED CONSENT

A. General Requirements for Informed Consent

Informed consent is a written agreement made between an investigator and a freely participating subject, that describes in easily understandable language: (a) the subject's role in the investigation, (b) the potential risks and benefits associated with study participation, (c) the confidential nature of all information obtained in the investigation, and (d) the provision for voluntary withdrawal without necessity for explanation by the participant. Additionally, no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Researchers must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study.

1. Statement of purposes of the research, expected duration of the prospective subject's participation, and the procedures to be followed in the research.
2. The fact that consent is being sought for research and that participation is voluntary.
3. Statement of reasonably foreseeable risks or discomforts to the prospective subjects.
4. The benefits to the prospective subject or others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
6. Statement of data confidentiality.
7. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
8. Statement that the subject's biospecimens (even if identifiers are removed) they may be used for commercial profit and whether the subject will or will not share in this commercial profit.
9. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
10. 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).
11. An offer to answer any questions the participant may have.
12. Contact information of all Principal Investigators, and also contact information for Tyler Junior College's Institutional Review Board (Executive Director, Institutional Effectiveness, Planning, and Research, 903-510-3217).

13. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.
14. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, item 1 is omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

B. Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. (See Appendix B for a sample form). An IRB can waive the requirement for the investigator to obtain a signed consent form for some or all subjects if any of the following apply:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;
3. That, as in the case of ethnographic fieldwork, the researcher can, by virtue of the probability of his or her long term presence and participation in the lives of people, achieve a personal rapport with people that would be disrupted by the use of a consent form;
4. That, in the case of covert research, there are no apparent risks and the research project would be seriously compromised by disclosure of the research in progress.

C. Waiver of Signed Informed Consent

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

PROCEDURE FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

- A. All proposals requiring IRB review should be sent to the chair of the IRB.

- B. The IRB generally meets the first Friday of each quarter during the academic year and other times as called by the IRB Chair. Investigators must submit all information well in advance of the anticipated start date of data collection and, in the case of sponsored research, in advance of submission of the proposal to the agency. For special circumstances in meeting a grant deadline, the IRB Chair should be contacted.

NOTE: Although approval must be obtained before submission, the protocol does not have to be approved prior to grant being submitted. It is recommended that the Principal Investigator contact the IRB as soon as possible to get review of protocol underway.

- C. Investigators should request the type of review most appropriate for their study. Proposals are first reviewed by the IRB Chair. If there is any disagreement with the type of review requested, the investigator will be contacted, the reasons for the disagreement explained, and any additional material necessary to continue the review process requested.
- D. All research involving human subjects must be submitted to the IRB. There are three categories of review; Exempt, Expedited and Full. The Exempt review determines whether or not the proposed research meets the requirements for exempt status, or whether the project should be submitted for review under another category. The Expedited review is applicable in instances of renewal, minor changes in previously reviewed research, and in special cases of limited human involvement with minimal risk. The Full review is required for all new research proposals that do not meet the requirements for Exempt status or Expedited review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive full committee review if they are not eligible for expedited review.
- E. Faculty who allow or require research projects by their students (when such projects involve the use of human subjects) should submit a Request for Institutional Review Board Approval for initial review for Exempt Status. If the research is found to be Exempt, a Class Research Project Application Form should be submitted for subsequent review at the beginning of every fall semester, or as needed, provided the research objectives and methodology are not changed.
- F. The following information should be submitted to the IRB (with the number of copies as indicated):

FORM	Exempt	Expedited	Full
Request Form for IRB Approval	2	2	2
Informed Consent Form, if appropriate	2	2	2
Data Collection Instruments (survey, etc.)	2	2	2
Progress Report, if renewal	2	2	2
Full Grant Proposal, if applicable	1	1	1

- G. The committee's actions, comments, and recommendations will be sent to the investigator. If a proposal is disapproved, the principal investigator may request to attend the next committee meeting.
- H. Any changes in a proposal or consent form must be promptly reported to the IRB Chair. In most cases these will receive an expedited review.
- I. All adverse reactions and unexpected side effects must be reported immediately, in writing to the IRB.
- J. Interim progress reports should be submitted if requested by the IRB to ensure that the rights and well being of subjects are protected.
- K. Annual renewals are mandatory. (Refer to Continuing Review Questionnaire)

APPEALS

Investigators may request a meeting with the IRB Chair to discuss the decision. A rationale must accompany that request. If the IRB Chair or designee sustains the decision, the investigator may request a meeting with the IRB.

ANNUAL RENEWAL PROCEDURES

Thirty days before the anniversary of the last approval date, the following should be submitted (two of each for expedited or full review):

- A. Continuing Review Questionnaire
- B. If any changes have been made, submit instruments, with any changes noted, and the consent form(s) and written explanation of study, with changes highlighted.

COMPLETION OF RESEARCH

When a project is completed, withdrawn, or past the phase involving human subjects, the IRB Chair should be informed in writing.

RECORD KEEPING

The following records must be maintained by the Institutional Review Board for three years:

- A. Copies of all research proposals reviewed; scientific evaluations, if any, that accompanied the proposal; approved sample consent documents; progress

reports and renewals submitted by investigators; and reports of injuries to subjects.

- B. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meeting, action taken; the vote on these actions including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a summary of the discussion of disputed issues and their resolution.
- C. Records of continuing review activities.
- D. Copies of all correspondence between the IRB and the investigators.
- E. A list of the IRB members detailing their names, earned degree, representative capacity, indications of experience sufficient to describe each members' chief anticipated contribution to the IRB, and any employment or other relationship between the member and Tyler Junior College (e.g. full-time employee).
- F. A statement of significant new findings provided to subjects, as required by the policy on informed consent, discussed above.