Guidelines for Human Subject Review
Institutional Review Board (IRB)

Research conducted by Teachers College of San Joaquin (TCSJ) students, faculty and staff must be reviewed by the TCSJ Institutional Review Board (IRB) before proceeding with data collection for a research study. The goal of the TCSJ IRB is to promote the ethical conduct of student, staff, and faculty research involving human subjects through safeguarding the rights and welfare of the research subjects, as set forth in the *Belmont Report* (National Commission for the Protection of Human Subject of Behavioral Research, 1979), *45 CFR Part 46*.

Research refers to systematic investigation or experimentation aimed at gathering data, information and facts for the advancement of knowledge. Human subject research involves the participation of human beings as participants in a study. If research involves the use of human participants (either directly or through records), the research requires human subjects review through the TCSJ IRB.

The Office of Institutional Research is responsible for establishing the policies and procedures for human subjects research, including guidance for researchers and relevant application forms or protocols. The Office of Institutional Research supports all IRB activities and maintains the records of IRB documents. The IRB reports to the Director of Graduate Studies at Teachers College of San Joaquin and its role is to review and approve, disapprove or require amendments of protocols for research that involves the use of human subjects.

The TCSJ IRB is comprised of persons knowledgeable in scientific, non-scientific and education related professions. Members are from varying disciplines who possess the professional competence to review research activities and represent a diversity of gender and ethnic/cultural backgrounds. Appointments are filled via nominations to the Director of Graduate Studies at Teachers College of San Joaquin and approved by the TCSJ Leadership Committee. All appointments are for a period of three years and may be renewed by the Director upon recommendation of the TCSJ Leadership Committee.

Research Guidelines:

Each academic year, the Chair of the IRB will publish dates for submission of research studies by researchers and anticipated response dates. Researchers should plan ahead and a minimum of two weeks should be allowed before a response can be expected. The Chair of the IRB is delegated to act on routine matters on behalf of the IRB and is the person who may initially communicate with researchers about their research protocols.

Effective July 1, 2011 all IRB members and researchers submitting TCSJ IRB Research Protocols (applications to conduct research) will be required to provide evidence of training on the protection of human subjects. The online tutorial can be completed at the following link:

http://phrp.nihtraining.com/users/login.php

One copy of the completion certificate should be kept by the researcher and one copy should be given to the Chair of the IRB.

TCSJ IRB Research Protocols (see Appendix A) are reviewed at one of three levels, depending on the level of risk to the human participants and on the federal regulations that define the categories of review, which are ***exempt, expedited, and full board review***. The final determination of what level of review is required is determined by the IRB staff, NOT the researcher. Whatever the level of review, the ethical treatment of human participants is always a requirement. The IRB reviews the purpose, procedures, and participant populations to be used and determines if the benefits of the activity outweigh the risks to the participant.

Exempt:

Exempt research involves only minimal risk. **The researcher is still responsible for completing and submitting all documentation to the Chair of the IRB for review of research that fall into the exempt category.** Documentation includes protocols (e.g. interview and data collection protocols) surveys and questionnaires. The Director of Graduate Studies, Masters Advisors, and a faculty member from the Graduate Department will assist the Chair of the IRB by reviewing protocols that may qualify as exempt research.

Research activities that are exempt fit one of six categories as designated by federal regulations (Code of Federal Regulations, 45 CFR, 46).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: a) research on regular or special educational 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 if:
    i. Information is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants; and,
    ii. Any disclosure of the human participants' responses outside the research could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation.
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 #2: i) the human participants are elected or appointed public officials or candidates for public office; or ii) federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or subject to, the approval of department or agency heads, and which are designed to study, evaluation or otherwise examine: i) public benefit or service programs; ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures; or iv) 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: i) if wholesome foods without additives are consumed or, ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant 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.

It is important to remember that a research activity qualifies as exempt if it is limited to the kind of activities listed above and only after review of the protocol (application). If the project includes such activities but also involves other activities that are more intrusive, more personal, or more risky than the above, it most likely will not qualify as exempt.

Expedited:

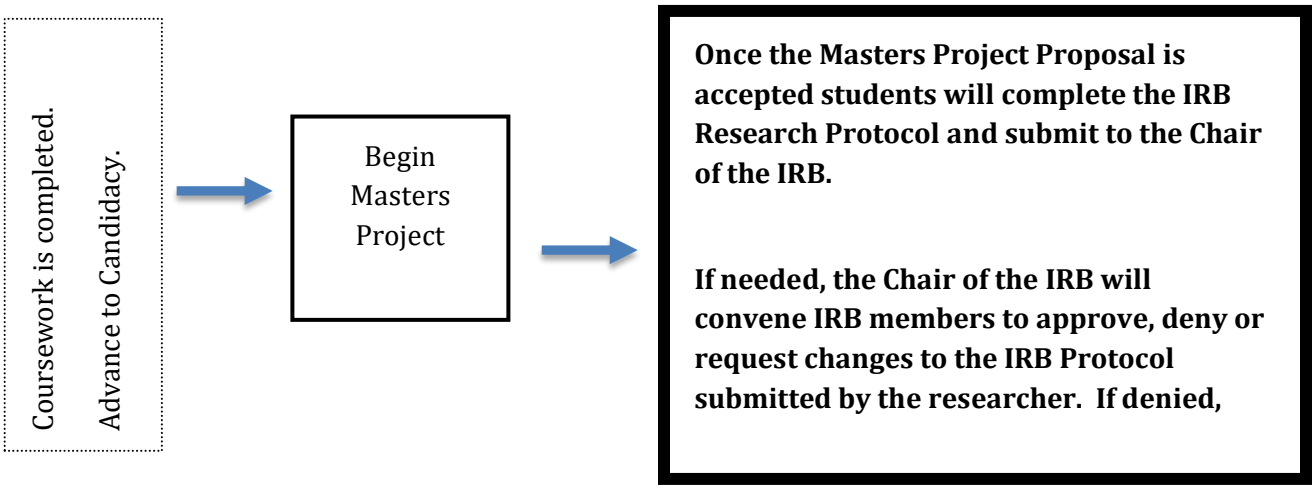
Research activities that fall into this category present no more than minimal risk to human participants, and involve procedures listed in one or more categories approved through federal regulations. Expedited protocols will be reviewed by three members of the IRB and either be approved, denied, request that changes be made, or the application will be referred to a Full Board Review.

Categories for expedited may include: Recording of data from participants 18 years or older using noninvasive procedures; e.g. video/audio recording; study of existing data that is not publicly available, or if participants can be identified; research on an individual or group behavior that involves no manipulation of the participants and does not involve stress to participants.

Full Board Review:

Research that involves greater than minimal risk is reviewed by the full IRB. Research that requires full board review includes but is not limited to:

Certain types of research involving children, pregnant women, fetuses, and other vulnerable populations which may have diminished capacity to provide consent; research involving prisoners; research that involves deception; or survey research that involves sensitive questions or is likely to be stressful for the participants.



When the Department of Graduate Studies receives an application for research it is reviewed to make sure the application is complete and the level of review is determined by the Chair of the IRB. If necessary, the Chair of the IRB will convene IRB members to review the TCSJ IRB Research Protocol. TCSJ IRB Research Protocols submitted by faculty, students and staff must be signed by the researcher and the advisor. After the Research Protocol is reviewed, candidates will be notified via email of the decision to accept or deny the application. If the researcher's application is denied, revisions will be requested and the application will be reconsidered upon re-submission.

Documents, Consent and Assent Forms:

The Chair of the IRB and TCSJ IRB also evaluates interview protocols, data collection protocols, advertisements, approach letters, consent/assent forms or information statements, telephone scripts, and debriefing statements to determine if they are accurate, explanatory, and written in simple, lay language appropriate for the intended participants.

Since the central requirement for human participants research is that people participate voluntarily, the consent process is one of the more important parts of the research project. The process must assure that the potential participant understands the study and its risks and benefits and can certify his or her willingness to participate or decline to participate in the study. Under certain circumstance the IRB can waive or alter the informed consent process. In the case of minors, an assent form is to be used in addition to the consent form from a parent or guardian. In some cases, a signed consent form is either inappropriate or unnecessary. According to Federal Regulations at 45 CFR Part 46.117c the IRB may waive this requirement if it determines either:

1. There is a risk of breach of confidentiality and the only link between the participant and the research would be the consent document. In this case, the participant's wishes should be followed.
2. The research presents no more than minimal risk of harm and involves no research that requires written consent outside the research context.

In general, on common survey research, where there is no more than minimal risk and anonymity is provided, a separate consent form is not needed. The survey itself can contain relevant information about the study. In this case, submitting the survey is an indication of consent. If the survey is being sent and returned through the Internet, participants should be alerted to how confidentiality is being protected. Researchers can block identifying information or arrange to have surveys returned by mail. If identification (through IP or email address) is possible, then steps taken to ensure confidentiality should be explained.

The Chair of the IRB or TCSJ IRB may determine there is insufficient information to approve or disapprove an application. If this is the case, the IRB will ask the researcher to provide additional information. When the information is received by the IRB, the application is reconsidered. The IRB may determine that the risks of the proposed activity outweigh the benefits and will withhold approval. The IRB will work with the researcher toward a compromise to reduce the risks and gain approval to carry out the research.

You must notify the IRB if you wish to change any aspect of your research by submitting copies of all change materials, along with an explanation of the changes made to your research. Substantial changes in the focus, procedures, or participant population of the research may require submission of a new application.

Call the IRB Chair at (209) 953-2119 or email Crescentia Thomas at cthomas@sjcoe.net if you have questions about the IRB process.