

**Trinity Valley Community College
Institutional Review Board**

EXEMPT PROTOCOL SUMMARY FORM

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Trinity Valley Community College's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally approved Categories of Exemption are:

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; (b) research on the effectiveness of or the comparison between 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 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 reasonably places the subjects at risk of criminal or civil liability or may be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 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 existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
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, 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.
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 an agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review should be directed to the Chair of the Institutional Review Board.

_____/_____/_____
Date Submitted

Trinity Valley Community
College
Institutional Review Board

File Number

Exempt Protocol Summary Form

Title of Research Project

Principal Investigator/Project Director
Department Phone Email

Co-investigator/Student Investigator
Department Phone Email

Co-investigator/Student Investigator
Department Phone Email

Anticipated Funding Source:

Projected Duration of Research: Months Projected Starting Date:

Other organizations and/or agencies, if any, involved in the study:

Exempt under code (see definitions on page one – check one) 1 2 3 4 5 6

SUMMARY ABSTRACT: Please supply the following information below: **BRIEF** description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, and who will have access to the data. Attach copy of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

Principal Investigator Signature

Date

Co-Investigator/Student Signature

Date

Signature of IRB Chair:			Date:
IRB Chair: Check 1 box:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Conditions	<input type="checkbox"/> Refer to Full Committee Review