

_____/_____/_____
Date Submitted

Trinity Valley Community
College
Institutional Review Board

File Number

FULL IRB REVIEW 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, if any, involved in the study:

Please answer the questions below and return this form with:

- ◆ A memo that briefly describes the intent of the project
- ◆ A completed copy of the Consent Form Checklist
- ◆ A copy of the Consent Form that will be provided to the participants

I. Project Information:

A. Project Activity Status:

- New Project
- Periodic Review of Continuing Project
- Revision to Previously Approved Project

B. This project involves Trinity Valley Community College students

- Yes No

C. Human Subjects from the following populations will be involved in this study

- Minors High School Students
- Mentally Disabled Prisoners
- Elderly None of the above

D. Total number of subjects to be studied

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II. Abstract Describing Project and Purpose (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.)

III. Protocol (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary)

V. Precautions (What steps will be taken to insure that each subject’s participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)

VI. Confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc)

VIII. Consent (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject)

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.

I certify that the protocol and method of obtaining informed consent as approved by the Trinity Valley Community College Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

_____/_____/_____
Investigator/Project Director Signature

_____/_____/_____
Co-Investigator/Student Signature (if appropriate)

Signature of IRB Chair:				Date: ____/____/____		
IRB Chair: Check 1 box:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Restrictions	<input type="checkbox"/> Tabled	<input type="checkbox"/> Disapproved		

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**Trinity Valley Community College
Human Subjects Research Project
Consent Form Checklist**

N/A	YES	NO	
			1. Is the consent form written in “lay language”?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. If minors are included in the study, is provision made for obtaining parental consent?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Does the consent form include each of the following basic elements of informed consent?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	b. A description of the procedures to be followed.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	c. A description of any benefits to the subject or others.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	d. A description of any reasonably foreseeable risks or discomforts.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	f. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	h. Appropriate FERPA notice and waivers (if appropriate).

If there was a “NO” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why it is appropriate as submitted.