QUINEBAUG VALLEY COMMUNITY COLLEGE

Documents Regarding The Use of IRBs at Quinebaug Valley Community College

As QVCC is a two-year teaching institution, the need for an Institutional Review Board (IRB) is infrequent if not rare. The College has in the past, however, used temporary review boards established for specific projects (and not in recent years). At the same time, to make this a more formal protocol, faculty at QVCC have worked with colleagues at neighboring Three Rivers Community College, to have on hand ready documentation for the creation and use of such a review board, when the need arises. The following are the resulting documents.

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___/___/___ Three Rivers/Quinebaug Community College _____

Date Submitted Research Review Request File Number

RESEARCH REVIEW PROTOCOL SUMMARY FORM

Title of Research Project

Principal Investigator/Project Director **Department** **Phone Extension** **Email address**

Co-investigator/Student Investigator **Department** **Phone Extension** **Email address**

Co-investigator/Student Investigator **Department** **Phone Extension** **Email address**

Anticipated Funding Source: _____

Projected Duration of Research: _____ **months** **Projected Starting Date:** _____

Other organizations and/or agencies, 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**

☐ **Revision to Previously Approved Project**

B. This project involves Three Rivers 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:_____

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.)

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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 appropriate Dean 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 Director of Institutional Research
- 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 Three Rivers Institutional Research Review Policy will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the appropriate Dean for review and approval prior to implementation.

_____ __/__/__ _____ __/__/__

Principal Investigator Signature — Co-Investigator/Student Signature (if appropriate)

Title of supervising dean or president:			
Signature of supervising dean or president:			**Date:**__/__/__
Dean: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**
Comments:			

Three Rivers Community College
Human Subjects Research Project
Consent Form Checklist

N/A	YES	NO	
			1. Is the consent form written in "lay language"?
			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?
			3. If minors are included in the study, is provision made for obtaining parental consent?
			4. Does the consent form include each of the following basic elements of informed consent?
			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.
			b. A description of the procedures to be followed.
			c. A description of any benefits to the subject or others.
			d. A description of any reasonably foreseeable risks or discomforts.
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. Information regarding whom to contact for answers to questions about the research study and the research subject's rights.
			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.
			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.

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Three Rivers Community College
Institutional Research Review Policy

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the 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.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators.

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. 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**, items 1 and 2 are 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.

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Three Rivers Community College

SAMPLE INFORMED CONSENT

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Director of Institutional Research must determine if the participants will be giving ***informed consent.*** (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____. In this study, you (your child/ward) will be asked to _____. Your participation should take about _____ minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include _____.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____.

Please feel free to contact _____ (names(s), title(s) of principal researchers) at _____ phone) if you have any questions about the study. Or, for other questions, contact the Director of Institutional of Research (860 892-5774).

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____
Signature of Participant Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

_____
Signature of Parent/Guardian Date

ASSENT format:

I understand what I must do in this study and I want to take part in the study.

_____
Signature of Child/Ward Date

Attach Consent Form that will be provided to the participants

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Three Rivers/Quinebaug Valley Community College
Research Review

EXEMPT PROTOCOL SUMMARY FORM

ACTIVITIES EXEMPT FROM INSTITUTIONAL REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Three River's Institutional Research Review Policy. 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 their Dean.

*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 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 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 place the subjects at risk of criminal or civil liability or 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 or 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 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) of the activity 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 can be directed to the Director, Institutional Research.

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__/__/__ **Date Submitted**

Three Rivers Community College

_____ **File Number**

Exempt Protocol Summary Form

_____
Title of Research Project

_____
Principal Investigator/Project Director **Department** **Phone Extension** **Email address**

_____
Co-investigator/Student Investigator **Department** **Phone Extension** **Email address**

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, who will have access to the data.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

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- Any problems connected with the use of human subjects once the project has begun must be communicated to the Director of Institutional Research.
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

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

Title of supervising dean or president:			
Signature of supervising dean or president:			**Date:** __/__/__
Dean: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**
Comments:			