**Fox Valley Technical 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 FVTC'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 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 IRB Committee Chair.

___/___/____
**Date Submitted**

**Fox Valley Technical College**
**Institutional Review Board**

**Project Number**:_____

## Exempt Protocol Request Form

**Title of Research Project**

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

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

| | | | |
|---|---|---|---|
| **Estimated Duration of Research:** | **Months** | **Projected Starting Date:** | |
| **Estimated Completion of Research Project:** | **Months** | **Projected Completion Date:** | |

**CITI (or other authorized DHHS training) Certification Number for PI: _____**

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

Has the researcher contacted the leadership (VP, Dean, Director) of the area where staff/students/data will be the focus of the research study and received approved to conduct the proposed research? ____Yes ____No
Comments: _____

Has the IRB of the researcher's institution of higher learning reviewed and approved the research including protection of human subjects? ____Yes ____No Institution Name: _____

Does the research activity interrupt the teaching/learning/working environment of the college to any extent? ____Yes ____No Comments: _____

**SUMMARY ABSTRACT:** Please attach the following information: 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. 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 Co-Investigator/Student Signature (if appropriate)

| | | | |
|---|---|---|---|
| **Signature of IRB Committee Chair:** | | | **Date:__/__/__** |
| **IRB Chair: Check 1 box:** | ☐ **Approved** | ☐ **Approved with Conditions** | ☐ **Refer to Full Committee Review** |

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# ELEMENTS OF INFORMED CONSENT

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.

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, and also contact information for FVTC's Institutional Review Board (Director of Accreditation and Planning – Michele Zick; zickm@fvtc.edu).

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.

**Fox Valley Technical 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 Institutional Review Board 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 FVTC's Director of Accreditation and Planning – Michele Zick (zickm@fvtc.edu).

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*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