Fox Valley Technical College Institutional Review Board

Charter and Standard Operating Procedures

October 2024

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INTRODUCTION

Fox Valley Technical College encourages and supports the scholarly endeavors of students, faculty, and staff of the College. Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. FVTC's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the Fox Valley Technical College Institutional Review Board. The FVTC IRB is appropriate to the mission and scope of the institution which typically engages only in education-related research.

Most research projects involving human subjects are exempt or excluded from IRB full review requirements. Non-exempt projects requiring full review may include, for example, a survey involving students under age 18. (For more specifics on non-exempt review see Section VIII. Procedures of the IRB)

The Institutional Review Board (IRB) for Human Subjects Research at Fox Valley Technical College has responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

I. INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the Fox Valley Technical College (FVTC) human subjects' protection committee. Currently FVTC has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board (IRB00006505). This committee is hereinafter referred to as "the IRB."

Fox Valley Technical College adopts the following reporting procedure:

All Principal Investigator(s) and all Fox Valley Technical College employees are required to report to the Chair of the IRB Committee any of the following upon knowledge of:

1. Unanticipated problems involving risks to subjects or others; and
2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Fox Valley Technical College IRB committee, the President of Fox Valley Technical College, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

II. PURPOSE

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at Fox Valley Technical College to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol.

IV. THE AUTHORITY OF THE IRB

A. Fox Valley Technical College registered as an Institutional Review Board through OHRP. Accordingly, FVTC agrees to consider ***all*** research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which FVTC has an "IRB Authorization Agreement" or

2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which FVTC has an "IRB Authorization Agreement" or

3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution or

4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining

whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete an Exempt Research Approval Form for approval and submit it along with any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Director of Accreditation and Planning. However, the Director of Accreditation and Planning may not approve the non-exempt research if it has not been approved by the IRB.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS

A. The IRB functions administratively through the FVTC College Effectiveness department. This structure provides for administrative coordination for the IRB with the various academic and administrative units at FVTC.

B. The IRB advises and makes recommendations to the President, to policy and administrative bodies, and to any member of the FVTC community on all matters related to the use of human subjects in research.

VI. THE MEMBERSHIP OF THE IRB

A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments reported to OHRP.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of FVTC regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with FVTC.

D. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

VII. MANAGEMENT OF THE IRB

A. The FVTC IRB Chair has authority to sign all IRB action items.

B. The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair.

C. Members and alternates of the IRB shall be appointed by the Chair of the IRB for a tenure of three (3) years which may be renewed. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be

informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

D. All IRB members are required to undergo formal training at the time of their initial appointment. Training that satisfies this requirement is the CITI training funded by FVTC, similar resources available through the OHRP website, or FVTC's course on IRB principles. The IRB members inform the IRB Chair of training completion dates and renewals such as the CITI training once every three years.

E. IRB members do not receive compensation for their service.

F. Liability coverage for IRB members is provided through FVTC's liability insurance coverage, whether or not the IRB member is an employee of FVTC.

G. Consultants with competence in special areas may be used when deemed appropriate.

H. Conflict of interest policy and procedure

1. Investigators shall not be involved in the selection of IRB members.
2. Investigators and IRB members who are FVTC employees and who apply for federal grants and contracts are subject to the FVTC Conflict of Interest Policy.
3. FVTC College Effectiveness department will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.
4. Other conflict of interest guidelines specifically for IRB members are found in section XIII of this Charter and Standard Operating Procedures.

VIII. PROCEDURES OF THE IRB

A. Research Review

No or Minimal Risk:
Under the auspices of the IRB, the IRB Chair will review Exempt Protocol Summary Forms eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise. Exempt types of research include (per Common Rule revised January 21, 2019):

1. **Educational Research** – Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. **Anonymous/non-sensitive research** (surveys, interviews, etc.) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

   (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required **by §45 CFR 46.111(a)(7).** Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly, or through identifiers linked to the subjects

3. **Benign behavioral interventions**. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met; (1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; (2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (3) The information obtained is recorded by the

investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects**,** and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**.** For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (e.g., playing an online game, solving puzzles, etc.)If the research involves deception, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research and the subject is informed that they will be unaware of or they will be misled regarding the nature or purposes of the research. **Children may not be included in research under this exemption.**

4. **Secondary research on existing data or specimens.** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met: (1) The identifiable private information or identifiable biospecimens are publicly available; or (2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or (3) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 164, Subparts A and E (HIPAA), for the purposes of "health care operations" or "research" as those terms are defined under HIPAA or for "public health activities and purposes" under HIPAA; or (4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

5. **Research conducted by federal agencies.** Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (1) Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs": The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act); The research or demonstration project must be conducted pursuant to specific Federal statutory authority; There must be no statutory requirements that the project be

reviewed by an IRB; and The project must not involve significant physical invasions or intrusions upon the privacy of participants. (2) Procedures for obtaining benefits or services under those programs; (3) Possible changes in or alternatives to those programs or procedures; or (4) Possible changes in methods or levels of payment for benefits or services under those programs. (5) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

6. **Food acceptance studies.** Taste and food quality evaluation and consumer acceptance studies; (1) If wholesome foods without additives are consumed; or (2) If a food is consumed that contains a food ingredient 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 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.

7. **Storage/Maintenance of Identifiable Data/bio specimen with broad consent.** FVTC will not implement.

8. **Use of identifiable data/biospecimens obtained with broad consent**. FVTC will not implement.

The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must cite the specific exemption category relevant to the proposed research.

Under federal regulations certain types of research qualify for an 'expedited' review. These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must the "Exempt Protocol Summary Form" to the IRB Chair at least eight (8) days prior to any proposal deadline in order to provide time for review and processing. The form is available via FVTC College Effectiveness department website. The PI will be notified by the IRB Chair of research approval.

More Than Minimal Risk

Protocols for **full-board (IRB) review** must be submitted three weeks prior to the proposal deadline. The prospective PI will submit to the IRB Chair the "Full IRB Review Protocol Summary Form." The form will be provided by the IRB Chair.

In the summary form, the investigator assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy.

The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

Actions of the IRB (for Full Review only)

The IRB may take one of the following four actions in regard to the proposed protocol and consent form: *Approved, Approved Subject to Restrictions, Tabled,* or *Disapproved.*

Approved

When a protocol has been approved, the Chair completes the "Action of the IRB" form, signs and dates it, and distributes one copy of the form to the principal investigator, the IRB files, and, if appropriate, the performance site.

Approval of the protocol will be based on the following:

a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.

c. Assurances of acceptable debriefing, if appropriate.
It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the

IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time.

There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.

e. Anticipated benefits, if any.

f. The personal risk to the subject in relation to expected benefits.

g. The adequacy of procedures for securing informed consent from the subject.

h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.

i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved Subject to Restrictions

If the protocol is approved subject to restrictions, then the Chair completes the appropriate form, signs and dates it, and sends the form with a memo to the PI outlining the restrictions. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above.

Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapproved

If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

B. Concluding the project

Pursuant to OHRP guidelines (1/21/19), continuing review is no longer required of exempt research. FVTC requested that the PI of an approved exempt project submit an email to the FVTC IRB Chair confirming the conclusion of the project.

C. Adverse Event Reporting Guidance

1. Principal Investigator(s) and any Fox Valley Technical College employee will report to the Chair of the IRB Committee any of the following upon knowledge of such:
    a. Unanticipated problems involving risks to subjects or others; and
    b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

IX. OPERATIONS OF THE IRB

A. IRB meetings are scheduled as required.

B. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

C. For non-exempt research (Full Review), the IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new protocol, who receive the complete study documentation for full review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that protocol. Other IRB members review summary information only, but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

D. Voting requirements

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying

backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

E. Appeals

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

F. Amendments

1. Amendments are categorized into minor changes and significant changes.

Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of **minor changes** to a research study include but are not limited to, the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to unvalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

Examples of **significant changes** to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed.

Minor modifications/changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB Chair.

G. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested, the board will act in an advisory capacity.

H. Cooperative Activities

Cooperative activities relating to human subjects are those which involve Fox Valley Technical College and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions are certified by OHRP; and

2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved IRBs.

X. RECORD REQUIREMENTS

A. The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and any reports submitted by investigators.

2. Detailed minutes of IRB meetings, showing:

a. Members present (any consultants/ guests/others shown separately).

b. Results of discussions on debated issues and record of IRB decisions.

c. Record of voting (showing votes for, against and abstentions).

3. Copies of all correspondence between IRB and the investigators.

4. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

5. Adverse reactions reports and documentation that the IRB reviews such reports.

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB.

XI. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB

A. Appropriate FVTC review form including protocol summary.

B. Complete FVTC review form which includes:

1. Title of the study and summary of the research to be conducted,

2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),
3. Sponsor of the study

4. Additional information as appropriate for the research
   a. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),
   b. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),
   c. Study design (including, as needed, a discussion of the appropriateness of research methods),
   d. Description of procedures to be performed,
   e. Provisions for managing adverse reactions,
   f. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,
   g. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Wisconsin as an individual under the age of 18), using legally authorized representatives (see XII.B.&C.), witnesses, translators and document storage,
   h. Remuneration to subjects for their participation
   i. Provisions for protection of subject's privacy,
   j. Inclusion/exclusion of women, minorities, and/or children;

C. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;

D. Copies of surveys, questionnaires, or other materials provided to subjects;

E. Changes in study after initiation including changes to consent forms;

F. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports;

G. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XII. ELEMENTS OF INFORMED CONSENT

A. Informed Consent - Basic and Additional Elements. New requirements (effective Jan 21, 2019)

1. Statement that the study involves research and an explanation of the purposes of the research
2. The expected duration of the subject's participation
3. Description of the procedures to be followed and identification of any procedures which are experimental
4. Description of any reasonably foreseeable risks or discomforts to the subject
5. Description of any benefits to the subject or to others which may reasonably be expected
6. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained
8. For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained
9. Research, Rights or Injury: An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury
10. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
11. Informed consent must begin with a concise and focused presentation of the key information most important for helping a potential subject decide whether to participate. Note: This requirement is met if the entire consent is only a few pages. If the consent is more than 4 pages, include a concise and focused presentation at the beginning.
12. One of the following:
13. Statement that identifiers might be removed from the data or biospecimens, and, after this deidentification, the data or biospecimens could be used for future research studies or distributed to another investigator without additional informed consent; OR
14. Statement that the subject’s data or biospecimens will not be used or distributed for any future research, not even if de-identified.

Additional Elements as Appropriate

- Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
- Statement that the subject's biospecimens may be used for commercial profit, and whether the subject will or will not share in this profit
- Statement regarding whether clinically relevant research results will be disclosed to subjects, and if so, under what circumstances
- For research involving biospecimens, whether the research will or might include whole genome sequencing.

B. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

C. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;

2. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see the FVTC Conflict of Interest Policy, for the definition of "significant financial interest");

3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or

4. Has identified him or herself for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. For Full Review, if assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the full review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Typically, there are three distinct phases of an IRB's consideration of a full review matter: discussion, deliberation and actions (including vote). In general, IRB member(s) who have a real, or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

APPENDIX A:
IRB REVIEW – REFERENCE GUIDE FOR FOX VALLEY TECHNICAL COLLEGE

The purpose of a research project and the investigator's plans for how the data involving human subjects will be used are usually the determining factors in deciding whether IRB review is mandated.

The regulatory definition of research that triggers IRB review is: "a systematic collection of data designed to produce generalizable knowledge".

> *Generalizable Knowledge: Investigations designed to draw general conclusions that will be disseminated to populations outside of the local setting. Examples of dissemination of results are publication of results in a scholarly journal, presentation at a professional conference, or placement of a report in a library.*

There is a wide range of activities that we call "research" in everyday parlance that do not meet this definition.

I. Routine classroom "teaching" assignments:
   A. IRB review is NOT required unless the data collected from surveys or interviews are being used to produce generalizable knowledge outside of the classroom.
   B. Internal class projects do not require IRB review; however, it is the Instructor's responsibility to ensure that students conduct their assignments in an ethical manner.
   C. If the faculty member or students wish to use data collected from class assignments for research and publication, application to the IRB for permission to use the data is required.
   D. If there is any doubt as to whether or not your activities could qualify as human subject research, please contact IRB Chair to determine the best way to proceed.

II. Independent research projects conducted by students, such as these, honors projects, and independent study projects:
   A. IRB review is required if data is collected through interactions with living people or access to private information. Application to the IRB for these student research projects must include an endorsement and acceptance of overall responsibility by a faculty member.

III. Marketing surveys, program evaluations and related data collections MAY be considered "research" requiring IRB review:
   A. IRB review is NOT required if the project is a work for hire where the client owns the resulting data, all rights to use the data belong to the client, and FVTC has no intention to use the data for other purposes.
   B. IRB review MAY be required if the project is a work for hire, where the client owns the data, but FVTC reserves the right to use the data for research and instructional purposes.

C. IRB review is DEFINITELY required if the project is FVTC research (student or faculty), where FVTC owns the data (even if it may be reported to a client), and FVTC (student or faculty) intends to use the data (immediately or long-term, alone or in combination with other date) in development of a scholarly product.

Activities clearly NOT research under the regulations requiring IRB review include:

A. Data collection related to practices, policies, demographics, or other information where the respondent is asked to report only factual information, and is NOT asked to report personal opinions, attitudes, beliefs or ideas.
B. An instructor polling a class for information that will be used to plan further class/course activities.
C. Use of survey software for program registration/attendance information.
D. Data collection for purposes of program planning or evaluation.
E. Oral histories, biographies, and reporting (journalism) do not normally require IRB review because they are typically descriptive of specific events or individuals, and not "designed to produce generalizable knowledge." Researchers using these methods should abide by (and/or train their students to abide by) the code of ethics prescribed by their respective disciplines and to treat respondents with courtesy and respect. In cases where the work might be construed as "designed to produce generalizable knowledge," researchers are advised to consult with IRB staff for recommendations on the best way to proceed.

Whether or not IRB review is required, risks to the participant should be minimized to the fullest extent possible. For most social/behavioral research, breach of confidentiality is the greatest risk involved in the work.

A. Risks can be biomedical, psychological, social (risks to reputation or potential embarrassment), legal (disclosure of illegal activities) and/or economic (loss of employment).
B. Anonymity is the best protection and should be considered whenever possible.
C. When anonymity is impossible, questions asking opinions rather than asking an individual to disclose their actual behaviors entail less risk. (For example: What do you think about college students who use marijuana? As opposed to: How often do you use marijuana?)
D. When anonymity is impossible, there should be protections in place to safeguard the identities of the respondents.

When IRB review is required, the level of review is determined primarily on the basis of the level of risks to participants.

A. **EXEMPT review** – risks must be no greater than minimal and data must include no participant identifiers.
    a. No greater than minimal risk = the level of risk an individual normally encounters in the course of routine daily activities.
    b. Signed informed consent is not required.

c. Exempt protocols are reviewed by the IRB administrator and the IRB Chair.
d. Review can usually be completed in one week or less.

B. **EXPEDITED review** – risks must be no greater than minimal and identifiers are included in the data.
    a. Signed informed consent may or may not be required.
    b. Expedited protocols are reviewed by the IRB Chair.
    c. Review can usually be completed in 1-2 weeks.
C. **FULL BOARD review** – risks are greater than minimal OR participants are members of a group for which the law requires additional protections.
    a. Signed informed consent is nearly always required.
    b. Protocols are reviewed by a convened quorum of the IRB membership in a face to face meeting. On occasion the investigator is asked to attend.
    c. Review can usually be completed in 2-4 weeks.

Other Participant Protections Considerations:

A. Research involving certain protected classes of participants REQUIRES full board review. These include minors (in most cases), and prisoners, and may also include others who lack the legal or mental capacity to consent to participate.
B. IRB review is PROSPECTIVE review. If review is required, review and approval must be complete before participant recruitment and/or data collection begin.
C. Faculty who may want to use their survey responses in an article or conference presentation should be aware that an increasing number of journals and professional conferences require evidence of IRB approval before they will accept a submission for consideration.
D. If the work as originally conceived did not require IRB approval, later IRB approval MAY be possible for use of an existing data set not originally intended for research purposes.