Chippewa Valley Technical College

Full Committee Review

Institutional Review Board

Research involving more than minimal risk to the participant requires review by the full Institutional Review Board. Full review covers all research that is not specifically suited for “expedited review” or “screened as exempt from review.” Full review by the entire IRB Committee is reserved for studies that have potential risk to human subjects. This may include:

- Research that involves the administration of drugs or other substances to subjects
- Research that materially affects the pregnancy of a woman or the health/well-being of fetuses in utero.
- Research involving subjects with life-threatening physical conditions.
- Research involving physically intrusive procedures.
- Research which previous experience has been shown to create a potential of risk to subjects.
- Research that may result in a significant level of psychological or physical stress.
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject’s privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified.
- Research involving prisoners.
- Research that places protected populations (such as children, mentally ill individuals, patients with medical disorders) at more than minimal risk.
- Research involving waivers of any HIPAA regulations.

When submitting the Research Approval Application Form, please remember that the Institutional Review Board (IRB) needs sufficient information to determine that all of the following criteria have been met:

- The research design is scientifically sound and will not expose participants to unnecessary risk.
- Risks to participants are reasonable in relation to anticipated benefits to the participants and to society.
- Risks to participants are minimized and, when appropriate, a plan is in place to monitor data collected to ensure the safety of participants.
- Selection of participants is equitable given the purposes of the research and the setting in which it will be conducted.
- Informed consent will be sought from each prospective participant or the participant’s legally authorized representative and will be appropriately documented.
- Additional safeguards are in place to protect participants who are likely to be vulnerable to undue influence or coercion.
- Adequate procedures are in place to protect the privacy of participants and maintain the confidentiality of data determine if it meets the above criteria. If the research is approved, the IRB will send a research approval letter and upon receipt the principal investigator may begin the project.

The quality of information presented to the IRB and the degree to which the above criteria are met will allow the IRB to make an approval decision in regards to your research study. The IRB could either approve, conditionally approve, table or disapprove your research project. Below are descriptions of the various decision actions the IRB may take.

Approve: If all the criteria above are met and approval is grated by the IRB, the researcher is allowed to proceed with their research project as outlined in their Research Approval Application. The IRB will send a research approval letter and upon receipt the principal investigator may begin the project.

Conditionally Approve: The IRB may determine that the risks to subjects are minimal but would like to see minor changes prior to this project being conducted. In this case conditional approval may be given. The IRB will communicate with the principal investigator and give an outline of the conditions that must be met in order to secure full approval. The principal investigator must respond to IRB in writing and this response is reviewed by the IRB Chair or other designee of the IRB. Research may not be conducted until all of the conditions of the IRB have been addressed and met. Full approval is necessary to conduct proposed research and this is gained through meeting the aforementioned conditions. If approved the IRB will send a research approval letter and upon receipt the principal investigator may begin the project.

Table: If there is insufficient information to assess risks and benefits for participants, changes are required that alter the conduct of the project, or major concerns exist in relation to any of the preceding criteria, then the IRB may table a protocol. The principal investigator will be notified in writing and he or she must submit a new proposal that would address the concerns of the IRB. Full approval is necessary to conduct proposed research. The IRB will review the new Research Approval Application and contact the principal investigator with their decision. If approved, the IRB will send a research approval letter and upon receipt the principal investigator may begin the project.

Disapprove: If the IRB determines that a project does not meet the criteria for approval and there are serious concerns related to one or more criteria, the IRB may disapprove a project. The investigator is informed of this decision in writing and is given feedback regarding the reasons for disapproval.

The IRB meets on an as needed basis. To submit for full IRB review, the investigator needs to complete the Research Approval Application Form found on the CVTC website. Applications are reviewed in the order received; thus, it is to the investigator's advantage to submit applications as early as possible.

If your research does not meet the criteria for exempt detrmination or expedited review as outlined by 63 FR 60364-60367 (November 9, 1998) and 45 CFR 46.110, please indicate you are requesting **Full Committee Review** when completing the **Research Approval Application Form** for the Institutional Review Board. Approval by the IRB needs to be granted prior to beginning your research at CVTC.