# FERRIS STATE UNIVERSITY

### INSTITUTIONAL REVIEW BOARD

1010 Campus Drive FLITE 410 Big Rapids, MI 49307 www.ferris.edu/irb

#### IRB Guidance on Student Research, Capstone Projects, and Theses

The scholarly activities of students, faculty and staff often involve engagement in research projects entailing the collection of data from human subjects that are used to advance knowledge and understanding. Projects such as this likely fall under federal regulations set forth in what is known as the "Revised Common Rule" (45 CFR 46) available at: <u>https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html</u>.

These federal rules and the policies derived from them at Ferris State University are intended to ensure that research on human subjects is done ethically and with full considerations of their rights and the process of consent. The following guidance in the form of questions and answers and flow diagram can aid students, faculty, and staff in understanding when to complete an IRB application.

#### 1. What types of projects/research need to be submitted to the IRB for determination?

There are generally three conditions that combine to create the need to submit an application to the IRB for human subjects review:

- a. Collection of data from or about living human subjects. Any project or research where data are collected prospectively or retrospectively from or about human subjects meets this part of the definition. This includes, but is not limited to, retrospective chart review, prospective data, surveys, blood samples, eye examinations, interviews, classroom performance, etc.
- b. Contribution to the "generalizable knowledge". If the intent is to advance understanding or knowledge and then contribute this through presentation (local, regional, national), poster or publication, this criterion is met. NOTE: The completion of a research project as a requirement for a graduate or professional degree granted at Ferris, whether it be a "thesis" requirement or capstone project, meets this criterion independent of the findings being presented or published.
- c. Application of a scientific method of inquiry. The use of a structured research method (e.g. sampling, data collection, hypothesis testing, descriptive analysis, analytics or statistical analysis, etc.) meets this criterion.

#### 2. What about projects I do as part of a research methods class at Ferris?

Research methods courses in undergraduate, graduate and professional degree programs are intended to teach students about how to design, organize and execute scientific methods of inquiry. Small scale projects that students conduct in research methods courses that are intended to be limited in scope and presented in the class or to the subjects of the study do not require approval by the IRB. NOTE: Capstone or thesis courses intended to provide time and structure for students to conduct the degree-level research DO NOT fall in this category and will likely require submitting an IRB application (see #1 above and attached flow diagram).

### 3. I worked on a specific project design as part of a research methods course and now I want to use it for my thesis or capstone project. Do I need to submit to the IRB?

Yes, if it meets the criteria in question #1, then it will need to be submitted to the IRB.

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- 4. How long will it take for the IRB to review an application? How often does the IRB meet? The IRB meets monthly during the Fall and Spring semesters. Most applications that are submitted to the IRB do not need to be reviewed by the full committee. Most projects can be reviewed by a small subset of the committee and therefore are processed in a matter of weeks, if the application is thoroughly completed.
- 5. I was told that my research project was probably "exempt" and therefore may not need to be submitted in an application to the IRB. Is this correct?

No. This is not the correct interpretation of the classification of "exempt". There are three main categories of IRB review (full board, expedited, and exempt). Each category is defined by the federal Common Rule. The designation of "exempt" status does NOT mean that the IRB application can be skipped. Certain rules and ongoing monitoring still apply to exempt research projects. As such, this determination is given by the IRB with further instructions after the application is reviewed and approved.

- 6. What happens if I submit an IRB application during the Summer semester? Because most applications allow for review by exempt or expedited procedures from the IRB, there is little to any delay that occurs over the Summer semester. If the project requires full committee review, then it will be delayed until the Fall semester. Project anticipating Full Review should be submitted no later than early Spring Semester to allow the Committee adequate time to review and provide comments as necessary.
- 7. Can I start my project while the application is under review? No. You may not start any components of research without final approval by the IRB office. Sometimes there are changes that need to made as directed by the IRB office.
- 8. A fellow student's project that was similar to mine was given a determination from the IRB that it was not human subjects research. What does that mean and do I need to submit an application? A determination from the IRB that a project is not human subjects research means that specific project was reviewed by the IRB but did not meet the Federal definition of research with human subjects. Each application is reviewed individually; thus, if you have a different project it should be submitted to the IRB for its own review and determination.

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