Salish Kootenai College Procedure for

Class Projects Requiring IRB Review

Purpose of this Procedure: This procedure defines which class projects require IRB review and describes the responsibilities of instructors and students involved in class projects which include collection of data from human subjects OR collection of data that may involve the intellectual property of the Confederated Salish & Kootenai Tribes..

Definitions:

Class projects include any collection and/or analyses of human subjects data that are assigned as an educational exercise in the context of a specific course.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Generalizable knowledge is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Cultural Intellectual Property refers to traditional cultural knowledge, cultural expressions, sacred cultural material, historical traditions and understandings, and other property such as natural resources that occur on the Flathead Indian Reservation.

Procedure for Determining Whether a Class Project Requires IRB Review

Class projects are designed to teach research methods or to help students understand concepts covered by the course through collection and/or analyses of human subjects data or materials which may be considered the cultural intellectual property of the CSKT. Class projects may involve a collection of original primary data through intervention or interaction with human subjects or may involve collection of data concerning historical uses of natural resource data. Class projects may also involve analyses of secondary data obtained from human subjects.

Class projects may involve activities that resemble human subjects research; however, class projects are not considered "research" as defined in the federal regulations for the protection of human subjects (45 CFR 46) IF they are conducted for training purposes only and do not yield generalizable knowledge.

In an effort to clarify the matter, the IRB has established the following guidelines for determining when institutional review and approval is necessary for class projects:

IRB review is not required for class projects that meet all of the following criteria:

1. The primary purpose is a learning experience in the methods and procedures of research; AND

2. The project Involves no more than minimal risk or standard educational practices; AND

3. The project does not include sensitive topics or interaction with vulnerable populations; AND

4. The data must be recorded and stored with no direct identifiers (i.e., names, dates of birth, social security numbers, etc.); AND

5. The data will not be published or presented outside the college and will not be used in further research by the student, other class members and/or the instructor.

IRB review is required for:

1. Class projects that do not meet the criteria specified above;

2. Class projects that may be published or presented outside of the college;

3. Independent studies such as honors theses, Master's theses, and similar independent research projects. All of these must be reviewed and approved by the IRB before students may begin their research.

Responsibilities of Instructors

- Instructors are responsible for ensuring appropriate design and ethical conduct of class projects involving human subjects data or cultural intellectual property of the CSKT.
- Instructors are responsible for review of each student's project to determine whether the project does or does not meet the above definition of research and therefore needs review by the IRB.
- Instructors provide for training in ethical conduct of research projects. If the project will require IRB review and involves human subjects, each student must complete the Collaborative Institutional Training Initiative (CITI) training and provide a certificate of training along with the submitted IRB materials.
- Instructors ensure that appropriate site permissions are obtained for all projects that are completed either as class projects or as formal research.
- Instructors advise students that data from human subjects must not contain any personal and identifying information.
- Instructors closely monitor class projects to ensure that students are following correct procedures and conducting the project as was proposed.
- Instructors, to the best of their ability, monitor that the student projects are not shared, presented and/or published outside the SKC community, or submitted into SKC's repository

without prior approval from the IRB. Should this occur, the instructor is to contact the IRB immediately.

Responsibilities of Students

- Students are responsible for following the guidelines for class projects as outlined in the course syllabus. Students are responsible for completing training in Human Subjects Protection if required as part of an IRB review.
- Students inform participants that their data will be destroyed after the class project is completed (end of the semester).
- Students must notify their instructor should the class project change in any way from what was originally proposed.
- Students do not share, present and/or publish any part of the class project outside the SKC community without prior approval from the IRB.