Institutional Research Review Policy

INTRODUCTION

As a learning community Three Rivers Community College supports and encourages it's faculty/staff and students in the pursuit of scholarly work and research. Often this work will involve the use of surveys or other protocols requiring the interaction with human subjects at the College. To ensure that members of the College community who may be affected by such are afforded the appropriate rights; 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 appropriate informed consent; that any research is conducted in an ethical manner and in compliance with recognized standards, the College is establishing an institutional research review policy. All research projects conducted at Three Rivers Community College must obtain authorization from the appropriate Dean prior to soliciting projection participation or beginning data collection.

The review of all research involving human subjects shall be guided by the United States Department of Health & Human Services Policy for Protection of Human Research Subjects, 45 CFR 46 Part A. These guiding regulations provide for three major categories of research that are generally exempt from the institutional review process which include research conducted in established or commonly accepted educational settings, research using educational tests, survey procedures, interview procedures or observation of public behavior when individuals can not be identified and institutional or organizational research designed to improve services or benefits when approved by the agency's head.

The primary responsibility for reviewing research projects at Three Rivers Community College rests with the Dean to which the principle investigator reports. In those situations when leadership of the research is inter-divisional the President will be the final approving authority. In all cases the Director of Institutional Research will review the proposed research projects that involve the use of human subjects to: ensure that individuals are treated ethically; ensure that the individuals involved in the project 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 confidentially and make an appropriate recommendation to the approving authority.

PURPOSE

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

BASIC PRINCIPLES

The basic principles that govern this research review policy are based on the Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects, (revised Jun 23,

2005). In general, the following principles apply to all research, including student projects, involving human subjects at Three Rivers Community College and must be considered when approving proposed research to ensure that adequate safeguards are provided:

- Risks to participants, where they exist, will be minimized and are reasonable in relation to anticipated benefits. (46.111a 1-2)
- Selection of subjects is equitable, especially in research situations involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (46.111a 3)
- Documentation of informed consent will be obtained from each prospective subject or the subject's legally authorized representative. (46.111a 4; see required elements for informed consent below)
- For monitoring the data collected to ensure the safety and privacy of the subjects as well as maintaining the confidentially of the data collected. (46.111a 6-7)
- In the case of vulnerable populations, additional safeguards have been included in the study to protect the rights and welfare of these subjects as a result of coercion or undue influence by the researcher. (46.111b)

An essential element of the research process is that of informed consent. Research subjects or their legal representative must be given sufficient opportunity to consider whether or not to participate with minimal possibility of coercion or undue influence. In light of this CFR 46.116 provides the following general requirements for informed consent.

- The consent form must provide a clear and non-technical explanation of the research project sufficient to inform a participant's decision to participate or not. (46.116a 1)
- The consent form must describe any foreseeable risks or discomforts, as well as possible benefits to the participant. (46.116a 2-3)
- The consent form must inform the participant of the extent to which confidentiality will be maintained. (46.116a 5)
- The consent form must identify a person to contact should questions regarding the research or the participant's rights arise. (46.116a 7)
- The consent form must provide a statement that participation is voluntary and that refusal to participate or termination of participation at any time during the project will result in no harm to the participant. (46116a 8)
- When appropriate the following should also be included:
    - The consent form must describe any alternative treatments being withheld by the researcher that might be advantageous to the participant. (46.116a 4)
    - The consent form must explain any compensation to be provided should harm to the participant occur. (46.116a 6)

There are some types of research that are exempt from the federal regulations for institutional review. To be exempt from review, a project must be in one of the following categories:

- Research that is conducted in a common educational setting, involving normal or special educational practices. (46.101b 1)

- Research involving educational tests, surveys, interviews, or observation of public behavior unless confidentially cannot be maintained or disclosure places the participants at risk. (46.101b 2)
- Research involving elected or appointed public officials or candidates for office, and personal identifiers are not collected. (46.101b 3)
- Research involving the study of existing data either publicly availably or recorded by the researcher(s) in a manner that maintains confidentiality. (46.101b 4)
- Institutional or organizational research designed to improve services or benefits when approved by the agency's head. (46.101b 5)

IMPLEMENTATION OF POLICY

This policy applies to all research conducted at Three Rivers Community College (TRCC) that utilize human subjects regardless of the source of funding if one or more of the following apply:

1. The research is sponsored by TRCC, or

2. The research is conducted by or under the direction of any employee or agent of TRCC, or

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

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

There may be situations that students involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals may be considered non-exempt research. The course instructor is responsible for determining whether such activity will require research approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to consult with the Director of Institutional Research to obtain guidance regarding these activities.

The principal investigator shall submit either the Exempt Protocol Summary Form or the Research Review Protocol Summary Form along with the supporting documentation to the appropriate Dean. The Dean will have the Director of Institutional Research review the research proposal for adherence to the basic principles for the protection of human subject and provide them with an appropriate disposition recommendation. The Dean will then make a final disposition decision and return a copy of the protocol summary form to the principal investigator while filing the original.