Moraine Valley Community College

Institutional Review Board Manual

March 2018

MORAINE VALLEY COMMUNITY COLLEGE

INSTITUTIONAL REVIEW BOARD MANUAL

CONTENTS

Introduction……..3

Background ……..4

Definitions……..4

Procedure……..6

Review Categories……7

Informed Consent……8

Use of Internet for Surveys/Recruiting Subjects……9

Use of Existing or Secondary Data……..10

Guidelines for External Research Projects……..10

Introduction

The Institutional Review Board (IRB) of Moraine Valley Community College (MVCC) has the responsibility for reviewing all non-medical research involving human subjects associated with MVCC to ensure compliance with the Code of Federal Regulations (45 CFR 46).

Moraine Valley Community College is guided by the ethical principles set forth in the Belmont Report and by the requirements of the Code of Federal Regulations (45 CFR 46). Approval for conducting research with human subjects must be obtained from the MVCC IRB prior to the recruitment and any involvement of subjects.

All researchers must follow the policies outlined in this Guide when they are conducting research that involves human subjects affiliated with MVCC, regardless of whether the research is externally funded or not. It applies to surveys, faculty projects, independent study projects, and all other research with human subjects.

The IRB reviews all research that involves human subjects if one or more of the following apply:

- The research is sponsored by this institution, or
- The research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
- 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
- The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

Researchers are responsible for complying with all IRB decisions and requirements. Failure to comply with the IRB findings is serious and can, in the worst case, result in the College losing the right to conduct any research involving human subjects.

The MVCC IRB is composed of seven members, six college staff and one external reviewer. The MVCC IRB consists of the following members: The Director of Institutional Research and Planning, Assistant Director of Institutional Research and Planning, Director of Resource Development and Institutional Effectiveness, Dean of Student Engagement, Manager of Staff Training and Development, MVCC faculty member, and one external reviewer.

This Guide was prepared to help researchers submit applications to the IRB for review. It discusses principles and policies related to the use of human subjects in research.

Background

Belmont Principles and Federal Regulations

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published its report entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The report sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those basic principles are respect for persons, beneficence, and justice.

Respect for persons recognizes the personal dignity and autonomy of individuals, and requires special protection of those persons with diminished autonomy, e.g., children. Researchers must get full consent from individuals before conducting research. Consent involves informing them about the research procedures, the purpose of the research, and the risks and anticipated benefits.

Beneficence entails an obligation to protect persons from harm by maximizing benefits and minimizing possible risks. The appropriateness of involving vulnerable populations must be demonstrated, and the consent process must thoroughly and completely disclose relevant risks and benefits.

Justice requires that the benefits and burdens of research be distributed fairly. Researchers should not select subjects simply because they are readily available.

The federal government regulates research with human subjects. The Code of Federal Regulations (45 CFR 46) incorporates the ethical principles described in the Belmont Report and provides basic guidelines for the Institutional Review Board (IRB).

Definitions

Research

Any systematic gathering and analysis of information designed to develop or contribute to *generalizable* knowledge. The purpose of gathering the data is one way to determine whether the project is generalizable. If the researcher intends to publish the results or present the information at a public meeting, the project is designed to contribute to a wider audience and is, therefore, generalizable.

Although the following list is not exhaustive, research includes:

- Interviews, surveys, focus groups, or observations that are designed to gather nonpublic information about individuals or groups.
- Studies of existing data, either public or private, where the identity of individuals is known.
- Studies designed to change subjects' physical or psychological states or environments.

Human Subjects

Human subjects are living individuals about whom an investigator obtains (a) data by intervention or interaction with the individual, or (b) identifiable private information.

Intervention
Intervention includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment are performed for research purposes.

Interaction
Interaction includes communication or interpersonal contact between investigator and subject.

Private Information
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Minimal Risk
Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives. Minimal risk is affected by the context of the research, including characteristics of the subjects.

Principal Investigator
A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research project, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. They assume full responsibility for the project, including the supervision of any co-investigators, research assistants, house staff and students.

Confidentiality
Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

Anonymity
Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, email address, etc.), or the project cannot link individual responses with participants' identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

Informed Consent
Informed consent is the voluntary agreement of an individual, who exercises free power of choice, without undue inducement or any other form of constraint or coercion to participate in research. The individual must have sufficient knowledge and understanding of the nature of the proposed research, the anticipated risks and potential benefits, and the requirements of the research to be able to make an informed decision.

Assent

Assent is an agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. Assent is generally required for participants under the age of 18, or participants 18 or older who are intellectually or emotionally impaired and not legally competent to give their informed consent.

Protected or Vulnerable Populations

Protected or vulnerable populations include, but are not limited to:

- Children/Minors (under the age of 18)
- Prisoners
- Pregnant women
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

Sensitive Data

Sensitive data are information that include, but are not limited to:

- Information relating to an individual's psychological well-being or mental health;
- Information relating to sexual attitudes, preferences, or practices;
- Information relating to the use of alcohol or drugs;
- Information relating to illegal behavior;
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation;
- Information that is audio or video recorded

Procedure

Individuals seeking to conduct research involving human subjects must complete a Research Proposal Form and submit it to the MVCC IRB Chair. This form may be found on the external and internal websites for the Institutional Research and Planning department. This may be done by electronic or non-electronic submission to the following address:

Dr. Sadya Khan
Director of Institutional Research and Planning
Moraine Valley Community College
9000 West College Parkway
Palos Hills, IL 60465-0937
Tel: (708) 974-5282
Fax: (708) 974-8283
Email: khans46@morainevalley.edu

Upon receipt of this form, the IRB will review and categorize the proposal into one of the three categories: Exempt, Expedited Review, or Full Committee Review. Please note that once the Research Proposal Form has been approved by the IRB, no changes can be made to the Research Proposal form, consent/assent forms, protocol, or any other attachments. The IRB Chair will respond to the researcher with confirmation of approval or disapproval and kept on

file in the Office of Institutional Research and Planning for a period of three years. Any modifications to the research must be submitted to the Director of Institutional Research and Planning in writing.

Review Categories

Moraine Valley Community College has three levels of review: Category I, Category II, and Category III, based on the potential risk to the human subjects.

Category I – Exempt (Research Department Review)

Under federal regulations certain types of research are exempt from review (Sections 101(b) or 101(i) of the U.S. Common Rule) unless the institution chooses to review it. According to MVCC IRB policy, all research with human subjects will be reviewed and must be approved prior to the gathering of any data, including those projects that fall within the federal "exempt" category. These projects involve little risk beyond that which a person encounters in daily life. Most MVCC research projects fall into this category. Research activities in which the only involvement of human subjects will be in one or more of the following areas will be reviewed as Category I applications:

(A) Research conducted in established or commonly accepted educational settings involving normal educational practices, such as testing, classroom observations, student research assignments, etc.

(B) Research involving the use of survey procedures, interview procedures, or observation of public behavior.

(C) Research involving the collection or study of existing data, documents, or records, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Category II – Expedited Review (Subcommittee Review)

If proposals meet certain criteria that are defined in the federal guidelines, the IRB subcommittee may review the proposals as a Category II. The IRB subcommittee will consist of the Director of Research and Planning, the Assistant Director of Research and Planning and one or two of the other four members of the Board as appropriate. Examples of Category II research include the following:

(A)Collection of data from voice, video, digital, or image recordings made for research purposes.

(B)Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Category III – Full Committee Review
Research proposals that do not meet the criteria for a Category I or II will be reviewed by the full MVCC IRB. By definition, proposals that require a Category III level of review present more risk to subjects than the other two levels of review.

Informed Consent

Informed consent is one of the primary ethical requirements of involving humans in any research activity. It assures that participants understand the research and what they will be expected to do so that they can make an informed decision about whether they want to participate in it.

Basic Elements of Informed Consent
Researchers must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study. (*Note that a signed consent form is not needed for most survey and focus group research; see number 8 below.)*

The informed consent must include the following and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all Principal Investigators, and also contact information for Moraine Valley Community College's Institutional Review Board (Director of Institutional Planning & Research, 708-974-5282).
8. Line for signature of participants and/or parents or legal guardian **except for questionnaire research in which return of questionnaire gives implied consent**.
9. Statement that participant is 18 years of age or older unless parent or legal guardian (includes high school administrator) has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent. An example of a consent form can be found at the end of this manual.

Use of Data: Anonymous versus Confidential
In the consent form, researchers should explain clearly how they will use the collected data and how it will be handled. The most secure procedure is not to ask for names or any other

identifying information—to keep the identity of the subjects completely anonymous. Only those studies that do not ask for names or any easily identifiable information may be described as anonymous. Anonymity means that the researcher cannot link the data to individually identifiable subjects.

Although anonymity may be useful for some studies, it is not practical for others. In studies that are not anonymous, subjects' data should be confidential. A coding procedure should be used in which each subject's identifying name or number is linked to a code number. The code number should be used on all data. A list linking the identifier to the code number should be kept secure, and a limited number of people should have access to the list. Researchers must tell subjects who will have access to the code list and what will happen to it upon completion of the study. When data are not anonymous, consent forms should include a statement such as, "We will take all reasonable steps to protect your identity." Researchers should not promise that they will maintain confidentiality, because any data could be obtained by court order.

Focus Groups

Participants in focus groups must be informed that research information may not be confidential, because all members of the group will be privy to whatever discussion occurs during the session. If focus groups are audio/videotaped, all members of the group must consent to be taped.

An example of a statement that could be used to explain confidentiality in focus groups is the following: "All reports based on this research and written by the researcher will maintain the confidentiality of individuals in the groups. Only group data will be reported and no participant names will be used. Since this is a group process, all members of the group will be privy to the discussions that occur during the session; therefore, the researcher cannot ensure that group members will hold this information confidential."

Use of Internet for Surveys/Recruiting Subjects

Internet research raises a number of complex issues for the research community. A few of the problems involved are the risks versus the benefits, consent, confidentiality, and the participation of minors. Researchers' claims about the benefits of their research depend in large part on their ability to collect useful data. But conducting research on the Internet raises questions about data sampling techniques and the validity and reliability of the data collected. It is easy to mislead the researcher about geographical location, age, race, or gender. Minors may respond to a study involving inappropriate subject matter without the researcher knowing it.

Although survey research online is similar to traditional survey research, Internet research increases the subjects' risk of being identified or having their personal information accessed by people other than the researcher. The risk of exposure can surface at different stages, from data gathering, to data processing, to data storage and dissemination. Participants may not know that there is a record of the exchange in a cache somewhere on their system or saved in their Internet service provider's log files.

All MVCC researchers who are using Internet surveys must:

- Include the Principal Investigator's contact information and IR director's contact information.
- Include either a statement saying there will be no future mailings or an opt-out message that permits addressees to have their names removed from any future mailings.
- If you plan future mailings, add a statement that says, "If you do not respond to this survey or return the opt-out message, you will be contacted again with this request X times during the next Y weeks."
- Use a blind copy format so that the list of recipients will not appear in the header.

Use of Existing or Secondary Data

If researchers plan to use data that already exist, the IRB must review the research if the data involve humans. If the data involve documents or records that are publicly available or if the information is recorded so that subjects cannot be identified directly or indirectly, the research will probably be reviewed at the Category I level. If the identifiers are recorded, researchers must describe in the IRB application the procedures they will use to protect the confidentiality of the subjects. If possible, the identifiers should be removed by a person who already has access to the data before the researcher gains access to the data.

Guidelines for External Research Projects

The following guidelines apply to all external research projects involving Moraine Valley Community College (MVCC). An external research project is defined as any research project or study not conducted directly by MVCC itself.

1. Normally, the College does not allow external persons or groups to conduct human subjects research, including surveys and focus groups, on its students. The College does not provide facilities of any type for external research projects.

2. Any external research project must demonstrate a direct benefit to the College in order for permission to be granted.

3. Before permission is granted, a written proposal must be submitted to the Director of Institutional Research and Planning. The proposal will include brief summaries of the rationale for the study, the methodology to be used, and the expected outcomes.

4. Unless the college feels that participation in a particular project is both educationally valuable and a natural part of the course content, class time will not be used for any project. In any event, faculty permission must be obtained before class time will be used.

5. Participation in any project must be voluntary, and all participants should be informed as to the purpose of the project, as well as to what precisely participation will involve.

6. Students, faculty, or staff involved in any research project will not be identified when the findings of that project are published.

All inquiries and proposals must be submitted to:

Dr. Sadya Khan, Director of Institutional Research and Planning
Moraine Valley Community College
9000 West College Parkway
Palos Hills, IL 60465-0937
khans46@morainevalley.edu