ILLINOIS VALLEY COMMUNITY COLLEGE

Institutional Review Board

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Preface

The Institutional Review Board (IRB) of Illinois Valley Community College (IVCC) is responsible for reviewing all non-medical research involving humans as subjects conducted by employees, students, or individuals not affiliated with the college, but wishing to conduct research involving employees, students, or college records. The IRB is composed of eight to ten members, at least six college employees and one external reviewer. IVCC members must include: *the IRB Chair; the Vice President for Academic Affairs; a second administrator, preferably a vice president; and a minimum of one faculty member each from the Social Science and Natural Science areas.* Faculty members will serve three-year terms. Two members of IVCC's Institutional Effectiveness Committee will also serve on the IRB for three-year terms.

This guide is intended for researchers who must submit applications to the IRB for review. It discusses principles and policies related to the use of human subjects in research, as well as IVCC's IRB procedures.

IVCC's IRB is recognized by the US Department of Health and Human Services (IRB00005395).

Fundamental Principles for Use of Human Subjects in Research

Belmont Principles and Federal Regulations

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The report "[i]dentifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects."[1] "Three basic principles relevant to the ethics of research involving human subjects are: respect for persons, beneficence, and justice."[1]

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

Beneficence entails an obligation to protect persons from "harm and to maximize possible benefits and minimize possible harms."[1] The appropriateness of involving vulnerable populations must be demonstrated, and the consent process must thoroughly and completely disclose relevant risks and benefits. Justice requires 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 (HSRRB).

[1] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

College Guidelines on Human Subjects

Illinois Valley Community College (IVCC) 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 IRB prior to the recruitment and any involvement of subjects. Researchers must submit a "Request to Conduct Human Subjects Research" form to the Institutional Effectiveness Office. This form can be found on IVCC's Institutional Effectiveness website: www.ivcc.edu/institutionaleffectiveness. Approval will cover a two-year period. For any projects continuing beyond two years, a "Request for Continuing Approval" form must be submitted to the IRB prior to the renewal date.

All IVCC researchers must follow these guidelines when conducting research involving humans, regardless of how the research is funded. These guidelines apply to surveys, faculty projects, independent study projects, and all other research with human subjects.

The IRB reviews all research involving human subjects when 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, facility, or digital space 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 HSRRB findings is serious and can, in the worst case, result in the college losing the right to conduct any research involving human subjects. Researchers must document their compliance and understanding of these procedures by a signed statement. The HSRRB Chair will provide the information for the completion of this requirement.

Definitions

Research, for the purposes of the IRB and federal regulations, refers to any systematic gathering and analysis of information designed to develop or contribute to generalizable knowledge. Research includes, but is not limited to, the following:

- Any interviews, surveys, focus groups, or observations designed to gather private 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.

The purpose of gathering data is one way to determine whether the project is able to be generalized. 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, able to be generalized.

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 includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.[2]

Interaction includes communication or interpersonal contact between investigator and subject.[2]

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 that the individual can reasonably expect will not be made public.[2]

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

Review Categories

IVCC has three levels of review, based on the potential risk to the human subjects: Category I, Category II, and Category III. The IRB Chair will determine in which category a request to conduct human subjects research falls.

Category I – Exempt

Although, under Federal regulations, certain types of research are exempt from review, IVCC requires all research with human subjects be approved prior to the recruitment and any involvement of subjects, including those projects that fall within the Federal "exempt" category.

Category I projects involve little risk beyond that which a person encounters in daily life. 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 (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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 subjects cannot be identified directly or through identifiers linked to the subjects.

[2] https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf

D. Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if a food is consumed contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research activities determined to be Category I (Exempt) proposals may be approved by a subcommittee consisting of, at a minimum, the IRB chair, one Vice President member, and one other IRB committee member.

The entire IVCC HSRRB will be notified via e-mail of all research projects approved using the Category I review procedure, within one week following approval.

Category II – Subcommittee Review

Category II projects (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories:

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

B. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The activities listed above should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means the activity is eligible for review through the subcommittee review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Research activities determined to be Category II (Subcommittee Review) proposals may be approved by a subcommittee consisting of the IRB Chair, one IRB administration member, one IRB faculty member, and, at least, one additional IRB member.

The Category II review procedure not be used where identification of the subjects and/or their responses would place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The Category II review procedure may not be used for classified research involving human subjects.

The entire IVCC IRB will be notified via e-mail of all research projects approved using the Category II review procedure, within one week following approval.

Category III – Full Committee Review
Research proposals which do not meet the criteria of Category I or II will be reviewed by the full IRB. By definition, proposals requiring a Category III level of review present more risk to subjects than the other levels of review. Proposals of this type will be delivered to IRB members one week prior to a meeting of the committee.

Research involving substantial risk may be required to have external verification of the research process. Such external verification may be conducted by the non-college member of the IRB when interests are not conflicting.

Review of Research
For some proposals, especially those which involve some subject risk, investigators may be asked to report back to the IRB regularly (semiannually or annually) to ensure appropriate measures are being taken to minimize subject risk. These research activities may be shared with IVCC's President and Vice Presidents, as determined by members of the IRB.

Change in Research Activity
If, during the course of the approved research, a change of conditions presents itself, the investigators and any individual doing external verification should report the change of conditions to the IRB promptly. Such changes may result in a full IRB committee review. Based on the review or a failure to report changes, revocation of IRB approval may result.

Persons or agencies sponsoring the research, IVCC's President, and Vice Presidents will be informed of such revocation, which may result in termination of the research activity.

Unanticipated Problems involving Subject Risk
Problems resulting from subject risk, even unanticipated risk, need to be reported to the IRB promptly. Problems will be considered as a change in research activity and may result in a full IRB committee review and subsequent revocation of approval.

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

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.

A signed consent form is not needed for most survey research (see item I below).

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

A. Statement of purpose of the study.
B. Short description of methodology and duration of participant involvement.
C. Statement of risks/benefits to the participants.
D. Statement of data confidentiality.
E. Contact information of all Principal Investigators, and also contact information for
F. IVCC's IRB Chair (815-224-0540).
G. Statement indicating participation is voluntary, refusal to participate will involve no penalty, and the right of the participant to withdraw from the study at any time without negative consequences.
H. An offer to answer any questions the participant may have.
I. Line for signature of participants and/or parents or legal guardian, except for questionnaire research where return of questionnaire gives implied consent.
J. Statement the participant is 18 years of age or older, unless a parent or legal guardian has given consent.

In situations where participants will be deceived, items 1 and 2 are omitted and participants are told (on the signed form) 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 must be signed by the participants "after the fact" in order to guarantee informed consent.

Use of Data: Anonymous versus Confidential

In the consent form, researchers should explain clearly use and handling of the collected data. 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 which do not ask for names or any easily identifiable information may be described as anonymous. Anonymity means 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 where participants are not anonymous, subjects' data should be kept confidential. A coding procedure should be used to 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, "All reasonable steps to protect your identity will be taken." Researchers should not promise they will maintain confidentiality, because any data could be obtained by court order.

Focus Groups

Participants in focus groups must be informed the 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 to explain confidentiality in focus groups is: "Since this is a group process, all members of the group will be privy to the session discussions. Therefore, the researcher cannot ensure group members will hold this information confidential. All reports written based on this research will maintain the confidentiality of individuals in the groups. Only group data will be reported and no participant names will be used."

Potential Problem Areas and Solutions

Online Surveys/Recruiting Subjects

Online 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. Conducting research online 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.

Although online survey research is similar to traditional survey research, online 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 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 IVCC researchers who are using online surveys must:

- Ensure the online survey program does not record IP addresses as part of the data file.
- Include the IRB Chair's email address and telephone number, in the survey:
  Kathy_Hart@ivcc.edu
  815-224-0540
- Include either a statement saying there will be no future emails or an opt-out message to permit addressees to have their names removed from any future emails, or
- Include a statement stating, "If you do not respond to this survey nor return the opt out message, you will be contacted again with this request X times during the next X weeks."

If utilizing an email program to distribute a link to an online survey, the researcher must use a blind copy (Bcc:) format so the list of recipients will not appear in the email header, where it is available for all recipients to view.

Use of Existing or Secondary Data

If researchers plan to use existing data, the IRB must review the research if the data involve humans. If the data involve publicly available documents or records or if the information was recorded so subjects cannot be identified directly or indirectly, the research will be reviewed at the Category I level.

If identifiers were recorded, researchers must describe the procedures they will use to protect the confidentiality of the subjects. If possible, identifiers should be removed by a person who already has access to the data before the researcher gains access to the data.

External Agency Deadlines and IRB Review

Proposals should be submitted to the IRB for review before being sent to an external funding agency. However, the IRB realizes agency deadlines must be met and turn-around time is often very short. Do not miss an agency's deadline while waiting for the IRB to review a proposal.

Guidelines for External Research Projects

The following guidelines apply to all external research projects involving IVCC. An external research project is defined as any research project or study not conducted directly by IVCC itself.

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

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

C. Before permission is granted, a written proposal must be submitted to the IRB Chair. The proposal will include brief summaries of the rationale for the study, the methodology to be used, and the expected outcomes.

D. Unless the college feels 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 members' permission must be obtained before class time will be used.

E. 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.

F. IVCC students or employees involved in any research project will not be identified when the findings of the project are published.

Submit all inquiries and proposals to:

Illinois Valley Community College Director of Institutional Effectiveness
815 N. Orlando Smith Road
Oglesby, IL 61348
Phone: (815) 224-0540
Fax: (815) 224-3033
Email: Kathy_Hart@ivcc.edu