

ILLINOIS VALLEY COMMUNITY COLLEGE
Human Subjects Research Review Board

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Preface

The Human Subjects Research Review Board (HSRRB) is the Institutional Review Board (IRB) of Illinois Valley Community College (IVCC) and has the responsibility for reviewing all non-medical research involving humans as subjects that is conducted by faculty, students or other employees of IVCC. The HSRRB is composed of eight to ten members, at least seven college staff and one external reviewer. The college members must include: *the Director of Institutional Research; a member of Academic Administration; 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. The external reviewer is Pam Wolf, LCPC. This guide was prepared to help researchers submit applications to the HSRRB for their review. It discusses principles and policies related to the use of human subjects in research.

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 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 Human Subjects Research Review Board (HSRRB).

College Guidelines on Human Subjects

Illinois 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 HSRRB prior to the recruitment and any involvement of subjects. Such approval will cover a two-year period. For any projects continuing beyond two years, a "Request for Continuing Approval" form must be made to the IVCC HSRRB prior to the renewal date.

The HSRRB, along with being recognized by US Health and Human Services (IRB00006487), has received Federal Wide Assurance (FWA00013787).

All IVCC researchers must follow the guidelines outlined in this guide when they are conducting research that involves humans, 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 HSRRB 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 HSRRB 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. Information will be provided by the HSRRB Chair for completion of this requirement.

Definitions

Research, for the purposes of the HSRRB and federal regulations, refers to any systematic gathering and analysis of information designed to develop or contribute to knowledge able to be generalized. Although the following list is not exhaustive, research includes:

- Any 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.

The purpose of gathering the 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.

Interaction includes communication or interpersonal contact between investigator and subject.

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 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.

Review Categories

Illinois Valley Community College has three levels of review, Category I, Category II, and Category III, based on the potential risk to the human subjects. The Director of Institutional Research will determine in which category a proposal falls.

Category I – Research Department Review (Exempt)

Under federal regulations certain types of research are exempt from review unless the institution chooses to review it. According to Illinois Valley Community College 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 IVCC 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 (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 that subjects cannot be identified directly or through identifiers linked to the subjects.

(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 that 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 least: one member from the Office of Institutional Research; one member currently serving as one of the following for the college: one Vice President or Associate Vice President; and one other committee member.

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

Category II – Subcommittee Review

If proposals meet certain criteria that are defined in the federal guidelines, the HSRRB subcommittee may review the proposals as a Category II. The HSRRB subcommittee will be headed by the Director of Institutional Research, and will consist of at least two additional members of the committee.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the HSRRB through the subcommittee review procedure authorized by 45 CFR 46.110 and 21 CFR. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that 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.

The categories in this list apply regardless of the age of subjects, except as noted.

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

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

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

Potential Category II Research

(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.

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 HSRRB. By definition, proposals that require a Category III level of review present more risk to subjects than do the other two levels of review. Proposals of this type will be delivered to members one week prior to the meeting. Contact the Director of Institutional Research for meeting times and minutes of past meetings.

Research that involves substantial risk may be required to have external verification of the research process. Such external verification may be conducted by a member of the HSRRB 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 HSRRB regularly (semiannually or annually) to ensure appropriate measures are being taken to minimize subject risk. These research activities may be shared with one or more of IVCC's President and Vice Presidents as determined by members of the HSRRB.

Change in Research Activity

If during the course of the approved research a change of conditions presents itself, it should be reported to the HSRRB promptly. It should be reported by the investigators and any individual doing external verification. Such changes may result in a full committee review by the HSRRB. Based on that review or failure to report changes, revocation of HSRRB approval may result.

Persons or agencies sponsoring the research, IVCC's President and/or 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 HSRRB promptly. Problems will be considered as a change in research activity and dealt with by the HSRRB accordingly.

Obtaining 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 in sequential order 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

Illinois Valley Community College's HSRRB (Director of Institutional Research, 815-224-0550).

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.

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.

Potential Problem Areas and Solutions

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 IVCC researchers who are using Internet surveys must:

- Include the HSRRB chair's e-mail address Robert_Mattson@IVCC.edu in addition to the HSRRB telephone number (815) 224-0550.
- 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 X 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 HSRRB 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 HSRRB 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.

External Agency Deadlines and HSRRB Review

It is recommended that applications to the HSRRB be submitted for review before a proposal is sent to an external funding agency; however, the HSRRB realizes that agency deadlines must be met and the turn-around time is often very short. There is no need to miss an agency's deadline because you are waiting for the HSRRB to review your project. Researchers should submit their applications to the HSRRB as soon as possible after the agency deadline so that they can be reviewed as quickly as possible.

Guidelines for External Research Projects

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

1. 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.
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. 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, the faculty member's 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 should be submitted to:

Illinois Valley Community College
Director of Institutional Research
815 N. Orlando Smith Road

Oglesby, IL 61348
Phone: (815) 224-0550
Fax: (815) 224-3033
Email: Matt_Suerth@IVCC.edu

Website References

US Department of Health and Human Services
Office for Human Research Protections

<https://www.hhs.gov/ohrp/regulations-and-policy>