KANKAKEE COMMUNITY COLLEGE
INSTITUTIONAL REVIEW BOARD MANUAL

CONTENTS

Introduction

The Institutional Review Board (IRB) at Kankakee Community College has the responsibility of ensuring that data derived from, or to be derived from, human subjects affiliated with Kankakee Community College is collected and used in a matter that complies with the requirements of the Code of Federal Regulations (45 CFR 46) and the US Food and Drug Administration 21CFR, Parts 50 and 56. The IRB will consist of the following members:

- Director of Institutional Effectiveness & Assessment
- A representative from Corporate and Continuing Education
- Three KCC faculty members
- An external reviewer from another institution of higher education

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.
All Human Subjects Research proposals not exempted from IRB review will be subject to review by this group. The IRB may:

1) approve a research proposal as submitted,
2) approve the proposal with specific modifications,
3) return the proposal to the investigator for more extensive modification, or
4) reject the proposal due to violations of Human Subject privacy or other protections.

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: respect for persons, beneficence, and justice.

1. 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.
2. 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.
3. 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

1. Research: a formal and systematic process of gathering and analyzing information applying the scientific method to a study or problem, designed to contribute to generalizable knowledge. Research includes, but is not limited to:
   a. Interviews, surveys, focus groups, or observations that are designed to gather nonpublic information about individuals or groups,
   b. Studies of existing data, either public or private, where the identity of individuals are known,
   c. Studies designed to change subjects' physical or psychological states or environments.

2. 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.

3. Minimal Risk: minimal risk is when the probability and magnitude of physical or psychological harm anticipated by the research are not greater than those normally encountered in the subjects' daily lives. Minimal risk is affected by the context of the research, including characteristics of the subjects.

Procedure

Individuals intending to conduct research involving human subjects must complete a Research Proposal Form and submit it to the Kankakee Community College IRB. This form contains a description of the intended projects, a description of the procedures to be used, and informed consent/assent forms for all participants. The IRB reviews and categorizes each proposal into one of three types:

1. Exempt (no review)
2. Expedited review, or
3. Full review

The IRB will respond directly to those proposals fitting the definition of exempt. Within three weeks of receiving the proposal, the IRB will respond to proposals requiring expedited or full review via written approval or disapproval sent to the researcher.

Review Categories

Category 1: Exempt: Research involving commonly accepted educational practices (e.g., testing, classroom observation) is exempt from IRB review. Included in this category are: typical exams given in class, student research assignments not involving human subjects; papers and projects; surveys; data reports conducted by Kankakee Community College departments as a part of routine operations; and historical, archival, or ethnographic studies.

Category 2: Expedited Review: Research that presents no more than a minimal risk to participants is subject to an expedited review. This category includes the collection of voice or video images and research on individual or group characteristics of behavior (e.g., cognition, language, cultural beliefs and practices, simple physical tasks, and so on).

Category 3: Full Review: This is necessary when the proposed research involves children, seriously ill or mentally or cognitively impaired adults, complex physical tasks, or the collection or recording of behaviors which could be damaging or stigmatizing to participants' reputation, financial standing, employability, insurability, or physicality.

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 likely be reviewed at the Category I level.

All individuals or agencies wanting access to existing Kankakee Community College data containing personally identifiable information (e.g., student records) must complete a Data Sharing Agreement. This agreement specifies how data are to be gathered, used, and secured. A copy of this agreement is located on page 10 of this manual.

Guidelines for External Research Projects

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

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 Effectiveness & Assessment. 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:
Lesley Cooper
Director of Institutional Effectiveness & Assessment
Kankakee Community College
100 College Drive
Kankakee, IL 60901-6505
Phone: (815) 802-8370
Fax: (815) 802-8101
lcooper@kcc.edu

Use of Internet for Surveys/Recruiting Subjects

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. At Kankakee Community College, researchers who are using Internet surveys must:

- Include the IRB Chair's email address in addition to the IRB telephone number.
- Include either a statement saying there will be no future mailings or an opt-out message that permits addresses 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. If you fail to respond, you will be dropped from the study."
- Use a blind copy format so that the list of recipients will not appear in the header.

Informed Consent

Researchers must obtain the signed **informed consent** of participants. For those less than 18 years of age, the researcher must obtain the 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: 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 consequence.
6. Statement regarding the participant's permission for the use of voice and/or image recordings.
7. An offer to answer any questions the participant may have.
8. Contact information of all Principal Investigators, and also contact information for Kankakee Community College's Director of Institutional Effectiveness & Assessment, Lesley Cooper.
9. Line for signature of participants and/or parents or legal guardian **except for questionnaire research in which return of questionnaire gives implied consent.**
10. 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 intentionally **deceived** as part of the research design, 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.

Anonymous/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. In studies that are not anonymous, subjects' data should be confidential. When data are not anonymous, consent forms should include a statement such as, "We will take all reasonable steps to protect your identity."

Policy Compliance

The Kankakee Community College Institutional Review Board (IRB) is responsible for the review of all research involving human subjects conducted by people affiliated with Kankakee Community College. In regard to research activities affiliated with Kankakee Community College, the IRB has the authority to approve, require modifications in, disapprove, suspend, or terminate research activities involving human subjects that do not comply with the Kankakee Community College IRB policy. The IRB also has the authority to observe or monitor ongoing research, as necessary, to protect human subjects. It is the responsibility of the principal investigator and/or faculty sponsor to adhere to the IRB policies, to respond promptly to the IRB requests, and to notify the IRB of any changes to the research protocol. Violations of the IRB policy may include, but are not limited to the following:

1. Breaches of IRB policies and procedures by a principal investigator or other investigators;
2. Adverse events that are not immediately reported by the principal investigator or other investigators after causing physical, psychological, social, or other harm to participants;
3. Changes in the risks and benefits of a study encountered during the course of the research; and/or
4. Other circumstances which require action in order to protect human subjects from harm.

Violations of the Kankakee Community College IRB policies may result in any of the following sanctions:

1. The data may be rendered as unusable;
2. The IRB may request the surrender of documents;
3. A citation of violation of academic integrity may be entered in the individual's professional file;
4. The collected data may be destroyed;
5. The principal investigator and/or other investigators may be required to provide a letter of apology to research participants and representatives of external organizations including a plan of correction to address deficiencies in human participants protections;
6. The principal investigator and/or other investigators may be required to provide a memorandum addressed to the IRB explaining the actions of the investigator(s), acknowledging a violation of IRB policies and procedures, and providing assurances that future violations will not occur;
7. The principal investigator may be required to submit an acknowledgement in published work or work submitted for publication that the research did not conform to IRB policies and procedures;
8. The IRB may direct a formal memorandum of censure to the principal investigator, and, where appropriate, the principal investigator's faculty sponsor, department head, or dean (or any other recipient of the data); and/or
9. Other actions warranted by the specific circumstances surrounding the violation.

The Kankakee Community College IRB will make a determination regarding the need for additional information or further investigation. Any appropriate agencies may also be notified of terminations and/or suspensions of the research.

APPENDICES

Appendix 1

_____/_____/_____

_____

Date Submitted

KANKAKEE COMMUNITY COLLEGE INSTITUTIONAL REVIEW BOARD

RESEARCH PROPOSAL FORM

Please fill out the following information and return this form along with:

- **Summary Abstract**
- **Protocol**
- **Consent/assent forms**

I. Basic Information

Title of Research Project

Principal Investigator/Project Director **Department** **Phone Extension**
email Address

Co-investigator **Department** **Phone Extension**
email Address

Projected Start Date:_____/_____/ **Projected Duration of_____**
Research:

Other organizations and/or agencies, if any, involved in the study:_____

Project Classification: **____ New Project** **____ Periodic Review of**
Continuing Project

Signature of IRB Director:			Date:
IRB Director: (Check 1 Box)	Approved	Approved w/ Conditions	Not Approved
LEVEL: (Check 1 Box)	1. Exempt; IRB Chair Only	2. Expedited Review	3. Full Committee Review

II. Summary Abstract

Please attach a description that addresses the following questions:

A. **Objectives/goals of the research** (What are the goals of the research to be conducted? What are the research questions?)

B. **All subjects/participants in the research** (Who will be the participants in the research? How many participants do you anticipate?)

C. **Solicitation of subjects' participation** (How will participants be contacted? Any incentives given for participation?)

D. **Location of the research** (What are the different locations that the research will be conducted? Has permission been obtained for research to be conducted outside of Kankakee Community College?)

E. **Description of all methods to be used for data collection** (What are the various procedures that will be used in collecting the data?)

F. **Benefits/risks** (Describe the potential benefits and risks associated with your study)

G. **Disposition/confidentiality of data** (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)

H. **Dissemination of results** (Describe how the results of the research will be disseminated. With whom will the results be shared?) Please note: a copy of the final report/results will be due to the IRB upon completion of the study.

III. Protocol

Please attach a copy of all the protocol to be used in the study. This includes any questionnaires, surveys, recruitment letters, flyers, interview questions, focus group questions, etc.

IV. Consent Forms

Please attach a copy of all consent/assent forms to be signed by the participants and/or any statement to be read to the participants regarding their participation in the study. A sample consent form is included on the following page.

Appendix 2

KANKAKEE COMMUNITY COLLEGE INSTITUTIONAL REVIEW BOARD

SAMPLE INFORMED CONSENT

To Be Used For Non-Exempt Research **(It is not necessary to use this form for survey research in which return of questionnaire gives implied consent**.)

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving ***informed consent***. (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____. In this study, you (your child/ ward) will be asked to _____. Your participation should take about _____ minutes.

There are no risks to you (your child/ward). **OR**
The only risks to you (your child/ward) include _____.
Benefits of this study include _____.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported. Any voice or image recording of you that is used during this study will be kept confidential and destroyed after use.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____.

Please feel free to contact _____ (names(s), title(s) of principal investigators) at _____ phone) if you have any questions about the study. Or, for other questions, contact the Director of the Institutional Effectiveness & Assessment, Lesley Cooper, at 815-802-8370.

If the participant is of age (18 years old or older), use:
I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____ _____
Signature of Participant Date

If the participant is not of age, use:
I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

_____ _____
Signature of Parent/Guardian Date

ASSENT format:
I understand what I must do in this study and I want to take part in the study.

_____ _____
Signature of Child/Ward Date

Appendix 3

SAMPLE DATA SHARING AGREEMENT

Between

Kankakee Community College and X College

This Data Sharing Agreement is intended to cover circumstances in which the above named Colleges need access to data that contains personally identifiable information (social security numbers, names, etc.) belonging to current and former students. These circumstances include the following purposes intended to improve educational opportunities for the residents of these districts:

1. **Increase collaboration between secondary and post-secondary systems;**
2. **Reduce the need for College remediation;**
3. **Promote greater awareness of post-secondary educational options including financial aid and academic resources;**
4. **Create seamless transition systems from secondary education to postsecondary education;**
5. **Ensure that individuals who are members of special populations have the opportunity to access and succeed;**
6. **Develop career pathways that contain multiple entry and exit points to facilitate student success and lifelong learning;**
7. **Increase curricular alignment and reduce curricular duplication;**
8. **Support the development of integrated and applied curricular content;**
9. **Increase the opportunities for students to earn college credit while enrolled in high school;**
10. **Increase the opportunities for students to obtain marketable postsecondary certificates or degrees that support their career goals;**
11. **Create professional development programs designed to simultaneously engage and support secondary and postsecondary partners;**
12. **Utilize data for program improvement.**

1.0 Period of Agreement

The period of this Agreement shall be in effect from September 2015 until terminated in writing by a partner organization.

2.0 Constraints on Use of Data

Data supplied by the parties to this Agreement or collected by on behalf of the parties' students, prospective students, employees or alumni is the property of the parties to this Agreement and shall not be shared with third parties without the written permission of the parties to this Agreement. Data shall not be sold or used, internally or externally, for any purpose not directly related to the scope of work defined in this Agreement without the written permission of the parties to this Agreement.

3.0 Data Security

The parties to this Agreement shall employ industry best practices, both technically and procedurally, to protect the data from unauthorized physical and electronic access. Methods employed are subject to annual review and approval by the parties to this Agreement.

3.1.1 Data Elements

Data shared shall be limited to the data elements specifically defined and authorized by the parties to this Agreement. If one or more of the parties wishes to collect additional data, they must submit a request in writing to the other parties. Under no circumstances shall any of the parties collect any information classified as Sensitive or Confidential without the express written approval of the parties to this Agreement.

3.2 Data Categories

The following definitions shall be used to classify data for security purposes:

Normal: The least restrictive class of data. Although it must be protected from unauthorized disclosure and/or modification, it is often public information or generally releasable under procedures of for processing public records requests. Examples of this class of data are: class schedules, course catalogs, general ledger data, and employee demographic statistics.

Sensitive: This class includes data for which specific protections are required by law or for which agencies are obligated to prevent identity theft or similar crimes or abuses. Examples of this class of data are: peoples' names in combination with any of the following: driver's license numbers, birth date, student ID number (SID), address, e-mail addresses, telephone numbers. Also included are: agency source code or object code, agency security data, education records including papers, grades, and test results, or information identifiable to an individual that relates to any of these types of information.

Confidential: Access to these elements are tightly controlled and audited. Examples of these data are: Social Security Numbers (SSN), financial profiles, medical data, and disciplinary records.

3.3 Data Handling Requirements

Data handling requirements may vary depending on the classification of data shared with each of the parties. However, it is anticipated that most data shared with the parties to this Agreement will involve a mix of data classes including Sensitive and possibly Confidential information. Therefore, whenever data elements are aggregated for collection, transmission, or storage, the aggregate data shall be handled using the protocols that apply to the most sensitive data element.

4.0 Personnel

4.1 Access to Data

The parties to this Agreement shall limit access to Sensitive and Confidential data to those staff members with a well-defined business need.

4.2 Security Training

The parties to this Agreement shall provide periodic training for staff on internal security policies and procedures, and on applicable state and federal legal requirements for protecting Sensitive and Confidential data.

4.3 Criminal Background Checks

The parties to this Agreement shall certify that all staff members with access to confidential information have been subjected to a bone fide criminal background check and have no record of any felony convictions. Any exceptions to this requirement must be approved in writing by the parties to this Agreement.

4.4 Prohibition on Mobile Devices and Removable Media

The parties to this Agreement shall have a written policy prohibiting the transfer or storage of unencrypted customer information on employee mobile devices or removable storage media for any reason. This policy shall be made available to each employee individually and shall be strictly enforced.

5.0 Compliance with Applicable Laws and Regulations

The parties to this Agreement shall comply with all applicable federal laws and regulations protecting the privacy of citizens including the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA). Where applicable, the parties to this agreement shall also comply with all provisions of the Financial Services Modernization Act (the "Gramm-Leach-Bliley Act").

6.0 Indemnification

The parties to this Agreement shall defend, indemnify, release, and hold said parties harmless from and against all Claims, Losses, and Expenses when arising out of or incidental to this Agreement regardless of the negligence or fault of the person.

7.0 Amendments and Alterations to this Agreement

The parties to this Agreement may amend this Agreement by mutual consent, in writing, at any time.

Appendix 4

Date Submitted: _____ **File Number:** _____

Kankakee Community College IRB CONTINUING REVIEW FORM

Principal Investigator:		**Project Title:**	

Federal Regulations mandate that all human subject protocols receive continuing review and approval **not less than once per year.** In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a "substantive and meaningful" review. Therefore, in order for the KCC IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/documents are required: ***a completed continuing review form and copies of all informed consent documents, surveys and/or questionnaires currently being used*.**

If a question does not apply to your protocol, so indicate (e.g., "Not Applicable" or "N/A").

I. Briefly summarize the study objectives and procedures: (attach additional pages if required)

II. Dates covered by this progress report: ☐ Previous 12 months; List here: _____

☐ Other period as described:

III. Project Summary

A. **Leadership:** have there been any changes in leadership, responsibility, or major personnel?

☐ Yes ☐ No

If Yes, then fully describe:

B. **Objectives:** have there been any changes ☐ Yes ☐ No

If Yes, then fully describe:

C. **Procedures:** have there been any changes? ☐ Yes ☐ No

If Yes, then fully describe:

D. **Informed consent documents:** have there been any changes?

☐ Yes

☐ No

If Yes, then fully describe:

E. **Research subjects:**

1. **List each group, cohort, etc., if applicable, including control groups, on separate lines. If only one group, description would be "All."**

	NUMBER OF SUBJECTS (at all sites for which you are the PI)		**AGE RANGE OF SUBJECT** (at all sites for which you are the PI)		**GENDER** (of subjects to date)	
Group	This Period	Next Period (anticipated)	This Period	Next Period (anticipated)	% Male	% Female

2. Was the subject population representative of the population base from which subjects could be selected with respect to:

   a. Gender representation? ☐ Yes ☐ No

   If No, explain:

   b. Minority representation? ☐ Yes ☐ No

   If No, explain:

3. **Have any subjects withdrawn from study since the study began?**

☐ Yes ☐ No

If Yes, explain:

4. **Are you aware of any breach in confidentiality? (e.g., unauthorized access to records)**

☐ Yes ☐ No

If Yes, describe:

F. **Unexpected problems**:

1. Have there been any **unexpected** problems?

☐ **Yes** ☐ **No** ☐ **N/A**

If Yes, please summarize these unexpected problems, the number of occurrences, and indicate if they required consent document changes, particularly in the "risks" section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits. If available, attach copies of data safety monitoring reports.

G. **Proposed Revisions/Amendments/Modifications:**

1. Are there revisions/amendments to the protocol, consent form(s), questionnaires, etc. that are included with this renewal?

☐ Yes ☐ No

If Yes, provide a brief description below and highlight the changes on the document(s) to be reviewed.

2. Will the revisions/amendments change the scope or research objectives of the protocol? Following are examples of actions considered to change the scope or research objectives: A change in the specific aims approved at the time of award (funding); a change from the previously approved use of human subjects; shifting the emphasis of the research from one disease to another.

☐ Yes ☐ No ☐ N/A

If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

3. Will the revisions/amendments change risks to subjects?
   ☐ Yes ☐ No ☐ N/A

   If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

H. **Publications, Presentations, Reports:** Provide a listing of all publications, presentations and reports that have resulted from this work since the last review. If none, please state this.

As **Principal Investigator**, I acknowledge that I am responsible for reporting any emergent problems; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's understanding and recommendations; that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

_____ _____

Signature of Principal Investigator **Date**

_____ _____

Signature of Co-Investigator **Date**

Signature of IRB Committee Chair:			**Date: / /**
IRB Chair: Check 1 box	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**