

# KANKAKEE COMMUNITY COLLEGE

## Institutional Review Board

### Human Subjects Research Submission Guide<sup>1</sup>

**Introduction:** Effective date, April 3, 2007, Kankakee Community College initiated an Institutional Review Board (IRB). Members of the IRB Committee are required to follow the procedures described in this manual. These procedures reflect federal regulations listed in Title 45: Public Welfare Department of Health and Human Services Part 46, Protection of Human Subjects. DHH's Protection of Human Subjects regulations were adopted by 16 Federal Agencies in 1991, including, DOE, DOJ, NSF, NASA, DOD, DOT, USAID, DOEd, HUD, and EPA.

Office of Institutional Effectiveness  
Director, Dr. Vicki Magee  
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2007

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<sup>1</sup> Thanks to Moraine Valley Community College for permission to use and/or modify their IRB guidelines.

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## **Preface**

The Institutional Review Board (IRB) of Kankakee Community College (KCC) has the responsibility for reviewing all research involving humans as subjects that is conducted by faculty, students or other employees of KCC. The IRB is composed of five members, four college staff and one external reviewer. For a current list of IRB members contact the Director of Institutional Effectiveness. KCC prepared this guide to help researchers submit applications to the IRB for review, and includes 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 (IRB).

### **College Policy on Human Subjects**

Kankakee 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 IRB prior to the recruitment and any involvement of subjects.

All KCC researchers must follow the policies 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 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.

## **Definitions**

### **Research**

For the purposes of the IRB and federal regulations, the term **research** refers to any systematic gathering and analysis of information designed to develop or contribute to *generalizable* knowledge. 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 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.

### **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 that 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.

### **Review Categories**

Kankakee Community College has three levels of review, Category I, Category II, and Category III, based on the potential risk to the human subjects. The IRB Chair, the Director of Institutional Effectiveness, or the Vice Chair in the absence of the Director of Institutional Effectiveness, will determine in which category a proposal falls.

### **Category I – Exempt Research – Requiring only IRB Chair Review**

Under federal regulations certain types of research are exempt from review unless the institution chooses to review it. According to Kankakee 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 Kankakee research projects fall into this category. The IRB Chair has the discretion to determine that a research project is exempt (Category 1) if the research activities include involvement of human subjects in one or more of the following areas.

(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.

### **Category II – Subcommittee Review of Research that may not require Full Review**

If proposals meet certain criteria that are defined in the federal guidelines, the research may not require a full IRB review. In these cases, an IRB subcommittee may review the proposals as a Category II. In this case, an IRB subcommittee will be convened consisting of a subset of the IRB Committee to include at least the Vice President of Instruction and Student Services, and one or two other of the members of the Board as appropriate.

Category II reviews include: (A) 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 IRB through the subcommittee review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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.

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

(C) 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.

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

### Potential Category II Research

- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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 IRB. By definition, proposals that require a Category III level of review present more risk to subjects than do the other two levels of review.

### **Note to Investigators:**

- **Continuing Review:** IRB approval is granted for one year. Researchers who receive IRB approval must reapply each year.
- **Reporting Incidents:** If any problems arise during the research, the investigator must inform the Vice President of Instruction and Student Services immediately or within 24 hours of the incident.
- **Reporting Change in Protocols:** Any change in research protocols must be reported to the Vice President of Instruction and Student Services for review. No research practice may take place until all protocol changes have been approved.
- **Developing Forms for Non-English Speaking Participants:** Please contact the IRB Chair if you are using forms in Spanish or another language.
- **For more information refer to KCC's IRB Procedures Manual**

### **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. In nearly all cases, Category I, II, and III proposals require informed consent.

### **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 Kankakee Community College's Institutional Review Board (Vice President of Instruction and Student Services, (815) 802-8350.
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 KCC researchers who are using Internet surveys must:

- Include the IRB Chair's e-mail address [vmagee@kcc.edu](mailto:vmagee@kcc.edu) in addition to the IRB telephone number (815) 802-8258.
- 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 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.

### **External Agency Deadlines and IRB Review**

It is recommended that applications to the IRB be submitted for review before a proposal is sent to an external funding agency; however, the IRB 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 IRB to review your project. Researchers should submit their applications to the IRB 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 Kankakee Community College (KCC). An external research project is defined as any research project or study not conducted directly by KCC 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 Vice President of Instruction and Student Services. 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: Dr. Vicki Magee, Director of Institutional Effectiveness and Planning  
Kankakee Community College  
100 College Drive  
Kankakee, IL 60901-6505  
Tel: (815) 802-8258  
Email: vmagee@kcc.edu  
Last update: 2007

## **Appendices**

Appendix A: IRB Application Form (Use for all except Continuing Review Form.)

Appendix B: Elements of Informed Consent/Assent

Appendix C: Sample Informed Consent Form (age 18+)

Appendix D: Informed Consent Checklist

Appendix E: Continuing Review Form

**Kankakee Community College IRB  
IRB APPLICATION: REQUEST TO CONDUCT HUMAN SUBJECTS RESEARCH**

Title of Research Project: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Department: \_\_\_\_\_

Phone: \_\_\_\_\_ email Address: \_\_\_\_\_

Co-investigator(s) Name, Department, Phone, email Address: \_\_\_\_\_

Funding Source – (circle one :)      Anticipated      Verified      None

Projected Duration of Research: \_\_\_\_\_ Projected Starting Date: \_\_\_\_\_

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

Using the following as an outline, please provide the following narrative:

1. **Abstract/Rationale/Background**
  - a. provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.
2. **Objectives** (include all primary and secondary objectives)
3. **Study Procedures**
  - a. Location of the research/project
  - b. Study duration and number of study visits required of research participants
  - c. Data Collection procedures (detailed), including timeline.
  - d. Clarify if the study is confidential or anonymous, type of data to be collected, and who will have access to the data
  - e. Attach copy of measures (questionnaires) and other materials that will be used in the study or to publicize the study
  - f. Attach Informed Consent (Assent) Form
  - g. Detailed study design, including timeline
4. **Inclusion/Exclusion Criteria, if any**
5. **Risks**
  - a. Any type of risks and expected frequency.
  - b. Steps taken to minimize the risks.
  - c. Plan for reporting unanticipated problems or study deviations.
  - d. Legal risks such as the risks that would be associated with breach of confidentiality.
  - e. Financial risks to the participants.
6. **Benefits**
  - a. Description of the probable benefits for the participant and for society.

**7. Payment and Remuneration**

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

**8. Costs**

a. Detail costs of study procedure to participants and identify who will pay for them.

**9. Attachments:** Please attach all consent forms, surveys, and any other publicity handouts or other materials that you will be using to conduct this research. If you have an IRB form completed from your home university, approved or pending, please submit that as well.

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

**Signature:**

**Investigator/Project Director** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Co-Investigator(s):** \_\_\_\_\_ **Date:** \_\_\_\_\_

Signature of HSRRB Committee Chair:			Date:	
HSRRB Chair: (Check 1 Box)	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved w/ Conditions		<input type="checkbox"/> Not Approved
LEVEL: (Check 1 Box)	<input type="checkbox"/> 1, Exempt; Research Office Only	<input type="checkbox"/> 2, Subcommittee Review	<input type="checkbox"/> 3, Full Committee Review	<input type="checkbox"/> 4, Continuation Review

## Appendix B

### **Kankakee Community College IRB 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.

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 KCC's Institutional Review Board Chair, Director of Institutional Effectiveness.
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 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.



Appendix D

**Kankakee Community College IRB  
INFORMED CONSENT CHECKLIST**

	YES	NO	
			1. Is the consent form written in “lay language”?
			2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
			3. If minors are included in the study, is provision made for obtaining parental consent?
			4. Does the consent form include each of the following basic elements of informed consent?
			a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation.
			b. A description of the procedures to be followed.
			c. A description of any benefits to the subject or others.
			d. A description of any reasonably foreseeable risks or discomforts.
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
			g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.
			h. Appropriate FERPA notice and waivers (if appropriate).

If there was a “NO” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why is it appropriate as submitted.

**Kankakee Community College IRB  
CONTINUING REVIEW FORM**

<b>Principal Investigator</b> :		<b>Project Title:</b>	
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**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."

Group	NUMBER OF SUBJECTS (at all sites for which you are the PI)		AGE RANGE OF SUBJECTS (at all sites for which you are the PI)		GENDER (of subjects to date)	
	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.

2. 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, so state.

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