Date 4/22/13 Reset Form Print Form

Holyoke Community College
Application for Research Involving Human Subjects

NOTE: Please use attachments where necessary

Principal Investigator				
	Last Name	*First Name*	*Middle Initial*	*Degree*

Principal Investigator (PI) Status	◯ HCC Faculty/Staff	◯ HCC Student	◯ Other (specify):
Principal Investigator Title			
Faculty Advisor (for HCC students ONLY)	*Last Name*	*First Name*	
Division/Department			
Principal Investigator's Address	*Street*	*City*	*State* / *Zip Code*

PI's Primary E-mail		PI's Phone No.		PI's Alt. Phone No.	

Co-Investigator(s) and Affiliation	
Project Title	
Proposed Project Dates	From: To:

Research Site(s)

☐ Holyoke Community College

If any of the investigation is to be conducted at other institutions or locations off campus, please enter for each facility the:

Institution's Name	Institution's Address

Describe procedures for obtaining permission to conduct research activities if applicable (e.g., for schools: a letter of approval from the principal).

Funding Source (include pending)	
Grant/Protocol No./Pending **NOTE: Please provide copy of the grant application**	

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1. Describe the purpose of the research, the procedures, the participants, and type of data analysis.

A. Objectives and Hypotheses:

The specific aims and hypotheses of the investigation should be described, including a definition of the area of the problem, the contribution the research is expected to make, and the relevance of the hypothesis to be tested. If specific hypotheses are not being tested, then the questions to be answered or the information hoped to be gained should be described.

B. Procedures:

A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with subjects and the means of observation to be used. Frequency, duration, and location of interviews, surveys, or observations should be indicated.

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C. Participants:

Describe the characteristics of the subjects, such as age range, gender , and ethnic background. List inclusion and exclusion criteria. Describe any special feature(s) of the study population. Explain the rationale for the involvement of subjects who are likely to be vulnerable to coercion or undue influence, such as children or minors, elderly persons, prisoners, pregnant women, persons with impaired decision-making ability, economically or educationally disadvantaged persons, or persons who are not fluent in English.

D. Data Analysis:

Explain how you are going to answer your study question using the data that you will collect (e.g., statistical tests). The information in this section must be consistent with the information provided in *Section A* (study question or hypothesis).

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2. State the minimum number of subjects, existing records, or specimens required.

3. Estimate the total number of subjects, existing records, or specimens required.

4. Are you studying or collecting data from anyone under the age of 18? ☐ Yes ☐ No

If minors (individuals under the age of 18) are participants, how will the assent process be conducted?

NOTE: Attach a copy of the assent form.

5. Describe:

a) the expected duration of the total study (i.e. recruitment, data collection, data analysis, etc.)
b) the duration of each subject's participation (e.g., completing a survey will take ten minutes)

A. Expected duration of the total study:

B. Duration of each subject's participation:

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6. Specify the potential risks and benefits to research participants.

A. Risks to subject and steps taken to minimize risks:

Describe any potential risks to the subjects (physical, psychological, social, legal, economic, or other) and assess their likelihood and seriousness. Describe the procedure for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. If applicable a data safety monitoring plan should be included. If appropriate, describe the steps you will take if a research participant becomes upset or distressed as a result of the study. Discuss community agencies or counseling services that participants can access if assistance is needed.

B. Benefits to subjects and/or society:

This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the potential benefits to individuals and/or society.

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7. How will the identity of subjects and/or their responses be recorded?

☐ Anonymous (direct identifiers, such as names of subjects, or indirect identifiers, such as codes, are never recorded with the research data and therefore cannot be linked to the subjects). Describe how the information will be recorded anonymously.

OR

☐ **Confidential** (coding or security measures are in place to protect the privacy of individual subjects). Describe the steps you will take to maintain confidentiality, including the identity of the subjects, their responses, and any data that you obtain from private records and/or capture on audiotape or videotape. If audio or video taping subjects, describe the disposition of the data and/or the tapes once the study has been completed.

8. Data Security

All information must be stored using at least two of the following safeguards.

NOTE: If you are using both electronic data and hardcopy data, you will need two safeguards for each type.

Electronic Data: (mark at least two that apply or select "not applicable")

- ☐ secure network (e.g. firewall)
- ☐ password access
- ☐ data recorded anonymously
- ☐ coded, with master list kept as a hardcopy or on a secure network (confidential)
- ☐ not applicable
- ☐ other (please specify):

Hardcopy Data: (mark at least two that apply or select "not applicable")

- ☐ locked office
- ☐ locked file cabinet
- ☐ data recorded anonymously
- ☐ data coded by PI or research team with a master list secured and kept separately (confidential)
- ☐ not applicable
- ☐ other (please specify):

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9. Recruitment Methods

A. Describe how you will have access to the study population (e.g., school principal recruiting students, instructor of a class, recruiting from general population).

B. Describe plans for how potential subjects will be recruited. Submit copies of any recruitment materials that will be used (e.g., posters, email or telephone scripts, letters, newspaper advertisements).

C. If payment to subjects is to be made or other incentives are offered, describe and justify. If compensation is in the form of academic credit, the amount and type of credit should be clearly stated as well as any conditions that must be fulfilled in order for the credit to be awarded. The nature and amount of compensation must not constitute undue inducement of the subject.

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10. Discuss how subjects will be informed about this study (e.g., through an information sheet and/or a consent form).

Inform Consent:

Explain how informed consent will be obtained. Please provide a copy of the cover letter, the information sheet, and/or the consent form with this application.

Submit this application with the following materials, if applicable:

- ☐ Formal research protocol (e.g., grant application)
- ☐ Questionnaires
- ☐ Interview questions
- ☐ Cover letter or information sheet for subjects
- ☐ Data collection sheets (e.g., a list or spreadsheet of the questions or data elements to be collected or studied)
- ☐ Letters of cooperation from other sites
- ☐ Recruitment materials (e.g., flyers, advertisements)
- ☐ Documentation that all investigators have completed online training for human subjects protection
- ☐ Documentation of external IRB approval from other sites where research is conducted

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CERTIFICATION

As the Principal Investigator for this study, I certify the following:

- ☐ I am aware of the resources available for review of: 1) the relevant HCC policies and procedures for the protection of human subjects; and 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46
- ☐ I will obtain records of informed consent for each subject or each subject's legally authorized representative. The informed consent form will include the elements listed in the HCC IRB Guidelines. I will ensure that research subjects are properly informed about the details of the research study, are provided the opportunity to have all questions answered, and have had all the elements of the informed consent document explained to them.
- ☐ I will ensure that members of the research team designated to conduct the informed consent process are knowledgeable about the study. I will submit requests to the IRB to alter the elements of informed consent or to waive the requirement for an informed consent document.
- ☐ I will provide a copy of the IRB-approved informed consent document to each subject or to the subject's legally authorized representative at the time of consent.
- ☐ I will retain all signed consent documents and research evidence for at least 3 years beyond the completion of the research.
- ☐ I will protect subjects from physical and psychological harm.
- ☐ I will avoid using deception that might pose a risk to subjects' welfare. When deception is necessary, I will debrief subjects at the conclusion of the study by: (a) informing them about the purpose of the study and the reasons for the procedures; (b) clarifying any misconceptions that they may have about the study; and (c) attempting to rectify any harm that they may have incurred during their participation in the study.
- ☐ I will not use coercion or deceit to force subjects to continue participating in the study against their will.
- ☐ I agree to store all materials related to the study in such a way as to protect the confidentiality of the data.
- ☐ I will abide by all determinations of the Institutional Review Board (IRB) and will accept the final authority and decisions of the IRB.
- ☐ I (and other research personnel) will complete the online human subjects protection training recommended by the IRB prior to enrolling subjects.
- ☐ I will not begin to enroll subjects prior to the research being reviewed and approved by the IRB.
- ☐ I will report promptly to the IRB any proposed changes in the research and I will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
- ☐ I will report immediately to the IRB any unanticipated problems involving risks to subjects or others in the research. I will cooperate with the IRB in its initial and continuing review, record keeping, reporting, and certification for the research.
- ☐ I will inform the IRB when the study is completed by submitting the **Application for Study Closure**.

Principal Investigator Signature _____

PI Name (First Last) _____

Date _____

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FACULTY ADVISOR ASSURANCE

(Necessary if PI is a student)

As a Faculty Advisor, I certify that:

- ☐ The research described in this protocol is being conducted under my supervision
- ☐ I am both familiar with, and approve of the procedures that are being utilized
- ☐ I agree with the risk assessment to human participants as detailed in this protocol application
- ☐ I will ensure that this research is conducted in an ethical manner, and in compliance with HCC IRB policies.

Faculty Advisor Signature

Faculty Advisor Name (First Last)

Date

IRB Chair Signature

IRB Chair Name (First Last)

Date

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IRB Decision

- ☐ Exempt
- ☐ Expedited, Approved
- ☐ Approved
- ☐ Modifications Required
- ☐ Rejected

Study Expiration Date	
Date PI is to be notified to submit application for Continuing Review or Study Closure	
Date(s) of Continuing Review	
Date(s) of Continuing Review	
Date Final Report Submitted	