HUDSON COUNTY COMMUNITY COLLEGE

APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

The Hudson County Community College IRB reviews all requests to conduct research involving human subjects. In completing the IRB application, be advised that persons reviewing it may be entirely unfamiliar with the field of study involved. Present the information in non-technical terms. It is the investigator's responsibility to provide information regarding the procedures, the informed consent process, and to supply the required documentation.

Prior to completing this application, please review the Hudson County Community College's Institutional Review Board Policies.

1. Based on Institutional Review Board Policies, indicate which level of review is appropriate for this project:

☐ **I. Full Review** A "full" IRB review is required when the research is defined as (a) a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102d); (b) that involves human subjects (i.e., a living person about whom a researcher collects either identifiable private information OR data through an intervention or interaction); and (c) involves greater than minimal risk to those human subjects.

This includes any research involving special populations (i.e., children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons) and/or sensitive behavioral research, research involving deception, or research that is harmful to subjects.

Categories of Sensitive Information (generally not eligible for exemption)
1. Information relating to sexual attitudes, preferences, or practices.
2. Information relating to the use of alcohol, drugs or other addictive products.
3. Information pertaining to illegal conduct.
4. Information that if released could reasonably damage an individual's financial standing, employability or reputation within the community.
5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Information pertaining to an individual's psychological well-being or mental health.
7. Genetic information.

☐ **II. Exempt**: The only involvement of human subjects will be in one or more of the following categories: Please identify exempted category.

a) ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **This applies only to Normal educational research in regular educational settings.**

b) ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **This exemption does not apply to children or prisoners.**

c) ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d) ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, 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.

e) ☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

f) ☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

☐ **III. Expedited** 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 expedited 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 expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Examples of proposals that may be expedited include:

- observation, interviews, questionnaires, or surveys of adults
- secondary analysis of restricted, identifiable or private use data
  NOTE: refers to:
    - public use datasets and
    - de-identified data –datasets that have been stripped of all identifying information and there is no way it can be linked back to the subjects from whom it was originally collected
- analyses linking survey data to geographical or community level indicators
- collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (restrictions apply)
- collection of biological specimens by noninvasive means
- collection of data through noninvasive procedures routinely employed in clinical practice (excluding procedures involving x-rays or microwaves)

PROJECT TITLE:

2. Principal Investigator's Name:

Department:

Telephone:

Mailing Address:

Faculty Sponsor: Telephone:
(Required if principal investigator is a student)

3. Project Start Date: Project End Date:

4. Is a proposal for external support being submitted? ◯ YES ◯ NO

Agency or Sponsor: Deadline:
(If yes, you must submit one complete copy of the proposal with this application.)

5. In order for the IRB to evaluate your application, the following required information must be provided:

- ☐ A copy of all questionnaires or survey instruments
- ☐ Informed consent document(s) or minor assent document(s)
- ☐ Letters of approval from cooperating institutions (if appropriate)
- ☐ All required signatures

(Failure to provide all required information will result in return of your application for correction prior to IRB approval.)

In the space provided below, provide complete answers to the following questions:

6. **Project Description**: Provide a brief summary of the proposed research.
The IRB must have sufficient information about what will happen to the subjects to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of transactions between the investigator and subject.

7. **Subject Selection**:

Will subjects be less than 18 years of age? ◯ YES ◯ NO

Age range of subjects From: To:

Will subjects be students at Hudson County Community College? ◯ YES ◯ NO

How many subjects will participate?

How will subjects be selected, enlisted, or recruited? Describe in box below.

8. **Informed Consent Process**: Describe the informed consent process and attach a copy of all consent and/or assent documents.

9. **Procedures**: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.

10. **Confidentiality and Anonymity**: How will subjects' privacy be maintained and confidentiality be guaranteed?

11. **Risks**: Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.

12. **Benefits**: Describe the anticipated benefits.

13. **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 put into practice. Any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the IRB Chair. The principal investigator and his or her designee are responsible for retaining Informed Consent Documents for a period of three years after completion of the project.

Signature Page

Print this last page. Both the Principal Investigator and the Faculty Sponsor (if a student is applying) must sign, date, and send this completed signature page to the Hudson County Community College Human Subjects Committee. No applications will be reviewed until this completed signature page is received by the Committee

14. **Signatures**: In preparing this IRB application, I certify that I have read and understand the Procedures and Guidelines of the IRB, and that I intend to comply with the letter and the spirit of the Hudson County Community College policy. I certify to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

A. Signature of Principal Investigator – Print

Principal Investigator: _____ Date: _____

B. Approval by Faculty Sponsor (required for all students)

I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.

Faculty Sponsor: _____ Date: _____

NOTE: Do not begin collection of data (including pilot studies) until you receive notification that your application has been approved by the IRB.