Harford Community College

Institutional Review Board
Charter and Standard Operating Procedures

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BACKGROUND

In 2002, the Maryland General Assembly passed House Bill 917, "Human Subjects Research – Institutional Review Boards." The new law took effect on October 1, 2002, and is now codified in Title 13, Subtitle 20 of the Health-General Article. The most relevant aspect of the law applies the federal regulations on the protection of human subjects to all research conducted in Maryland, not just federally funded research.

According to the federal regulations, an Institutional Review Board (IRB) established in each institution must determine that a research proposal meets the following criteria, in order to approve the proposal:

- Risks to research subjects are minimized.
- Risks to subjects, if present, are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable (this criterion is concerned mainly with research involving vulnerable populations, such as children, prisoners, mentally disabled persons, etc.) – and the rights and the welfare of subjects must be protected.
- Informed consent is obtained, if necessary, and documented.
- There are adequate provisions to protect the privacy of subjects and the confidentiality of data, when appropriate.

INTRODUCTION

Through the Strategic Plan, Harford Community College encourages and supports faculty, administrators, and staff of the College to develop and execute scholarly work and research. The Harford IRB is charged with the review of proposed research projects that involve the use of human subjects and to assure compliance with Maryland state law. Specifically, the IRB reviews human subject research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel and outside institutions are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects volunteer to participate in research only after being provided with legally effective informed consent; that all College research is conducted in an ethical manner and in compliance with established standards. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects.

It is not the role of the IRB to evaluate or provide rulings on methodological approach of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. It is however, the responsibility of the IRB to evaluate each project in terms of the ethical standards with regard to issues such as informed consent, confidentiality, and any risk to the participants.

This Charter and Standard Operating Procedures clearly define the operating procedures for the IRB and provide definitions of the types of research/evaluation that must be submitted to the IRB for review.

I. INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures document establishes and empowers the Harford Community College Institutional Review Board. The IRB at Harford Community College is registered with the federal Office for Human Research Protections (OHRP) as an Institutional Review Board (*IRB # 00006991*).

II. BASIC PRINCIPLES

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 [see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at Harford Community College, to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to any anticipated benefits, to subjects, and to the importance of the knowledge that may reasonably be expected to result.

3. Adequate provisions must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the Harford Community College population base in terms of gender and minority representation unless scientifically justified.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. All research programs that involve human subjects must be reviewed by the IRB and must receive approval of a formally constituted review *prior* to their initiation or *prior* to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

III. SCOPE OF AUTHORITY

Harford Community College's application for a Federalwide Assurance (FWA) through OHRP has been approved and therefore HCC agrees to consider *all* research involving the use of humans, or data maintained by the college as being subject to federal regulations regardless of the source of funding.

It is not the role of the IRB to evaluate or provide rulings on methodological approach of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. It is however, the responsibility of the IRB to evaluate each project in terms of the ethical standards with regard to issues such as informed consent, confidentiality, and any risk to the participants.

All research projects submitted by persons not affiliated with Harford Community College must make application to the IRB.

Projects/grants relying on summary statistics on the College/IR Website describing students or employees do not require IRB review or approval prior to dissemination.

IV. RB APPLICATION PROCESS

A. Process

It is the responsibility of all employees of the College to be familiar with the IRB Charter and to submit applications for review as indicated. The application process is determined by the level of IRB review indicated. Application to the IRB must be made prior to soliciting subject participation or data collection.

Federal guidance describes three levels of IRB review. The determination of the level of review is dependent on the purpose of research, the subjects under review, the type of intervention to be studied, and the data to be collected and analyzed.

Exempt Research projects involve

- educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques or classroom management methods.
- use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior where the identification of the subjects is not possible.
- 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.

Expedited research projects involve

- activities that present no more than minimal risk to human subjects, and involve only procedures specified in federal regulations.
- research that may include clinical trials, research on new drugs, new medical devices. A full listing of the studies to be considered here can be found at http://www.hhs.gov/ohrp/policy/expedited98.html.

Full IRB Committee research projects involve

- projects exposing subjects to risks greater than those normally encountered in daily life or in routine medical, dental, or psychological examinations.

The following charts are provided to help clarify the types of projects that will require IRB review and the appropriate application process.

Chart 1: Examples of Projects NOT Requiring IRB Review
Chart 2: Examples of Projects Requiring IRB Review

Chart 1 and Chart 2 are not meant to be exhaustive. If College employees have questions about a specific project and its relationship to review by the IRB, the issue should be presented directly to the Chair of the IRB.

Chart 1 **Examples of Projects NOT Requiring IRB Review**		
Description of Project	Application to IRB NOT Required	Application Steps to the Harford Community College IRB
Course based student learning outcomes assessment investigation where the results will only inform or improve classroom instruction and do not involve a control group design.	X	NO IRB APPLICATION NEEDED
Surveys administered to HCC students for the purpose of informing and improving the educational environment at HCC.	X	
Standardized surveys administered to HCC students where the information provided is anonymous and there is no means to link responses to student level characteristics of academic records (e.g. CCSSE, PACE).	X	
Surveys designed by HCC employee(s) and sent to HCC employees or students asking for perceptions of services provided by the campus where there is no means to link responses to individuals.	X	

Chart 2 **Examples of Projects Requiring IRB Review***		
Description of Project	**Application to IRB Required**	**Application Steps to the Harford Community College IRB**
Projects initiated by faculty or HCC employees where results may be published in professional journals or presented at a professional meeting(s).	X	1. Complete the *Exempt Review Checklist* 2. The IRB Chairperson will review and communicate the outcome of the IRB review to the Principal Investigator/Lead within 5 business days from submission of all required documents
Course based outcome assessment project/research initiated by HCC employees intended to inform instruction which include a control group.	X	
All requests by persons not affiliated or employed by HCC who are requesting to include person level data on HCC students/employees in their research and or dissertation.	X	1. Complete the *Expedited/Full Review Checklist* 2. IRB Chairperson will review along with 2 additional IRB members 3. IRB Chairperson will communicate the outcome to the Principal Investigator/Lead within 14 business days from submission of all required documents
Grants submitted by HCC to any governmental or non governmental agency where the methodology includes collection of person level data on HCC students/employees.	X	
Grant submitted to any agency external to the College where an HCC employee is a contributor and where person level data on HCC students or employees will be required.	X	

* In instances where students may be involved in course activities such as conducting surveys of HCC students, staff or faculty or members of the community, the course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. At minimum, if the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete an Exempt Protocol Summary Form for approval and submit it along with the protocol and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

B. Appeals

The Principal Investigator (PI) of any proposal may appeal the decision of the IRB when a protocol has been disapproved or approved with recommendations and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

C. Informed Consent

"Informed consent" means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html. Given that the research conducted on campus may involve minors, informed consent for participation is of concern to the IRB. The IRB will review the content of the informed consent, and the method for assuring the informed consent is adequate and appropriate. Some research may not impose on the rights and welfare of human subjects to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects.

V. MEMBERSHIP AND ADMINISTRATIVE REPORTING

A. The Analytics and Planning Office will be responsible for managing all administrative requirements of the IRB. The Chair of the IRB will be the Associate Vice President of Analytics and Planning at the College.

B. The Chair appoints the Vice-Chair of the IRB with the concurrence of the IRB. The Vice-Chair presides over all convened IRB meetings in the absence of the Chair and has the authority to sign all IRB action items in the absence of the Chair. The Vice-Chair must be a voting member of the IRB.

C. The IRB is administratively responsible for reporting to the Vice President for Student Affairs and Institutional Effectiveness and the President of the College.

D. The IRB shall be composed of at least seven voting members. Alternates and non-voting members are also appointed. Alternates will have the authority to vote at IRB meetings only in instances where a voting member is unable to attend. Although an alternate may be designated for more than one IRB member, each alternate may represent only one

regular member at a convened meeting. All appointments to the IRB will be communicated by the Chairperson of the IRB and as required, reported to the OHRP.

E. The composition of members on the IRB will reflect the diversity of the campus and bring expertise that will assure adequate review of the research brought before the IRB. In addition to members representing various academic and service divisions focus of the campus.

F. Members and alternates of the IRB shall be appointed by the Chair of the IRB for tenure of three (3) years. However, the term of appointment may be terminated by notice of the committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or in capacity to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

G. The IRB Chair must complete formal training at the time of the initial appointment. Training that satisfies this requirement is the on-line tutorial offered by OHRP at https://www.hhs.gov/ohrp/education-and-outreach/index.html

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H. IRB members do not receive compensation for their service.

I. Liability coverage for IRB members is provided through Harford Community College's liability insurance coverage, whether or not the IRB member is an employee of HCC.

J. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

VI. OPERATIONS OF THE IRB

A. Meetings

1. IRB meetings are scheduled as required.

2. The place and time of the meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days before the meeting.

3. For applications requiring full IRB review, the IRB Chair assigns one primary reviewer and at least one secondary reviewer. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s)

may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The assigned reviewers lead the discussion of that protocol during the formal meeting. Other IRB members review summary information only, but have access to complete study documentation upon request.

B. Voting requirements

1. At all IRB meetings convened to review the proposal(s), a quorum of the IRB must be present. At a minimum, the membership in attendance must include at least one member whose primary concerns are in non-scientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting.

3. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting.

4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

C. Documentation

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.

2. Copies of all correspondence between the IRB and the investigators.

3. Detailed minutes of IRB meetings, showing:

   a. Members present (any consultants/ guests/others shown separately).
   b. Results of discussions on debated issues and record of IRB decisions.
   c. Record of voting (showing votes for, against and abstentions).

4. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

4. Other correspondence or documents generated by the IRB.

D. Document Retention

1. These documents and records shall be retained according to requirements of the funding agency but at minimum for three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

2. In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments.

3. All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave HCC, signed consent forms are to be transferred to the IRB Chair.

E. Conflict of Interest

It is the responsibility of all IRB members to identify and avoid any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. It is the responsibility of the IRB members to inform the IRB Chair should they have a conflict of interest during review of any proposal.

F. Training and support to the campus

An additional responsibility of the IRB at Harford will be to provide ongoing professional development, regarding the application process, sound procedures for collection, analysis and reporting of results.