



Institutional Review Board

Standard Operating Procedures

08/2010

Institutional Review Board #IRB00006185, Columbus State Community College IRB #1

These Standard Operating Procedures establish and empower the Columbus State Community College (CSCC) human subjects protection committee.

Standard Operating Procedures

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INSTITUTIONAL AUTHORITY

These Standard Operating Procedures establish and empower the Columbus State Community College (CSCC) human subjects protection committee. Currently, CSCC has one committee registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board #IRB00006185, Columbus State Community College IRB #1 (see Appendix 2). This committee is hereinafter referred to as “the IRB.”

Columbus State Community College Policy No. 13-08, effective April 1, 2007, defines the role of the IRB.

1. *Purpose:* As a publicly funded institution of higher education, Columbus State Community College is responsible for providing a safe environment for students and employees that conduct human subject research and for the individuals that are part of a Columbus State Community College IRB approved research project. The college shall allocate the resources necessary to establish the policy and procedure to ensure the safety of its students and employees.
2. Columbus State Community College will utilize an Institutional Review Board (IRB) to protect the welfare of human subjects used in research.
3. The President shall establish Procedures to administer this policy to ensure compliance with the federal regulations that govern an IRB as codified in the Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects and any additional federal, state, local laws or professional guidelines.

Columbus State Community College Procedure No. 13-08 (C), effective April 1, 2007, explains how the IRB operates.

1. The Institutional Review Board (IRB) will be appointed by the President and will function under the direction of the Vice President of Knowledge Resources and Planning, whose office will maintain the protocol and documentation.
2. The IRB will meet the requirements of the Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Subpart 46.107.
3. Research studies, projects, and surveys initiated and conducted by CSCC faculty, staff, students, and managers; or those studies, projects, and surveys utilizing CSCC faculty, staff, students, and/or managers as subjects must be reviewed and approved in writing by the IRB before the research study, project, or survey is initiated.
4. Columbus State Community College (CSCC) faculty, staff, students, and managers conducting research studies, projects, and surveys or others conducting studies, projects, and surveys utilizing CSCC faculty, staff, students, and/or managers as

subjects will consult the Columbus State Community College's Institutional Review Board (IRB) website for guidelines or contact the IRB Administrator in the Grants Office for assistance.

PURPOSE

The primary purpose of the IRB is to protect the welfare of human subjects used in research. In addition, the IRB develops and publishes [guidelines](#) on the use of human subjects in research.

BASIC PRINCIPLES

The basic principles that govern the IRB in assuring protection of the rights and welfare of subjects are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ([The Belmont Report](#)), The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. (See <http://ohsr.od.nih.gov/guidelines/belmont.html>)

Therefore, the following principles apply to all research, including student projects, involving human subjects at CSCC 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 anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Adequate provision(s) 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 population base in terms of gender and minority representation, unless the nature of the study justifies a specific subject population.
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, and must receive approval of, a formally constituted review committee *prior* to their initiation or *prior* to initiating any changes to the protocol (i.e., amendments, see [Modifications, Level of Review for Amendments](#)). Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

THE AUTHORITY OF THE IRB

CSCC holds a Federal-wide Assurance (FWA) through OHRP (see Appendix 1). As part of this Assurance, CSCC agrees to consider all research involving the use of humans as research participants as being subject to federal regulations, regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution, or
3. 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
4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, s/he is encouraged to complete a protocol for approval and submit it, along with any accompanying consent form(s), cover letter(s), and/or questionnaire(s), in order to obtain the guidance of the IRB regarding these activities.

The IRB reviews all projects and programs involving human subjects in accordance with these Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

The IRB has approval authority of human subject protocols, and can disapprove, modify, or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the **Institutional Official**, who is appointed by the President, and responsible for research oversight within the institution. However, the Institutional Official may not approve the research if it has not been approved by the IRB.

The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol, especially in cases where the consentee is from a vulnerable population.

The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy, or duplicate records while being sensitive to causing the least inconvenience or disruption of ongoing research.

THE IRB'S FUNCTIONAL RELATIONSHIPS

The IRB functions administratively through the Institutional Official and is staffed by the Grants Coordinator who serves as the **IRB Administrator**. This structure provides for administrative coordination for the IRB with the various academic and administrative units in the College.

The IRB advises and makes recommendations to the President, to policy and administrative bodies, and to any member of the College community on all matters related to the use of human subjects in research.

THE MEMBERSHIP OF THE IRB

The IRB is composed of five (5) voting members. Non-voting members may also be appointed. All appointments are made by Executive Memorandum and reported to OHRP.

The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of College regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed in accordance with the following procedure:

1. Each protocol submitted to the IRB Administrator will be reviewed prior to being scheduled for initial review to determine whether special expertise is needed.
2. The determination of whether special expertise is needed will be made by the Institutional Official, on the basis of the following criteria: the availability of behavioral expertise for the review of behavioral studies, and the availability of

- individuals (IRB members or consultants) with experience with particular vulnerable populations.
3. Experts will be selected by the IRB Institutional Official from the IRB's roster of members and consultants.
 4. If an IRB member is selected, the member's feedback will be included in the member's normal review of the protocol. If a consultant is selected, the consultant's feedback will be in the form of a written report which will be shared with IRB members as soon as practical before the initial review of the protocol.

The IRB must include both men and women, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with the College.

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

MANAGEMENT OF THE IRB

The IRB Chair is appointed in writing by the President. The Institutional Official, in consultation with the Provost and Deans of the various divisions and faculty leadership, makes recommendations to the President regarding membership. The IRB Chair is a voting member of the IRB and presides over all convened IRB meetings. The Chair has authority to sign all IRB action items.

The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair, with the concurrence of the IRB, and has authority to sign all IRB action items in the absence of the Chair.

The IRB Administrator is a non-voting member of the IRB and is responsible for the overall management of the IRB.

Members of the IRB shall be appointed by the Chair of the IRB for tenure of two (2) or 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 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 no reasonable justification, or for other manifestations of unwillingness or inability 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.

The IRB receives staff support from the IRB Administrator; at CSCC, the Grants Coordinator has that role.

All IRB members are required to undergo and provide evidence of formal training at the time of their initial appointment. CSCC provides this training, good for three years, through Collaborative Institutional Training Initiative (CITI). The IRB Administrator will maintain evidence of training completion. Continuing education of IRB members is accomplished through "Information Items" attached to meeting agendas on an "as needed" basis and through maintenance of links on the College's IRB web site.

IRB members do not receive compensation for their service.

Liability coverage for IRB members is provided through CSCC's liability insurance coverage, whether or not the IRB member is an employee of CSCC.

Consultants with competence in special areas may be used when deemed appropriate; for example, use of prisoners as human subjects.

Resources (for example, meeting area, filing space, reproduction equipment, and computers) are provided by, or arranged through, KRP.

Conflict of interest policy and procedure:

1. Investigators shall not be involved in the selection of IRB members.
2. Investigators and IRB members who are CSCC employees and who apply for federal grants and contracts are subject to the [CSCC Conflict of Interest Policy](#).
3. The IRB Administrator will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.
4. Other conflict of interest guidelines specifically for IRB members are found in the [Conflict of Interest Guidelines for IRB Members](#) section of these Standard Operating Procedures.

PROCEDURES OF THE IRB

Initial Review

CSCC offers review of protocols describing research that poses no or minimal risk.

Exempt Human Subjects Protocol

Under federal regulations, certain types of research are [exempt](http://www.hhs.gov/ohrp/humansubjects/guidance/hcdc95-02.htm) from federal policy unless the appropriate federal agency heads have determined otherwise (See <http://www.hhs.gov/ohrp/humansubjects/guidance/hcdc95-02.htm>).

Exempt types of research include:

1. 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.
2. 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.
3. 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 (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.
4. 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.
5. 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.
6. 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.

The IRB, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must complete an *Exempt Protocol* citing the specific exemption category and providing justification for the exemption.

Prospective Principle Investigators (PIs) seeking an exemption will follow the [Exempt Protocol Guidelines](#) and submit one (1) original of the [Exempt Human Subjects Protocol](#) to the IRB Administrator. The protocol may be submitted electronically as a portable document file (pdf); however, page 2 with **original** signatures must be provided separately. The protocol form and guidelines are available on the [IRB website](#).

The IRB Chair shall review an *Exempt Human Subjects Protocol* for the determination of “exempt” from human subjects review based on the federal regulations. However, if the IRB Chair has significant concerns about the study, the protocol will be referred to the full IRB for review. All protocols and actions will appear on the IRB agenda and in minutes.

Actions of the IRB

The IRB may take one of the following actions in regard to the proposed *Exempt Protocol*:

1. Not Research
When a protocol is determined not to constitute research, it will be returned to the principal investigator with a completed *Approval and Determination* form.
2. Exempt
When a protocol is determined to be exempt from review, the IRB Chair will sign and date the protocol. It will be returned to the Principal Investigator with a completed *Approval and Determination* form.
3. Referred to Full IRB
If the protocol requires full IRB review, it may be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the material from the PI, the IRB Administrator will distribute copies to each IRB member. All materials must be submitted ten (10) working days prior to the IRB meeting so that the members can independently and adequately review the material.

Full Human Subjects Protocol

Research topics that do not meet the criteria for exempt will be reviewed by the full IRB.

The list of categories of research that may be reviewed by the IRB include:

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. 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. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
5. Collection of data through noninvasive procedures, examples include:
 - a. Weighing or testing sensory acuity;
 - b. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
6. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.

Prospective Principal Investigators (PIs) will follow the [Full Protocol Guidelines](#) and submit one (1) original of the [Full Human Subjects Protocol](#) to the IRB Administrator. The protocol may be submitted electronically as a portable document file (pdf); however, page 2 with

original signatures must be provided separately. The protocol form and guidelines are available on the [IRB website](#).

In the protocol, the investigator thoroughly discusses the purpose of the research, the benefit to CSCC, methodology for CSCC students or employees, risk to subjects, obtaining consent, and disposition of the data. In addition, the investigator should present any information that will aid the IRB in understanding the nature of the research.

Protocols for full-board IRB review must be submitted ten (10) working days prior to the regularly scheduled IRB meeting.

The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB. It is strongly recommended that new investigators have an advance copy of their protocol reviewed by an IRB member or alternate before submitting final copies to the IRB Administrator.

Actions of the IRB

The IRB may take one of the following four actions in regard to the proposed protocol:

1. Not Research

When a protocol is determined not to constitute research, it will be returned to the principal investigator with a completed *Approval and Determination* form.

2. Approved

When the IRB approves the protocol, the Chair signs and dates it. The consent form (if one is included) on the protocol face page is stamped with the CSCC IRB number and the Chair signs there also. Copies will be returned to the Principal Investigator with a completed *Approval and Determination* form. The original is maintained in the IRB files.

Approval of the protocol will be based on the following:

- a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.
- b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
- c. Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly

recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

- d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.
- e. Anticipated benefits, if any.
- f. The personal risk to the subject in relation to expected benefits.
- g. The adequacy of procedures for securing informed consent from the subject.
- h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.
- i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

3. Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

4. Disapproved

If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

Continuing Review

Protocols determined to be exempt are also exempt from requirements related to continuing review. However, if an investigator decides to modify an exempt human subjects research project in such a way that it would no longer qualify for exemption, the investigator must submit the modified research protocol to the IRB for review prior to implementation of the modified research project.

The determination of exempt for program validation surveys used for accreditation or other purposes will expire after three years. At that time, a new protocol will be submitted to the IRB for review and determination. For continuing review, the surveys follow the guidance for exempt protocols.

For approved non-exempt protocols, the IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Principal Investigators will be informed of the due dates for progress reports by receipt of a *Continuing Review Report* with cover memo. This *Continuing Review Report* is to be completed and returned to the IRB Administrator along with the informed consent document currently in use with the project being reviewed. These items will be distributed to the Institutional Official or full board, as appropriate, and the PI will be notified of the action taken (Approved, Approved with Conditions, or Referred to Full Committee Review).

When a *Continuing Review Report* is submitted, the IRB shall consider the following: changes to the research, protocol deviations and violations since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project have been amended within the past **five** (5) years, the PI will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within thirty (30) days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

Procedures Pertaining to both Initial and Continuing Review

The IRB shall have authority to determine which studies need verification from sources other than the investigators, that no material changes have occurred since previous IRB review, particularly: (i) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (ii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

PIs shall be informed at the time of protocol approval (both initial and continuing) that they must immediately bring to the attention of the IRB Chair any proposed changes (see [Modifications](#)), any unanticipated adverse events (see [Adverse Events](#)), or any serious or continuing noncompliance in the program which may affect the status of the research as it relates to the use of human subjects.

Adverse Event Reporting Guidance

PIs shall be informed at the time of protocol approval (both initial and continuing) that any changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects.

OPERATIONS OF THE IRB

There is at least one IRB meeting scheduled every month.

The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least ten (10) working days prior to the meeting.

Voting Requirements

1. A quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific 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. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.
3. PIs, 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 (even if this means being unable to continue the meeting because of quorum requirements).
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.

Appeals

When a protocol has been disapproved, the PI may appeal the decision of the IRB. A written request for appeal must be presented to the IRB Administrator within thirty days of the date on the **IRB Action Response: Not Approved** form. 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.

Modifications

Modifications are categorized into minor changes and significant changes. To submit modifications to the IRB, the Principal Investigator completes the [**Request for Modification of Previously Approved or Exempt Protocol**](#).

Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of **minor changes** to a research study include but are not limited to, the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to unvalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical, or typographical errors).

Examples of **significant changes** to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);

- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Level of Review for Amendments

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed. However, if an amendment is determined to increase the level of risk beyond minimal risk, the IRB Chair will refer the amendment to the full IRB.

Minor modifications/changes may be reviewed and approved using an “administrative approval” process. Administrative approval may be given by the IRB Chair. Such approvals are then put on the agenda of the next IRB for concurrence.

Sponsor Modifications

Modifications can be made only to IRB approved studies. A sponsor may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol.

Sponsor generated modifications (or addenda) require review and approval by the IRB. The investigator should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

Grievances

Upon receipt of grievances (e.g., of a research subject against a PI), the IRB will investigate and act within its authority. (See [The Authority of the IRB](#)).

RECORD REQUIREMENTS

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

1. Copies of all research proposals reviewed and scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. 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).
3. 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. Copies of all correspondence between IRB and the investigators.
5. Any statements of significant new findings (unanticipated risks or adverse events) provided to subjects.
6. Adverse event reports and documentation that the IRB reviews such reports.
7. All Modification forms and attachments, if provided.
8. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least 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.

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

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

PRINCIPLES OF INFORMED CONSENT

When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists, (e.g., participation in a research project), the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or CSCC as indicated below.

For anonymous Internet-based surveys, it is sometimes appropriate to use implied informed consent. Participants still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey.

Other Internet-based surveys include "I agree" or "I do not agree" buttons on the website for participants to choose whether or not they consent to participate.

If, for study design, the researcher needs to keep track of who participated or the IRB determines that some sort of documented consent is required, instead of "signed" informed consent, the researcher may email the consent form to participants. They type name and the date into the spaces provided on the consent form, and return it to the researcher via email. This process may be appropriate for data collected via email, chatrooms, online interviews, etc.

Keeping data confidential and secure is important in all research projects. Paper consent forms and surveys may be kept in a locked file within a locked office with limited access. Data stored on a personal computer or laptop may be protected with encryption or password protected software. When establishing surveys using online sites, a PI determines how the survey site protects data. All survey sites can provide a security certificate that indicates how confidentiality is protected. The PI may use various options (shredding paper, audio tapes, and CDs; deleting hard drives using secure file deletion software; or clearing a flash drive. Federal regulations require that data is stored for three years.

The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the agreement of the minor (assent), in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a Legally Authorized Representative (LAR). The LAR must be authorized either by a power of attorney or a court order.

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. (See <http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm>). The IRB may approve a telephonic consent procedure under which the subject's legally authorized representative (LAR) is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a

fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

Some research may not impose on the rights and welfare of human subjects so as 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 in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which ***it is proposed to mislead the subjects*** during data collection, the IRB

has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

Guidelines for drafting consent forms or cover letters are presented in the [Full Human Subjects Protocol](#).

The IRB will direct each researcher obtaining signed consent forms to retain the original signed forms for at least four years beyond the termination of the subject's participation in the proposed activity.

Should the investigator leave CSCC, signed consent forms will be transferred to the IRB for the required retention period.

CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;
2. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see the [CSCC Conflict of Interest Policy](#), for the definition of "significant financial interest");
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified him or herself for any other reason as having a conflicting interest.

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of a 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 s/he is a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Administrator immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, a potential reviewer must peruse the matters for which s/he is assigned as a reviewer immediately upon receipt of materials to determine whether s/he may have a conflict.

Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation, and actions (including vote). In general, an IRB member who has a real or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

Minutes of IRB meetings will reflect the absence of a member, by name, when he or she leaves the meeting during deliberations and actions regarding matters for which s/he has, or may be perceived to have, a potential conflict of interest.

Appendix 1

This is an automated message from an unmonitored address. Please do not reply.

Your institution's electronic submission of a Federalwide Assurance (FWA) has been approved by the Office for Human Research Protections (OHRP), and the FWA number assigned to your institution, Columbus State Community College, is **FWA00010584**. You will find this approval listed on our website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>. Funding agencies use this website to verify that an institution holds an active OHRP-approved FWA.

Whenever information provided to OHRP changes for your institution's FWA, you must submit an update/renewal. You may do this electronically by going to the OHRP Electronic Submission System at <http://ohrp.cit.nih.gov/efile/>. Your FWA must be renewed at least every 3 years.

Effective February 1, 2005, OHRP stopped mailing copies of approved Federalwide Assurance (FWA) documents to filing institutions. This was necessitated by the volume of FWA documents OHRP is managing. Over 10,000 FWAs have been approved. OHRP encourages FWA institutions to continue to submit documents (new and updates/renewals) electronically (<http://ohrp.cit.nih.gov/efile/>). When an electronic submission is processed, an automatically generated e-mail notifies the Human Protections Administrator and Signatory Official, as well as the person submitting the electronic record, that the FWA document has been approved. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested.

Sincerely,

Division of Policy and Assurances
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
(240) 453-6900
Toll-Free within the U.S. (866) 447-4777

Appendix 2

From: <jmakle@uscgtrs.ustrs.gov>
To: <sstumpp@cscoc.edu>, <doobmar@cscoc.edu>, <vmoeiler@cscoc.edu>, <sstumpp@cscoc.edu>
Date: 9/7/2007 11:22 AM
Subject: Electronic IORG-IRB/IEC(s) Registration for Columbus State Community College
Processed by OHRP as IORG0005147

CC: <jmakle@oscophc.dhhs.gov>
This is an automated message from an unmonitored address. Please do not reply.

The registration submitted electronically for your institutional review board/institutional ethics committee (IRB/IEC) organization (ORG) has been processed and assigned IORG0005147. The IORG number represents the overall registration, with each IRB/IEC receiving a distinct identification number. The following IRB/IEC(s) are registered with the Office for Human Research Protections (OHRP):

IRB00006186 Columbus State Community College IRB #1

This registration is listed on our website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>. Funding agencies use this website to verify that an institutional review board/independent ethics committee (IRB/IEC) has an active registration.

Whenever information provided to OHRP changes for this IORG-IRB/IEC registration, your organization must submit an update/renewal. You may do this electronically by going to the OHRP electronic Submission System at <http://ohrp.cit.nih.gov/efile/>. The IORG-IRB/IEC registration must be renewed at least every 3 years.

OHRP encourages organizations to continue to submit IORG IRB/IEC registration documents electronically (<http://ohrp.cit.nih.gov/efile/>). When an electronic submission is processed, an automatically generated e-mail notifies the person submitting the electronic record, the Information Provider, the Chair(s) of the IRB/IEC(s), and the Head Official on the IRB/IEC registration that the document has been processed. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested.

Sincerely,

Division of Policy and Assurances
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20862
(240) 453-6903
Toll-Free within the U.S. (866) 447-4777