COLUMBUS STATE
COMMUNITY COLLEGE

Institutional Review Board

Standard Operating Procedures

June 2022

Institutional Review Board IRB00006185, Columbus State Community College IRB#1
Federalwide Assurance 00010584

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INSTITUTIONAL AUTHORITY

These Standard Operating Procedures establish and empower the Columbus State Community College human subjects protection committee. The College 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 1). 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.

A. 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.
B. Columbus State Community College will utilize an Institutional Review Board (IRB) to protect the welfare of human subjects used in research.
C. The Columbus State 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 Columbus State Institutional Review Board (IRB) will be appointed by the President and will function under the direction of the Director of Institutional Effectiveness, 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 Columbus State faculty, staff, students and managers; or those studies, projects and surveys utilizing College faculty, staff, students and/or managers as subjects must be reviewed and approved in writing or reviewed and acknowledged in writing (e.g. survey notification and cooperative research) by the IRB before the research study, project or survey is initiated.
    a. Survey notifications are projects that include human subjects that may not be traditionally classified as research as defined by the federal regulations that govern all IRBs.

b. Cooperative research is research for which the Columbus State IRB formally cedes authority and relies upon another IRB for review and continuing oversight in order to comply with federal regulations which requires certain research projects to be reviewed by a single IRB.

4. College faculty, staff, students and managers conducting research studies, projects and surveys or others conducting studies, projects and surveys utilizing Columbus State faculty, staff, students and/or managers as subjects will consult the College's IRB website for guidelines or contact the IRB administrator in the Office of Institutional Effectiveness for assistance.

PURPOSE

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

BASIC PRINCIPLES

The basic principles that govern the IRB in assuring protection of the rights and welfare of subjects are set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (known as the Belmont Report).

The following principles apply to all research, including student projects, involving human subjects at Columbus State 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. Continuing full protocol research programs are subject to periodic review, to be carried out no

less often than once a year.

THE AUTHORITY OF THE IRB

Columbus State holds a Federalwide Assurance (FWA) through OHRP (see Appendix 2). As part of this assurance, Columbus State 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.

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 has approval authority of human subject protocols, and can approve, require modifications (to secure approval), or disapprove 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 Director of Institutional Effectiveness (the institutional official). However, the Director of Institutional Effectiveness 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 subject 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 provides continuing advice and counsel to personnel engaged in activities involving human 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 IRB approval. If the instructor has any doubt concerning the classification of these activities, the instructor 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'S FUNCTIONAL RELATIONSHIPS

The IRB functions administratively through the Office of Institutional Effectiveness under the management of the Director and staffed by 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 Columbus State 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 at least five voting members. Nonvoting members may also be appointed. The IRB chair is appointed by the Columbus State President and reported to OHRP. All other appointments are made by the President upon the recommendation of the Director of Institutional Effectiveness (the institutional official), in consultation with the IRB chair, the deans of the various divisions, and faculty leadership.

The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Board 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.

The IRB must include at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the College. The IRB must be diverse in its membership, including race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes.

No person shall be excluded from serving on the IRB for reasons of sex, race, color, religion, ancestry, national origin, age, disability, genetic information (GINA), military status, sexual orientation, and gender identity and expression.

MANAGEMENT OF THE IRB

The IRB chair (the 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 (the vice chair) is appointed by the chair, with the concurrence of the IRB members. The 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 has authority to sign all IRB action items in the absence of the chair.

The IRB administrator is a nonvoting member of the IRB and is responsible for the overall management and support of the IRB.

Members are appointed for a tenure of three years. However, the term of appointment may be terminated by notice of the board 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 chair must be informed. 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 board adequately. In either event, a replacement will be appointed according to the process stated above (see Membership of the IRB). Tenure on the IRB may be extended by mutual agreement between the member and the chair.

All voting and nonvoting IRB members are required to undergo and provide evidence of formal training at the time of their initial appointment. Columbus State provides this training through the Collaborative Institutional Training Initiative (CITI) Human Research - IRB Members, Basic Course. The IRB administrator will maintain evidence of course completion. Continuing education of IRB members is accomplished through “Information Item” meeting agenda topics or emails shared on an as needed basis using the OHRP and CITI, among others, as sources for current trends and developments.

IRB members do not receive compensation for their service.

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

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 Director of Institutional Effectiveness (the institutional official) or IRB chair, on the basis of the following criteria: the availability of individuals (IRB members or consultants) with expertise relevant to the review of the specific study, and the availability of individuals (IRB members or consultants) with experience with particular vulnerable populations.
3. Experts will be selected by the Director of Institutional Effectiveness or IRB chair 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.

Conflict of interest in the selection of IRB members and management of the IRB:

1. Principal investigators or co-principal investigators shall not be involved in the selection of IRB members.
2. Principal investigators or co-principal investigators and IRB members who are Columbus State employees and who apply for federal grants and contracts are subject to the Columbus State Community College Conflict of Interest Policy (No. 3-20).
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.

Resources (for example, meeting area, filing space, reproduction equipment, and computers) are provided by, or arranged through, the Office of Institutional Effectiveness.

PROCEDURES OF THE IRB

Initial Review

The IRB shall review and have authority to approve, require modifications (to secure approval), table (to await complete information), or disapprove all research activities covered by this policy.

All protocols and actions will appear on the IRB agenda and in minutes.

There are four types of protocols or notifications described in this section – Non-Research/Survey Notification, Exempt Protocol, Expedited Protocol, and Full

Protocol.

Non-Research/Survey Notification

There are projects that include human subjects that may not be traditionally classified as research as defined by the federal regulations that govern all IRBs (See Purpose). However, the IRB, operating under Columbus State Procedure No. 13-08 (C), in part, reviews all questionnaires that are administered to or administered by Columbus State students, faculty, staff, and administration.

Examples of these types of projects may include surveys or focus group questions concerning social processes, institutions, quality assurance, quality improvement, program validation, or accreditation activities.

Procedure

Project leaders seeking to administer a survey or other project for non-research review will submit to the IRB administrator a completed Survey Notification form, along with the questionnaire or survey instrument. The documents may be submitted electronically.

For surveys administered on a regular basis, like program validations, accreditation surveys, and internal quality of service surveys; and the surveys do not change over time, the project leader submits a completed Survey Notification form, as stated above, to serve as the initial notification. On the form, the project leader will indicate that the survey will be administered on a regular basis and provide the timeline of the survey (e.g. semesterly, annually). Future notification is required only if substantive changes are made to the survey questions, methodology, or scope of the project.

The project will be reviewed by the IRB chair or other designated IRB member.

All forms are available on the Columbus State IRB website.

Actions of the IRB

The reviewers may take one of the following actions in regard to the proposed survey notification:

Accepted as Not Research

When a survey notification is determined to not constitute research, it will be signed by the chair and returned to the project leader with a completed IRB Action Response form that will include the date data collection may begin.

Modification Required

When the reviewers determine that modification or clarification is required to secure a determination of non-research, the notification will be returned to the project leader with a completed IRB Action Response form that will specify the required modification or clarification. No data collection may begin until the notification is determined to not constitute research.

Tabled
Tabled action means that the survey notification was not sufficiently complete for the reviewers to reach a final decision. The project leader is notified and the additional information necessary for completion of the review is requested on the IRB Action Response form. No data collection may begin until the notification is determined to not constitute research.

Should, after the initial request for additional information and one follow-up request, the project leader is nonresponsive or does not provide the required information for a period of six months, the project will be administratively closed. Once a project is administratively closed, it will not be reopened. If the project leader later wishes to proceed with the project, the project leader will be required to follow the submission process in effect at the time of resubmission.

Referred for Exempt Review
When the reviewers determine that the project scope reaches beyond the confines of non-research, the Survey Notification will be returned to the project leader with a completed IRB Action Response form recommending that the project leader/principal investigator complete an Exempt Human Subjects Protocol form and submit the associated documents for review. No data collection may begin. (See Exempt Human Subjects Protocol)

Exempt Human Subjects Protocol

Research activities that pose no more than minimal risk in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from the requirements of federal policy, except that such activities must comply with the requirements of this section and as specified in each category (45 CFR 46.104).

Categories of exemption:

1. Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).
        i. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
        ii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least

one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;
b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or 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:
    a. If wholesome foods without additives are consumed, or
    b. 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 2018 Common Rule specifies two additional exemptions, 7 and 8, related to use of information under what is called broad consent. Exemptions 7 and 8 will not be

implemented at Columbus State at this time.

Limited IRB Review:
Limited IRB review may be required for some research activities within exempt categories 2 and 3, listed above, in order to ensure that the research plan includes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data, as well as other criteria as applicable. The limited review may be conducted by the IRB chair or one or more experienced reviewers within the IRB. The considerations for privacy and confidentiality safeguards may include the extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified, the use of the information, the extent to which the information will be shared or transferred to a third party or otherwise disclosed or released, the likely retention period or life of the information, the security controls that are in place to protect the confidentiality and integrity of the information, and the potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Research Involving Minors:
Exemption categories 1, 4, 5 and 6 may be applied to research involving minors if the conditions of the exemption are met. Category 2(a) and (b) only may apply to minors involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Category 2(c) may not be applied to research involving minors. In addition, the IRB shall determine that adequate provisions are made for soliciting the assent of the minors, when in the judgment of the IRB, the minors are capable of providing assent and that adequate provisions are made for soliciting the permission of each minor's parents or guardian. (See Principles of Informed Consent)

Research Involving Pregnant Women, Fetuses, or Neonates:
Each of these exemptions may be applied to research involving pregnant women, fetuses, or neonates if the conditions of the exemption are met.

Research Involving Prisoners:
Each of these exemption categories do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Procedure
Prospective principal investigators seeking an exemption will follow the Exempt Protocol Guidelines and submit to the IRB administrator a completed Exempt Human Subjects Protocol form, along with the associated documents, citing the specific exemption category and providing justification for the exemption. The protocol may be submitted electronically and must contain all required original or digital signatures.

The IRB reviewers, not the investigator, shall make the final determination as to

whether a project is or is not exempt.

The proposed exempt protocol will be reviewed by the IRB chair and vice chair or other designated IRB member.

For those seeking grant funding that requires preliminary IRB approval of exempt research (e.g. National Science Foundation grants), the IRB chair will provide a preliminary approval letter based upon the project abstract. Final approval is determined only after the completed Exempt Human Subjects Protocol form, along with the associated documents, is submitted to the IRB administrator. Data collection may not begin until the protocol is approved.

All protocol forms and guidelines are available on the Columbus State IRB website.

Actions of the IRB

The reviewers may take one of the following actions in regard to the proposed exempt protocol:

Approved

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 IRB Action Response form that will include the date data collection may begin.

Modification Required

When the reviewers determine that modification or clarification is required to secure approval as exempt, the protocol will be returned to the principal investigator with a completed IRB Action Response form that will specify the required modification or clarification. No data collection may begin until the protocol is determined to be exempt.

Tabled

Tabled action means that the protocol was not sufficiently complete for the reviewers to reach a final decision. The principal investigator is notified and the additional information necessary for completion of the review is requested on the IRB Action Response form. No data collection may begin until the protocol is determined to be exempt.

Should, after the initial request for additional information and one follow-up request, the principal investigator is non-responsive or does not provide the required information for a period of six months, the protocol will be administratively closed. Once a protocol is administratively closed, it will not be re-opened. If the principal investigator later wishes to proceed with the research, the principal investigator will be required to follow the protocol submission process in effect at the time of re-submission.

Referred for Expedited Review
When the reviewers determine that the protocol reaches beyond the confines of exempt from review but does not require a full IRB review, it will be returned to the principal investigator with a completed IRB Action Response form recommending that the principal investigator complete an Expedited Human Subjects Protocol form and submit the associated documents for review. No data collection may begin. (See Expedited Human Subjects Protocol)

Referred to Full IRB
If the protocol requires full IRB review, it will be returned to the principal investigator with a completed IRB Action Response form recommending that the principal investigator complete the Full Human Subjects Protocol form and submit the associated documents for review. No data collection may begin. (See Full Human Subjects Protocol)

Expedited Human Subjects Protocol

The federal regulations provide for certain types of research involving no more than minimal risk to be reviewed by means other than the full IRB. Under an expedited review procedure, the review will be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by the full IRB. (45 CFR 46.110)

The IRB may use the expedited review procedure to review the following:

1. Some or all of the research appearing within the research categories listed below, unless the reviewer determines that the study involves more than minimal risk.
2. Minor changes in previously approved research.
3. Research for which limited IRB review is a condition of exemption (see Exempt Human Subject Protocol).

All IRB members will be advised of research proposals that have been approved under the expedited review procedure.

Applicability

1. Research activities that (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. 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.
2. The categories in this list apply regardless of the age of subjects, except as

noted.

3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB.
6. Categories one through seven pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application is not required.
    b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, non-pregnant 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.
    b. From other adults and minors, 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.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this

category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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 the regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
8. 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.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Procedure

Prospective principal investigators will follow the Expedited Protocol Guidelines and submit to the IRB administrator a completed Expedited Human Subjects Protocol form, along with the associated documents and evidence of completion of the Social/Behavioral Research Investigator course within the past two years (CITI training). In the protocol, the principal investigator will thoroughly discuss the purpose of the research, the benefit to Columbus State, the methodology for Columbus State students or employees, the potential risk to subjects, the process and documents related to obtaining informed consent, and the disposition of the data. In addition, the principal investigator should present any information that will aid the IRB in understanding the nature of the research. The protocol may be submitted electronically and must contain all required original or digital signatures.

All protocol forms, guidelines, and instructions for obtaining CITI training are available on the Columbus State IRB website.

Actions of the IRB

The reviewers may take one of the following actions in regard to the proposed expedited protocol:

Approved
When the IRB approves the protocol, the chair signs and dates the protocol. The consent form (if one is included) is stamped with the Columbus State IRB number and includes the signature of the chair and effective date with no expiration date (unless continuing review is required). An electronic copy will be sent to the principal investigator with a completed IRB Action Response form that will include the date data collection may begin.

Modification Required
When the reviewers determine that modification or clarification is required to secure approval, the protocol will be returned to the principal investigator with a completed IRB Action Response form that will specify the required modification or clarification. No data collection may begin until the protocol is approved.

Tabled
Tabled action means that the protocol was not sufficiently complete for the reviewers to reach a final decision. The principal investigator is notified and the additional information necessary for completion of the review is requested on the IRB Action Response form.

Should, after the initial request for additional information and one follow-up request, the principal investigator is non-responsive or does not provide the required information for a period of six months, the protocol will be administratively closed. Once a protocol is administratively closed, it will not be re-opened. If the principal investigator later wishes to proceed with the research, the principal investigator will be required to follow the protocol submission process in effect at the time of re-submission.

Referred to Full IRB
If the protocol requires full IRB review, it will be returned to the principal investigator with a completed IRB Action Response form recommending that the principal investigator complete the Full Human Subjects Protocol form and submit the associated documents for review. No data collection may begin. (See Full Human Subjects Protocol)

Full Human Subjects Protocol
A full IRB review is required for research that is not eligible for exempt or expedited review. (45 CFR 46.111)

Some characteristics of studies requiring full IRB review:

- Projects for which the level of risk is determined to be greater than minimal.
- Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.

- Projects that involve vulnerable populations.
- Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied, when appropriate:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented or appropriately waived.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as minors, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
9. 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.
10. Assurances of acceptable debriefing, if appropriate. It is the responsibility of the principal investigator 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.

Procedure

Prospective principal investigators will follow the Full Protocol Guidelines and submit to the IRB administrator a completed Full Human Subjects Protocol form, along with

the associated documents and evidence of completion of the Social/Behavioral Research Investigator course within the past two years (CITI training). In the protocol, the principal investigator will thoroughly discuss the purpose of the research, the benefit to Columbus State, the methodology for Columbus State students or employees, the risk to subjects, the process and documents related to obtaining informed consent, and the disposition of the data. In addition, the investigator should present any information that will aid the IRB in understanding the nature of the research. The protocol may be submitted electronically and must contain all required original or digital signatures.

All protocol forms, guidelines, and instructions for obtaining CITI training are available on the Columbus State IRB website.

Protocols for full IRB review must be submitted 10 days prior to the regularly scheduled IRB meeting. The principal investigator must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

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

Approved
When the IRB approves the protocol, the chair signs and dates the protocol. The consent form (if one is included) is stamped with the Columbus State IRB number and includes the signature of the chair, effective date, and expiration date. An electronic copy will be sent to the principal investigator with a completed IRB Action Response form that will include the date data collection may begin.

Modification Required
When the IRB determine that modification or clarification is required to secure approval, the protocol will be returned to the principal investigator with a completed IRB Action Response form that will specify the required modification or clarification. No data collection may begin until the protocol is approved.

Tabled
Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. The principal investigator is notified and the additional information necessary for completion of the IRB review is requested on the IRB Action Response form.

Should, after the initial request for additional information and one follow-up request, the principal investigator is non-responsive or does not provide the required information for a period of six months, the protocol will be administratively closed. Once a protocol is administratively closed, it will not be re-opened. If the principal investigator later wishes to proceed with the

research, the principal investigator will be required to follow the protocol submission process in effect at the time of re-submission.

Disapproved
If the protocol fails to meet one or more of the criteria used by the IRB for the approval of research, the principal investigator will be informed of the reasons for this decision on the IRB Action Response form. The principal investigator may revise and resubmit the protocol for another review or choose to appeal the decision (See Appeals).

Continuing Review

Federal regulations (45 CFR 46.109(e)) require any research involving human participants to be reviewed no less frequently than once every 12 months, if it has gone through full board review. Regulations require the continuing review process to be substantive in nature and include all considerations addressed in initial review activities. Each continuing review must be conducted in accordance with the federally provided guidance and interpretation of the regulations that are current as of the time of the continuing review.

Protocols determined to be non-research, exempt, or expedited are exempt from requirements related to continuing review. However, if a principal investigator decides to modify a protocol in such a way that it would no longer qualify as non-research, exempt, or expedited, the protocol will become subject to continuing review. The IRB reserves the right to review protocols that otherwise would not require continuing review. If such a review is conducted, documentation of the rationale for the review is required.

Pursuant to OHRP guidelines, the IRB review 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 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 project 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.

When a Continuing Review Report is submitted, the IRB shall consider the following, when appropriate:

- Changes to the research and/or the informed consent process and documents
- Protocol deviations since the last scheduled review

- Reports of unanticipated problems involving risks to subjects and noncompliance
- Data safety monitoring reports and investigator compliance

Procedure
The IRB administrator sends a Continuing Review form to the principal investigator 45 days before the due date. By the due date, the principal investigator submits to the IRB administrator the completed Continuing Review Report, noting the status of either continuing or final (see Final Report). Current consent documents must be submitted if the principal investigator has either enrolled participants in the project within the past year or is currently enrolling participants. The documents may be submitted electronically and must contain all required original or digital signatures.

The items will be distributed to the IRB chair or full board, as appropriate, for review.

Actions of the IRB
The reviewers may take one of the following actions in regard to the Continuing Review Report:

Approved
When the reviewers approve the Continuing Review Report, the chair signs and dates the form. The consent form (if one is included) is stamped with the Columbus State IRB number and includes the signature of the chair, effective date, and expiration date. An electronic copy will be sent to the principal investigator.

Modification Required
When the reviewers determine that modification or clarification is required to secure approval, the principal investigator will be notified and may be required to submit a Request for Modification form (see Modifications).

Disapproved
If the report fails to meet one or more of the criteria used by the IRB for the continued approval of research, the principal investigator will be informed of the reasons for this decision. The principal investigator may revise and resubmit the report for another review. The research cannot continue until the continuing review report is approved.

Final Report
Continuing review and re-approval of a research project at least annually is required so long as the project continues to involve human subjects. A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing

review. The Continuing Review Report is submitted by the principal investigator as a Final Report.

The Continuing Review/Final Report form is available on the Columbus State IRB website.

Additional Procedures

Principal investigators shall be informed at the time of protocol approval (both initial and continuing) that they must bring to the attention of the IRB any proposed modifications, unanticipated problems, or serious or continuing noncompliance in the research project which may affect the status of the research as it relates to the use of human subjects.

Modifications

Investigators are responsible for ongoing requirements in the conduct of approved research. This includes obtaining prior approval from the IRB for any modifications of the previously approved research before implementing the proposed modification.

Modifications are categorized into minor changes and significant changes.

Minor Modification

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.

Examples of minor changes to a research project 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 un-validated 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).

Minor modifications 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 meeting for concurrence.

Significant Modification

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 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.

Significant modifications will generally be reviewed at the same level of review in which the protocol 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.

Sponsor Modification
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 and will generally be reviewed at the same level in which the protocol was first reviewed. The investigator should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment, and follow-up of participants.

Procedure
Principal investigators seeking a modification for an approved research protocol will submit to the IRB administrator a completed Request for Modification form, along with any associated documents, for review. The form may be submitted electronically and must contain all required original or digital signatures.

The Request for Modification form is available on the Columbus State IRB website.

Actions of the IRB
The reviewers may take one of the following actions in regard to the request for modification:

Approved
When the reviewers approve the modification, the chair signs and dates the form. The consent form (if one is included) is stamped with the Columbus State IRB number and includes the signature of the chair, effective date, and

expiration date. Expiration date only appears on full protocols or protocols that require a continuing review. An electronic copy will be sent to the principal investigator.

Modification Required
When the reviewers determine that modification or clarification is required to secure approval, the principal investigator will be notified specifying the modification or clarification needed.

Referred to Full IRB
If a modification is determined to increase the level of risk beyond minimal risk, the IRB chair will refer the amendment to the full IRB. The principal investigator will be notified of this action.

Unanticipated Problems or Noncompliance

During the course of a research project, unanticipated problems involving risk to subjects or others and noncompliance may occur and need to be reported to the IRB. The IRB must ensure that the reporting and review of these events occur in a timely, meaningful way so that research participants can be protected from avoidable harms.

Definitions

- Unanticipated problems involving risk to subjects or others: Any information, including any incident, experience, or outcome that meets ALL three of the following criteria:
    1. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and the characteristics of the subject population being studied.
    2. Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
    3. Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.
- Noncompliance: Failure to follow the regulations, requirements and/or determinations of the IRB.
- Continuing noncompliance: A pattern of noncompliance that suggests the likelihood that, without intervention, instances of noncompliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.
- Serious noncompliance: Noncompliance that adversely affects the rights or welfare of subjects.

Unanticipated problems and noncompliance must be reported to the IRB within five business days of the knowledge or notification. Severe instances must be reported within one business day of the knowledge or notification.

Procedure
Principal investigators, or any person associated with the project, shall report any unanticipated problem or instance of noncompliance by submitting to the IRB administrator a complete Unanticipated Problems/Noncompliance form. The form may be submitted electronically and must contain all required original or digital signatures.

The Unanticipated Problems/Noncompliance form is available on the Columbus State IRB website.

Action of the IRB
Upon receipt, the IRB chair will review the report and determine if the report will be routed for expedited or full board review. The IRB will act within its authority as deemed necessary by each case (see Authority of the IRB). In some cases, a modification of the protocol may be necessary to eliminate apparent immediate risks to the subjects (see Modifications). The principal investigator will receive an acknowledgment letter that may or may not request additional actions.

Grievances
Upon receipt of grievances (e.g., of a research subject against a principal investigator), the IRB will investigate and act within its authority. (See Authority of the IRB)

Letter of Support to Recruit Columbus State Students or Employees
A letter of support to recruit Columbus State students, faculty, staff, or administrators will be considered as long as no College employees or agents will be engaged in the research study (see interpretation of engagement below).

Interpretation of Engagement of Institutions in Human Subjects Research from the Office for Human Research Protections (OHRP):

> In general, an institution is considered engaged in a particular human subjects research project when its employees or agents for the purposes of the research project obtain:
>
> 1. data about the subjects of the research through intervention or interaction with them;
> 2. identifiable private information about the subjects of the research; or
> 3. the informed consent of human subjects for the research.

Procedure
Principal investigators seeking a letter of support to recruit Columbus State students or employees will submit to the IRB administrator the required documents as stated

on the IRB website. The request may be submitted electronically.

The request will be reviewed by the IRB chair or other designated IRB member.

Action of the IRB
The reviewer may take one of the following actions in regard to the request for a letter of support:

Granted
When a request for a letter of support is granted, a letter is drafted with the specifics of the allowable activity and sent to the principal investigator.

Denied
When a request for a letter of support is denied, a letter is drafted stating the reasons for the denial and sent to the principal investigator.

PRINCIPLES OF INFORMED CONSENT

Informed consent is one of the primary ethical requirements underlying research involving humans; it reflects the basic principle of respect for persons. Informed consent is designed to provide potential research subjects or the subjects' legally authorized representative (LAR) with all of the relevant information a reasonable person would expect in order to assist them to make a fully informed, autonomous decision as to whether they wish to voluntarily participate in a research project. (45 CFR 43.116)

In the case where minors are involved in research, the IRB may accept the permission of the minors' parents or legal guardians, along with the assent (affirmative agreement) of the minors to participate in research. The IRB shall determine that adequate provisions are made for soliciting the assent of the minors, when in the judgment of the IRB, the minors are capable of providing assent and that adequate provisions are made for soliciting the permission of the minors' parents or guardians. Permission by parents or guardians shall be documented in accordance with the requirements as listed below. When the IRB determines that the assent of the minors are required, it shall also determine whether and how assent must be documented. This determination will be made on a case-by-case basis and take into consideration the age, maturity, and degree of literacy of the minors that may be participating in the research. In most cases, where applicable, the assent of the minor will take the form of a signature alongside the consent signature of the parent or guardian.

General Requirements of Informed Consent

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the informed consent of the subject/LAR.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject/LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of

coercion or undue influence.

3. The information that is given to the subject/LAR shall be in language understandable to the subject/LAR.
4. The prospective subject/LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject/LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
6. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's/LAR's understanding of the reasons why one might or might not want to participate.
7. No informed consent may include any exculpatory language through which the subject/LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements of Informed Consent

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. One of the following statements about any research that involves the collection

of identifiable private information or identifiable biospecimens:

a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research projects or distributed to another investigator for future research projects without additional informed consent from the subject/LAR, if this might be a possibility; or
b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research projects.

Additional Elements of Informed Consent
The elements listed below are only applicable when appropriate.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's/LAR's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Broad Consent
Broad consent will not be implemented at Columbus State at this time.

General Waiver or Alteration
The IRB may waive or alter the requirement to obtain informed consent for research if the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects.

2. The research cannot practicably be carried out without the requested waiver or alteration.
3. If the research involves using identifiable private information or identifiable biospecimens, the research cannot practicably be carried out without using such information or biospecimens in an identifiable format.
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
5. Whenever appropriate, the subjects/LARs will be provided with additional pertinent information after participation.

Screening, Recruiting or Determining Eligibility
The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject/LAR, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject/LAR.
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Documentation of Informed Consent
Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed, including in an electronic format, by the subject/LAR. A written copy shall be given to the person signing the informed consent form.

The informed consent form may be either of the following:

1. A written informed consent form that meets the requirements as stated above. The investigator shall give either the subject/LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject/LAR.
2. A short form written informed consent form stating that the elements of informed consent required by this policy have been presented orally to the subject/LAR, and that the key information was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject/LAR. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject/LAR. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject/LAR, in addition to a copy of the short form.

OHRP recommends that IRBs affix the approval and expiration dates to all approved informed consent documents and stipulate that copies of these dated documents

must be used in obtaining consent. This procedure helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review. Expiration dates are affixed only to consent documents for protocols requiring continuing review.

Principal investigators obtaining signed consent forms must retain the original signed forms for at least three years beyond the termination of the subject's participation in the proposed research activity.

Waiver of Written Consent

The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject/LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
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.
3. If the subjects/LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects/LARs with a written statement regarding the research.

Procedure

Any waiver of documentation of written consent by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the principal investigator must be explicitly requested and include justifiable reasons in the initial protocol or modification request. Being granted a waiver documentation of written consent does not eliminate the investigator's obligation to obtain informed consent from research subjects before they begin their participation in the project.

Guidelines for drafting consent forms and cover letters are available on the Columbus State IRB website.

OPERATIONS OF THE IRB

The IRB will review research at convened meetings at which the majority of members are present. The agenda and protocol material to be reviewed are distributed to IRB members seven days prior to the meeting. Meeting dates are posted on the Columbus State IRB website.

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. 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 (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 principal investigator 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 form. Upon written notification of appeal from the principal investigator, 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 principal investigator 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 principal investigator 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.

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, if applicable.
4. Copies of all correspondence between the IRB and the investigators.
5. Any statements of significant new findings provided to subjects.
6. Unanticipated problem, noncompliance, and grievance reports; and documentation of the IRB action taken in response to such reports.
7. Any suspension or termination of IRB approval.
8. All Modification forms and attachments, if provided.
9. General project information provided to subjects (e.g., fact sheets, brochures).
10. Documentation of the rationale for conducting continuing review of research that otherwise would not require continuing review.
11. Documentation of the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
12. Written procedures for the function and management of the IRB.
13. A list of the IRB members identified by name; terms of service; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

These records shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The College or IRB may maintain the records in printed form or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

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 a principal investigator or co-principal 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;
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 he or she 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 he or she is assigned as a reviewer immediately upon receipt of materials to determine whether he or she 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 he or she has, or may be perceived to have, a potential conflict of interest.

AUTHORIZATION AGREEMENTS

The Columbus State IRB can serve as the IRB of record for other institutions and can rely on another IRB for review and continuing oversight when there is an IRB Authorization Agreement (or equivalent document) in place as an effort to avoid duplication of effort. This is at the discretion of the Columbus State IRB and will only be done in cases where the other institution has a valid Federalwide Assurance.

Investigators must request authorization agreements prior to conducting human subjects research on new studies, and before adding new research team members or study sites to approved studies.

The primary factors the IRB considers when reviewing an Authorization Agreement request are, when applicable:

- The qualifications of the investigator
- The external IRB
- The research methods and procedures
- The study population
- Where the research is taking place
- Any risk to participants
- What research activities will be conducted by each institutions' investigator(s)

While authorization agreements help investigators avoid duplicate IRB review, they do not lessen investigators' responsibilities for oversight of the research at all institutions and sites. It is also important to note that institutions, not investigators, make the final determination about whether an authorization agreement can be executed, and which IRB will be the IRB of record.

Procedure
Investigators requesting the Columbus State IRB cede review (relying IRB) to an external IRB (IRB of record) will submit to the Columbus State IRB administrator a completed Authorization Agreement Request form, along with a copy of the protocol, consent documents, approval letter from the external IRB, any other relevant study documentation submitted to the external IRB, and evidence of formal training (when applicable). The documents may be submitted electronically.

Investigators requesting the Columbus State IRB serve as the IRB of record will submit to the Columbus State IRB administrator the protocol form and associated documents appropriate for the research project (see Initial Review), along with a completed Authorization Agreement Request form. For approved studies, investigators will submit the Authorization Agreement Request form along with a Request for Modification form (see Modifications).

The Authorization Agreement Request form is available on the Columbus State IRB website.

The IRB chair will review the request and determine if the request will be routed for expedited or full board review.

Actions of the IRB
The IRB may take one of the following actions in regard to the request for an Authorization Agreement:

Approved
The investigator and external IRB contact person will receive notification of the approval of the request. (See Procedure for the Execution of the Authorization Agreement)

Modification Required
The investigator and external IRB contact person will receive notification of the requested modification. An exchange will result to resolve the issues, as appropriate.

Procedure for the Execution of the Authorization Agreement
After the Authorization Agreement Request is approved, the Authorization Agreement is signed by the Columbus State signatory official. The external IRB contact person will receive an electronic copy with a request for the signature of the external institution's signatory official. The agreement will become effective upon the date of the last signature and will remain in effect until either: (i) the conclusion of the listed research project or (ii) such time that either institution provides 30 days written notice of termination to the other institution.

The document must be kept on file at both institutions and provided to OHRP upon

request.

When Columbus State is the relying IRB, the investigator will receive an electronic copy of the signed agreement to signify final approval and may begin the research activity as it relates to Columbus State.

When Columbus State is the IRB of Record, the investigator will receive an electronic copy of the signed agreement along with the IRB Action Response or approved modification.

APPENDIX 1 – IRB Registration

From: <jmaklc@osophs.dhhs.gov>
To: <sstumpp@cscc.edu>, <doolomar@cscc.edu>, <vmoeller@cscc.edu>, <sstumpp@c
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: <jmaklc@osophs.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 (IORG) 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 20852
(240) 453-6903
Toll-Free within the U.S. (866) 447-4777

APPENDIX 2 – Federalwide Assurance

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 3 – Definitions of Key Terms

Human subject - a living individual about whom an investigator is conducting research by obtaining information or biospecimens through intervention or interaction with the individual, and using, studying, or analyzing the information or biospecimens; or by obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens.

Intervention - includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction - includes communication or interpersonal contact between investigator and subject.

Legally authorized representative (LAR) - an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minor – any person who has not reached the age of 18.

Private information - includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

> **Identifiable private information** - private information for which the identity of the subject is, or may readily be, ascertained by the investigator or associated with the information.

Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. However, the following activities are deemed not to be research for the purposes of this policy: scholarly and journalistic activities, public health surveillance activities, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions.

Significant financial interest - A financial interest of monetary value - whether that

value can be easily determined or not - that belongs to any of the following: the investigator, the investigator's spouse, or any dependent children.

Written or in writing - refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

Revision and Editorial History

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