



Institutional Review Board

Charter and Standard Operating Procedures

October 15, 2012

Institutional Review Board #IRB00008704, Owens State Community College IRB #1

This Charter and Standard Operating Procedures establishes and empowers the Owens State Community College (OSCC) Human Subjects Protection Committee.

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TABLE OF CONTENTS

INTRODUCTION	1
INSTITUTIONAL AUTHORITY	1
PURPOSE.....	3
BASIC PRINCIPLES	3
THE AUTHORITY OF THE IRB	4
THE IRB’S FUNCTIONAL RELATIONSHIPS	5
THE MEMBERSHIP OF THE IRB	6
MANAGEMENT OF THE IRB	7
PROCEDURES OF THE IRB	8
Initial Review	8
Exempt Human Subjects Protocol.....	8
Actions of the IRB	9
Full Human Subjects Protocol	10
Actions of the IRB	11
Continuing Review.....	12
Procedures Pertaining to Both Initial and Continuing Review.....	13
Adverse Event Reporting Guidance and Procedures.....	14
OPERATIONS OF THE IRB	14
Voting Requirements	15
Appeals.....	15
Modifications	15
Level of Review for Modifications	16
Sponsor Modifications	16
Grievances.....	16
Cooperative Activities.....	16
RECORD REQUIREMENTS.....	17
Records of the IRB.....	17
Research Data	18
Definition	18
Collection and Retention.....	18
Transfer in the Event an Investigator Leaves OSCC.....	18
INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.....	19
PRINCIPLES OF INFORMED CONSENT	20
CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.....	23
OWENS STATE COMMUNITY COLLEGE IRB APPROVAL DOCUMENT (Appendix A)	24
OWENS STATE COMMUNITY COLLEGE FWA APPROVAL DOCUMENT (Appendix B)	25

Owens State Community College Institutional Review Board Charter and Standard Operating Procedures

INTRODUCTION

Owens State Community College (OSCC) encourages and supports the scholarly endeavors of students, faculty, and staff of the College. Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. OSCC's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel and students are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the Owens State Community College Institutional Review Board.

The Institutional Review Board (IRB) for Human Subjects Research at Owens State Community College has responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled confidentially. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

INSTITUTIONAL AUTHORITY

Owens State Community College Policy 3358:11-4-19 establishes, empowers, and defines the role of the Owens State Community College Institutional Review Board. Currently, OSCC has one committee registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board #IRB00008704 Owens State Community College IRB #1 (see Appendix A). This committee is hereinafter referred to as "the IRB."

- (A) *Purpose.* The board of trustees establishes an institutional review board for the purpose of protecting the rights and welfare of human subjects in research.
- (B) *Definitions.* "Research" at the college means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

“Generalizable knowledge” means findings of the research will be made public (e.g. at a conference, published in a journal or book, etc.)

“Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, **or** (2) identifiable private information.

Intervention includes both physical procedures by which data 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. **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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

“Institutional Review Board” means an independent administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

“Minimal Risk” means 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.

- (C) *Application.* Owens State Community College is a publicly funded institution of higher education and is required to comply with federal, state, local laws, regulations and professional protocols. Specifically, 45 C.F.R. 46.101 for protection of human research subjects shall apply to the institutional review board and to individuals who conduct research at/for/or in sponsorship of Owens State Community College, regardless of the source of funding.
- (D) *Authorization.* The institutional review board is authorized to take administrative action to apply federal, state and local regulations as well as professional protocols, procedures and guidelines for the purpose of protecting the rights and welfare of human subjects in research conducted at/for/or in sponsorship of Owens State Community College.
- (E) *Implementation.* The college’s chief academic officer shall make appointments to the institutional review board. The institutional review board shall review all research involving human subjects, and the board shall function under the direction of the assigned

institutional official, who is responsible for research oversight and whose office shall support the activities of the institutional research board.

The Owens State Community College Institutional Review Board Standard Operating Procedures explains how the IRB operates.

1. The Institutional Review Board (IRB) will be appointed by the Chief Academic Officer and will function under the direction of the Office of the Provost which 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 on behalf of Owens State Community College, related to OSCC employment or academic studies, or personal research unrelated to a planned academic program of study at another college or university that is conducted by Owens employees or students must be reviewed and approved in writing by the IRB before the research is initiated.
4. Owens State Community College employees or students conducting research studies, projects, and surveys or others conducting studies, projects, and surveys utilizing OSCC employees or students as subjects will consult the Owens State Community College's Institutional Review Board (IRB) website for guidelines or contact the IRB Administrator in the Provost's Office for assistance.

PURPOSE

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

BASIC PRINCIPLES

The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("[The Belmont Report](#)") published by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

Therefore, the following principles apply to all research, including student projects, involving human subjects at OSCC 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 to ensure that the selection of subjects is equitable and takes into account the purposes of the research, the setting in which the research will be conducted, and the special problems of research involving vulnerable populations.
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7. All research programs that involve human subjects must be reviewed by, and must receive approval of, a formally constituted review committee *prior* to their initiation or *prior* to initiating any changes to the protocol (i.e. amendments, see Modifications, Level of Review for Amendments). Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

THE AUTHORITY OF THE IRB

OSCC holds a Federal-wide Assurance (FWA) through OHRP (see Appendix B). As part of this Assurance, OSCC 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 (unless the research is conducted at another institution with which OSCC has an “IRB Authorization Agreement” as specified in OSCC’s FWA), or
2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which OSCC has an “IRB Authorization Agreement” as specified in OSCC’s FWA), or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, he/she

is encouraged to complete a protocol for approval and submit it, along with any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

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

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

The IRB has the authority to determine the human subject research protocols that may be conducted at OSCC, and can disapprove, modify, approve, suspend, or terminate studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Institutional Official, who is appointed by the Chief Academic Officer, and responsible for research oversight within the institution. However, the Institutional Official may not approve the non-exempt research if it has not been approved by the IRB.

The IRB has authority to:

1. require progress reports from the investigators and oversee the conduct of the study,
2. suspend or terminate approval of a study, or to place restrictions on a study,
3. observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population, and
4. access, and 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 on-going research.

THE IRB'S FUNCTIONAL RELATIONSHIPS

The IRB functions administratively through the Institutional Official. This structure provides for administrative coordination for the IRB with the various academic and administrative units at OSCC.

The IRB advises and makes recommendations to the Chief Academic Officer, to policy and administrative bodies, and to any member of the OSCC 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 5 but not more than 11 voting members. Alternate members may also be appointed who are authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made by the Chief Academic Officer and reported to OHRP.

The IRB Administrator, a non-voting member of the IRB, will be appointed by the Chief Academic Officer and will be responsible for the overall management of the IRB.

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

1. Each protocol submitted to the IRB Administrator will be reviewed prior to being scheduled for initial review to determine whether special expertise is needed.
2. The determination of whether special expertise is needed will be made by the Institutional Official, on the basis of the following criteria: the availability of behavioral expertise for the review of behavioral studies, and the availability of individuals (IRB Members or consultants) with experience with particular vulnerable populations.
3. Experts will be selected by the IRB Institutional Official from the IRB's roster of members and consultants.
4. If an IRB member is selected, the member's feedback will be included in the member's normal review of the protocol. If a consultant is selected, the consultant's feedback will be in the form of a written report which will be shared with IRB members as soon as practical before the initial review of the protocol.

The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with OSCC. No more than two persons can be from the same academic school.

No person shall be excluded from serving on the IRB based on age, color, disability, national origin, race, religion, sex, sexual orientation, gender identity, military status, or veteran status.

MANAGEMENT OF THE IRB

The IRB Chair is appointed in writing by the Chief Academic Officer from current committee members. The Institutional Official, in consultation with Deans of the various schools, makes recommendations to the Chief Academic Officer regarding membership. The IRB Chair is a voting member of the IRB and presides over all convened IRB meetings. The Chair has authority to authorize all IRB action items.

The IRB Vice-Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice-Chair is appointed by the Chief Academic Officer and has authority to authorize all IRB action items in the absence of the Chair and is responsible for communication to the principal investigator.

The IRB Secretary is a voting member of the IRB and takes and distributes the minutes of the IRB. The Secretary is elected by the IRB membership.

Members and alternates of the IRB shall serve for three (3) years. Initial appointments shall be made for one, two, or three years. Members may resign from the IRB by notifying the Chair in writing. The term of appointment may be terminated by notice from the Chair. If a member is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chief Academic Officer will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

IRB Officers shall serve for one year renewable terms.

The IRB receives staff support from the IRB Administrator.

All IRB members are required to undergo formal training at the time of their initial appointment. Training that satisfies this requirement is the on-line tutorial offered by OHRP (see <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>) and is good for three years. The IRB Administrator will maintain evidence of training completion. Continuing education of IRB members is accomplished through "Information Items" attached to meeting agendas on an "as needed" basis and through maintenance of links on the College's IRB web site.

IRB members do not receive compensation for their service.

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

Consultants with competence in special areas may be used when deemed appropriate.

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

Conflict of interest policy and procedure:

1. Investigators shall not be involved in the selection of IRB members.
2. Investigators and IRB members who are OSCC employees and who apply for federal grants and contracts are subject to the [OSCC Model Ethics Policy](#) .

PROCEDURES OF THE IRB

Initial Review

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

Exempt Human Subjects Protocol

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise (See [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101\(b\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b))).

Exempt types of research include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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

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

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

Actions of the IRB

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

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

Full Human Subjects Protocol

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

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

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) From healthy, 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; or
 - (b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; examples include
 - (a) weighing or testing sensory acuity;
 - (b) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
6. Continuing review of research previously approved by the convened IRB as follows:

- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- (b) where no subjects have been enrolled and no additional risks have been identified; or
- (c) where the remaining research activities are limited to data analysis.

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

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

Protocols for full-board IRB review must be submitted fourteen (14) working days prior to the regularly scheduled IRB meeting.

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

Actions of the IRB

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

1. *Not Research* - When a protocol is determined not to constitute research, it will be returned to the principal investigator with a completed *Approval and Determination* form.
2. *Approved* - When the IRB approves the protocol, the Chair signs and dates it. The consent form (if one is included) on the protocol face page is stamped with the OSCC IRB number and the Chair signs there also. Copies will be returned to the Principal Investigator with a completed *Approval and Determination* form. The original is maintained in the IRB files.

Approval of the protocol will be based on the following:

- a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.
- b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.

- c. Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.
 - d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.
 - e. Anticipated benefits, if any.
 - f. The personal risk to the subject in relation to expected benefits.
 - g. The adequacy of procedures for securing informed consent from the subject.
 - h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.
 - i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.
3. *Approved Subject to Conditions*- If the protocol is approved subject to conditions, the Chair completes the *Approval and Determination*, signs and dates it, and sends the form with a memo to the PI outlining the restrictions. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above.
 4. *Tabled* - A protocol is tabled when it was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.
 5. *Not Approved* - If the protocol is not approved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

Continuing Review

Protocols determined to be exempt are also exempt from requirements related to continuing review. However, if an investigator decides to modify an exempt human subjects research project in such a

way that it would no longer qualify for exemption, the investigator must submit the modified research protocol to the IRB for review prior to implementation of the modified research project.

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

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

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

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

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

Procedures Pertaining to both Initial and Continuing Review

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

PIs shall be informed at the time of protocol approval (both initial and continuing) that they must immediately bring to the attention of the IRB Chair any proposed changes (see Modifications), any

unanticipated adverse events (see Adverse Events), or any serious or continuing noncompliance in the program which may affect the status of the research as it relates to the use of human subjects.

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

Adverse Event Reporting Guidance and Procedures

The federal Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

All PIs and all OSCC employees are required to report to the Chair of the IRB any of the following upon knowledge of:

1. Unanticipated problems involving risks to subjects or others; and
2. Serious or continuing non compliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the OSCC IRB, the Chief Academic Officer, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

OPERATIONS OF THE IRB

There is at least one IRB meeting scheduled every month. The meetings will be convened if needed.

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

The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new protocol, who receive the complete study documentation for review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers who are assigned based on their expertise lead the discussion of that protocol. Other IRB members are required to review summary information only, although they will be provided with the complete study documentation. If external reviewers are assigned, they must be subject to the same conflict of interest policies as IRB members.

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 non-scientific areas.
2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. 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 PI may appeal the decision of the IRB. A written request for appeal must be presented to the IRB Administrator within thirty days of the date on the **IRB Action Response: Not Approved** form. Upon written notification of appeal from the PI, the IRB shall name an ad hoc committee of three or more faculty and/or consultants to review the protocol a second time. The ad hoc committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the ad hoc committee will be referred to the IRB. The PI will be promptly notified of actions of the ad hoc committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

Modifications

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

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

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

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

- Addition or deletion of study team members;

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

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

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Level of Review for Modifications

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

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

Sponsor Modifications

Sponsor generated modifications (or addenda) require review and approval by the IRB and can be made only to IRB approved studies. However, the research protocol may be amended before the study has received final approval from the IRB. If this occurs, investigators must await receipt of the IRB approval letter before proceeding with the research.

For sponsor modifications, the investigator should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested, the board will act within its authority. (See Authority of the IRB)

Cooperative Activities

Cooperative activities relating to human subjects are those which involve OSCC and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions have Federalwide Assurances (FWAs) approved by OHRP;
2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and
3. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The Institutional Official will verify (via the OHRP website) that the other institutions have approved FWAs.

RECORD REQUIREMENTS

Records of the IRB

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

1. Copies of all research proposals reviewed and scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Detailed minutes of IRB meetings, showing:
 - a. Members present (any consultants/ guests/others shown separately).
 - b. Results of discussions on debated issues and record of IRB decisions.
 - c. Record of voting (showing votes for, against, and abstentions)
3. Records of continuing review activities, updated consent documents, and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.
4. Copies of all correspondence between IRB and the investigators.
5. Any statements of significant new findings (unanticipated risks or adverse events) provided to subjects.
6. Adverse event reports and documentation that the IRB reviews such reports.
7. All Modification forms and attachments, if provided.
8. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after the final project closeout, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug

Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

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

Research Data

Definition

Research data include laboratory notebooks, as well as any other primary records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, including subject informed consent forms, regardless of the form of the media on which they may be recorded.

Collection and Retention

Under federal regulations, OSCC must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of research.

The PI is responsible for the collection, management, and retention of research data. Research data must be archived electronically on the institutional IRB drive for a minimum of five¹ years after the final project closeout, with primary data included. In addition, any of the following circumstances may justify longer periods of retention:

1. If the terms of a sponsored research agreement administered by OSCC require a longer retention period;
2. Data must be kept for as long as may be necessary to protect intellectual property resulting from the work;
3. If any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained for a minimum of seven years as required by federal regulation, or until such charges are fully resolved; and
4. If a student is involved, data must be retained at least until the degree is awarded, or until it is clear that the student has abandoned the work.

Beyond the period of retention specified here, the destruction of research records is at the discretion of the institution. Records will be retained on the institutional IRB drive. For additional information regarding specific records retention procedures see the [OSCC Records Retention Manual](#).

Transfer in the Event an Investigator Leaves OSCC

In general, when the principal or co-investigators involved in research projects at OSCC leave the college, they may take copies of the research data for projects on which they have worked.

¹ Maintaining records for five years after final project closeout is based on the longest required retention period under the various applicable federal regulations.

As required by academic practice, the use of such data (for example, to conduct additional research, or for presentation or publication) is dependent on the agreement with the PI, or as may be formally agreed-upon beforehand by the PI and other co-investigators in a data use agreement. In all cases, the PI must retain the research data on the OSCC IRB drive. If a PI leaves OSCC or a project is moved to another institution, the research data may be transferred with the approval of the dean of the school employing the PI, the Institutional Official, and with the agreement from the new institution, which, at a minimum, shall provide:

1. Adoption by the new institution of all custodial responsibilities for the data, including acceptance of all OSCC and federal security requirements for restricted data that is transferred;
2. Formal recognition of OSCC's continued ownership of the data by the new institution; and
3. Guaranteed access by OSCC to all project data, should such access become necessary.

INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB

- A. Professional qualifications to do the research including a description of necessary support services and facilities and evidence of completion of the online [tutorial](#) offered by OHRP.
- B. Appropriate OSCC review form including protocol summary.
- C. Complete study protocol which includes/addresses:
 1. Title of the study and summary of the research to be conducted,
 2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),
 3. Sponsor of the study,
 4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),
 5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),
 6. Study design (including, as needed, a discussion of the appropriateness of research methods),
 7. Description of procedures to be performed,
 8. Provisions for managing adverse reactions,

9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,
 10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Ohio as an individual under the age of 18), using legally authorized representatives, witnesses, translators and document storage,
 11. Remuneration to subjects for their participation, if any,
 12. Any compensation for injured research subjects,
 13. Provisions for protection of subject's privacy,
 14. Extra costs to subjects for their participation in the study, if any,
 15. Inclusion/exclusion of women, minorities, and/or children;
- D. Investigator's brochure (when one exists);
- E. The case report form (when one exists);
- F. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;
- G. Copies of advertisements and surveys, questionnaires, or other materials provided to subjects (Surveys and questionnaires contained in grants can be provided at initial review or prior to administration);
- H. Copies of relevant grant applications (if any);
- I. Agency permission for access to subjects/resources/data to complete the study;
- J. Requests for changes in study after initiation including changes to consent forms;
- K. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports; and
- L. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

PRINCIPLES OF INFORMED CONSENT

When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists, (e.g., participation in a research project), the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving

consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or OSCC as indicated below.

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

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

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

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

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

"Informed consent" means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at [OHRP Informed Consent Guidance](#). The IRB may approve a telephonic consent procedure under which the subject's legally authorized representative ("LAR") is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

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

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

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

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

Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which *it is proposed to mislead the subjects* during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

Guidance for drafting consent forms or cover letters is presented in the [OHRP Informed Consent Guidance](#).

CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

An IRB member is said to have a conflicting interest whenever that IRB member, family member, or anyone with whom the member has a business or employment relationship:

1. Is an investigator or sub-investigator on the protocol;
2. Has an “interest” in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could result in financial benefit to the IRB member, family member, or anyone with whom the member has a business or employment relationship (see the Board of Trustees 3358:11-4-11 Ethics Policy)
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified him or herself for any other reason as having a conflicting interest.

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

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

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

APPENDIX A- OWENS STATE COMMUNITY COLLEGE IRB APPROVAL DOCUMENT

From: Charmaine.Anderson@hhs.gov

To: Debra Rathke, Denise Shuster, Renay Scott

Subject: Electronic IORG-IRB Registration for Owens State Community College Processed by OHRP as IORG0007253

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

The registration submitted electronically for your institutional review board (IRB) organization (IORG) has been reviewed and accepted by the Office for Human Research Protections (OHRP) and assigned IORG0007253. The IORG number represents the overall registration, with each IRB receiving a distinct identification number. The following IRB(s) are registered with OHRP:

IRB00008704 Owens State Community College IRB #1

This registration is listed on our website at <http://ohrp.cit.nih.gov/search/search.aspx>. Funding agencies use this website to verify that an institutional review board (IRB) has an active registration.

Whenever information provided to OHRP changes for this IORG-IRB registration regarding the contact person who provided the IRB registration information or the IRB chairperson, your organization must submit an update/renewal within 90 days of the change. You must do this electronically via the OHRP website at <http://ohrp.cit.nih.gov/efile/>, unless your institution or organization lacks the ability to register its IRBs electronically.

The IORG-IRB registration must be renewed at least every 3 years. The expiration date for your IORG-IRB Registration is 2/15/2015 8:31:49 AM.

When an IRB registration submission has been reviewed and accepted by OHRP, an automatically generated e-mail notifies the person submitting the electronic record, the Information Provider, the chairperson(s) of the IRB(s), and the Senior Officer or Head Official on the Institution or Organization operating the IRB that the document has been reviewed and accepted by OHRP. This, of course, is dependent upon the electronic file submitted to OHRP providing correct 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 B - OWENS STATE COMMUNITY COLLEGE FWA APPROVAL DOCUMENT

From: Hal.Blatt@hhs.gov

To: Debra Rathke; Thomas Perin

Subject: Electronic FWA Application for Owens State Community College Approved by OHRP as FWA00018805

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, Owens State Community College, is FWA00018805. The expiration date for your FWA renewal is 04/25/2017. You will find this approval listed on our website at <http://ohrp.cit.nih.gov/search/search.aspx>. Funding agencies use this website to verify that an institution holds an active OHRP-approved FWA.

Your institution's FWA is effective for 5 years and must be renewed by the end of that period in order to remain effective. In addition, your institution must update its FWA within 90 days after changes occur regarding:

- the legal name of the Institution,
- the Human Protections Administrator, or
- the Signatory Official.

All updates and renewals of the FWA must be submitted electronically using the OHRP Electronic Submission System at <http://ohrp.cit.nih.gov/efile>, unless your institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it should contact OHRP by telephone (see <http://www.hhs.gov/ohrp/assurances/status/contact/index.html>) or in writing and explain why it is unable to submit its FWA electronically.

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. A copy of the approved FWA is also attached to the email. Of course, this depends on correct e-mail addresses being provided for these individuals.)

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