OKLAHOMA CITY COMMUNITY COLLEGE

NO. 6000 INSTITUTIONAL REVIEW BOARD

1. Introduction

1.1. Purpose: To ensure that all research involving human subjects is conducted in conformance with ethical principles relating to the health, welfare, safety and rights of the participants, and in accordance with policies and regulations established by the United States Department of Health and Human Services, Oklahoma City Community College (OCCC) has established an Institutional Review Board. The Institutional Review Board ("IRB") shall evaluate all human subject research as defined by this procedure and 45 CFR Part 46.

1.2. Scope: This procedure applies to all OCCC faculty, employees, and students of OCCC who propose to engage in Human Subject Research, development, and related activities. This procedure also applies to researchers who are not faculty, employees, or students of OCCC, but who propose to use human participants in research, development, and related activities affiliated with OCCC.

1.3. Definitions and Acronyms:

1.3.1. Acronyms: The following acronyms are commonly used:

1.3.1.1. CFR – Code of Federal Regulations
1.3.1.2. DHHS – United States Department of Health and Human Services
1.3.1.3. FDA – Food and Drug Administration
1.3.1.4. FWA – Federalwide Assurance
1.3.1.5. IEC – Independent Ethics Committee
1.3.1.6. IRB – Institutional Review Board
1.3.1.7. OHRP – Office for Human Research Protection

1.3.2. Definitions:

1.3.2.1. ***Approved Assurance*** means a written agreement between an Institution and a Federal Department or Agency that the Institution will comply with regulatory requirements of that Department or Agency.

1.3.2.2. ***Certification*** means the official notification by OCCC or other institution to the supporting federal department or agency, in accordance with this policy, that a research project or activity involving human subjects has been reviewed and approved by the IRB in accordance with an Approved Assurance.

1.3.2.3. ***Chair of the IRB*** is a regular voting member.

1.3.2.4. ***Department or Agency Head*** means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

1.3.2.5. ***Expedited Review*** means the IRB review process used when no more than a minimal risk to human subjects exists as explained in detail in Section 3.5 of this procedure.

1.3.2.6. ***Exempt Status*** means the status granted to a research proposal which falls into one or more of the categories listed in 45 CFR 46.101(b) and which is determined by the IRB or a primary reviewer to pose no risk to human subjects.

1.3.2.7. ***Generalizable Knowledge*** means knowledge expressed in conclusions, theories, principles and/or statements of relationship, for the purpose of benefiting people beyond those who are participants in the research or investigation. Although participants may benefit directly from the research or investigation, this benefit is never the only or the primary goal of the research or investigation. If publication or presentation is the intended outcome of the proposed project, it is likely that the project is intended for the purpose of developing or contributing to generalizable knowledge. However, a project may not be ruled out simply because there is no intent to publish or present the project results.[1]

1.3.2.8. ***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.

1.3.2.9. ***Human Subject Research*** means a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge and involving a living individual about whom the investigator conducting the research obtains data through intervention or interaction with the individual or identifiable private information.

1.3.2.10. ***Identifiable Private Information*** means Private Information (as defined in 45 CFR 46.116 and also defined in this document 1.3.2.17) in which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

1.3.2.11. ***Informed Consent*** means the legally effective consent obtained by the investigator from the subject or his or her representative, which satisfies the requirements set forth in 45 CFR 46.116 and section 2.3 below.

1.3.2.12. ***Institutional Review Board ("IRB")*** means the board at OCCC responsible for conducting initial and continuing reviews of, and providing oversight for all human subject research conducted on the OCCC campus or under the authority of OCCC.

1.3.2.13. ***IRB Approval*** means the determination of the IRB that the research has been reviewed and may be conducted within the constraints established by the IRB and other institutional and federal requirements.

1.3.2.14. ***Investigator (or researcher)*** means any faculty, staff, employee or student of OCCC or another institution who engages in any research activity.

1.3.2.15. ***Legally Authorized Representative*** means 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.

1.3.2.16. ***Minimal Risk*** means that 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.

[1] Amdur, Speers and Bankert (in Institutional Review Board: Management and Function, Bankert and Amdur, eds.).

1.3.2.17. ***Principle Investigator (or lead investigator) ("PI")*** means the lead investigator or researcher involved in an investigation and who is ultimately responsible for the project, its investigators, participants, human subjects, and data.

1.3.2.18. ***Private Information*** means 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).

1.3.2.19. ***Research/Investigate*** means (as defined by CFR part 46) a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

1.3.2.20. ***Research Subject to Regulation*** means research for which a federal department or agency has specific responsibility for regulating research activity.

1.3.2.21. ***Quorum*** of the IRB means a majority of the appointed members of the IRB including at least one member whose primary concerns are in a non-scientific area.

2. Researcher's Submission and Documentation:

2.1. Any faculty member, employee or student of OCCC, and any researcher from another institution, who wishes to engage in Human Subject Research must submit the following electronic copies to the Chair of the IRB no later than two weeks before the second Friday of the month.

2.1.1. IRB Application for Exempt, Expedited and Full Board;

2.1.2. Description of Research Proposal describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information. The Description of Research Protocol is defined more fully in section 2.2;

2.1.3. Copies of any questionnaires, surveys or similar instruments to be used in the proposed research;

2.1.4. Evidence of completion of the OHRP Human Subject Assurance Training modules for researchers (or equivalent training);

2.1.5. Informed Consent Forms;

2.1.6. For researchers from other institutions, copy of home institution's IRB approval;

2.1.7. Approval forms from applicable government agencies.

2.2. Description of Research Protocol. A paper describing the proposed research must be submitted prior to approval by the IRB. The description should contain the following sections: abstract, the protocol, research method, subjects, potential benefits, potential risks, management of risks, personnel, compensation, and other.

2.2.1. The Abstract should contain a summary of the proposed study including the duration of research, the main focus of the research, and a summary of the risks, benefits and risk management procedures.

2.2.2. The Protocol should be written in such a manner as to communicate easily the research proposal to those from diverse disciplines. It should contain the following information:

2.2.2.1. A brief literature review of prior research on the same topic or issue and why this research is needed.
2.2.2.2. A discussion of objectives, methods and potential results of the research.
2.2.2.3. Justification of the use of human subjects.
2.2.2.4. Explanation of specific questions and hypotheses to be tested.

2.2.3. The Method for data collection and research on human subjects must include an explanation of the interaction with the subjects. Any questionnaires or tests to be used in the research must be included as well as the procedure for protecting confidentiality. Any devices, new drugs, or sources of radiation not customarily encountered by the subjects in their daily lives must receive approval from the appropriate governmental organization prior to submission to the IRB. A tentative time line or flow chart should be included. Frequencies, duration, and locations should be included for each research tool used.

2.2.4. The Subjects section should include a discussion of the sample size and method of obtaining the sample group. Justification must be made for the use of members of the desired population especially those populations who have limited or no capability of providing informed consent. The use of pregnant women, human fetuses, neonates, children (under the age of eighteen), mentally disabled, economically disadvantaged, educationally disadvantaged, and prisoners require additional justification and explanation of adherence to the rules and standards of 45 CFR 46, subpart B, C, and D.

2.2.5. The Potential Benefits section should highlight the justification of the study focusing on the significance of new knowledge and its contribution to society.

2.2.6. The Potential Risks section must disclose all risk of harm or discomfort the subjects may experience as a result of the research including physical, psychological, or social. Violations of normal expectations should also be specified. Based on the researcher's knowledge, any extraordinary moral, legal or ethical concerns related to this type of research should be identified.

2.2.7. The Management of Risk section will explain the procedures for protecting and/or minimizing potential risks. The means of protecting confidentiality will also be discussed in this section. Assessment of the expected effectiveness of the risk management techniques should be included. This section should include the management of risks to both the individual and the sample population.

2.2.8. The Personnel of the research team and any additional organizations (such as OCCC) involved with the research should be listed. Included with the names should be the individual's qualifications for research and their role in the project. Documentation of approval and agreement from any personnel or department at OCCC or any other organization involved in the research should be included with this section.

2.2.9. The Compensation of Subjects section should discuss if or how the subjects will be compensated for their participation in the research as well as how this will influence the

subjects and the research. If extra credit is given for student participation, permission must be received from the appropriate instructor and consideration must be given to students opting not to be included in the research. If prizes are used, the researcher must provide the means of maintaining confidentiality of the participants as well as the means of ensuring equitable opportunity to receive a prize.

2.2.10. The Other section is used for the researcher to address any pertinent information not previously identified.

2.3. Informed Consent Forms: 45 CFR 46.116 states that "no investigator may involve a human being as a subject in research…unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." The purpose of an informed consent is to insure the safety and security of human subjects involved in research, to comply with federal regulations (45 CFR 46), and to protect the Oklahoma City Community College and the investigator from negligence or liability.

2.3.1. Rules of an Informed Consent: As stated in 45 CFR, "except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative 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."

2.3.2. Informed Consent Documentation: An informed consent shall contain the following information, according to this procedure and 45 CFR 46:

2.3.2.1. 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 which are experimental;

2.3.2.2. A description of any reasonably foreseeable risks or discomforts to the subject;

2.3.2.3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

2.3.2.4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

2.3.2.5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

2.3.2.6. 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;

2.3.2.7. 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; and

2.3.2.8. 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. (45 CFR 46)

2.3.3. Other Possible Informed Consent Documentation: When appropriate, an informed consent may require additional information according to the type of research involved. 45 CFR 46 describes examples related to specific types of research:

2.3.3.1. 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;

2.3.3.2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

2.3.3.3. Any additional costs to the subject that may result from participation in the research;

2.3.3.4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

2.3.3.5. 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; and

2.3.3.6. The approximate number of subjects involved in the study. (45 CFR 46)

2.3.4. Informed Consent Waiver: The informed consent shall be approved by the IRB, as according to this procedure, and the IRB may waive some components of the regulations if they meet one of the following criteria:

2.3.4.1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

2.3.4.1.1. Public benefit or service programs;

2.3.4.1.2. Procedures for obtaining benefits or services under those programs;

2.3.4.1.3. Possible changes in or alternatives to those programs or procedures; or

2.3.4.1.4. Possible changes in methods or levels of payment for benefits or services under those programs; and

2.3.4.1.5. The research could not practicably be carried out without the waiver or alteration. (45 CFR 46).

2.3.4.2. Also, the IRB may waive an informed consent procedure if the research process meets one or more of the following criteria:

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

2.3.4.2.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

2.3.4.2.3. The research could not practicably be carried out without the waiver or alteration; and

2.3.4.2.4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (45 CFR 46)

2.3.4.3. As further stated by 45 CFR 46, the informed consent does not "preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." And, as stated by federal regulations, "Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law."

3. Procedures for Initial Review of Research:

3.1. Submission: The Chair of the IRB must receive the investigator's electronic documents no later than two weeks before the second Friday of the month. The electronic documents include the following:

3.1.1. IRB Application for Exempt, Expedited and Full Board;

3.1.2. Description of Research Protocol describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information. The Description of Research Protocol is defined more fully in section 2.2;

3.1.3. Copies of any questionnaires, surveys or similar instruments to be used in the proposed research;

3.1.4. Evidence of completion of the OHRP Human Subject Assurance Training modules for researchers (or equivalent training);

3.1.5. Informed Consent Forms;

3.1.6. For researchers from other institutions, copy of home institution's IRB approval;

3.1.7. Approval forms from applicable government agencies.

3.2. Distribution: The Chair of the IRB will dispense to the appropriate IRB members electronic copies of the complete documentation no later than one week before an expedited or full review. If the Chair decides on an expedited review, the Chair will submit these forms to two members of the IRB. If the Chair or the expedited review team decides on a full review, the Chair will submit these forms to all members of the IRB.

3.3. Preliminary Evaluation: Upon receipt of the submissions described in section 3.1 above, the Chair of the IRB shall evaluate exempt status and then take one or more of the following actions:

3.3.1. Determine that the proposed research activity does not constitute Human Subjects Research, and, therefore, does not require IRB review. The Chair shall document this determination and provide an electronic copy of the Preliminary Evaluation Form to the researcher within two weeks of the meeting and keep an electronic record of the application forms for OCCC.

3.3.2. Determine that the proposed research activity involves human subjects but only in one or more of the categories set forth in 45 CFR 46.101(b), and is, therefore, exempt from IRB expedited and full review. The Chair shall document this determination and follow the process stated in 3.3.1.; or

3.3.3. Determine that the proposed research activity is Human Subjects Research that is eligible for expedited review under 45 CFR 46.110 and this policy, and involves no more

than minimal risk to human subjects. The Chair shall submit such proposals to two IRB members for expedited review; or

3.3.4. Determine that the proposed research activity is Human Subjects Research that is not exempt or eligible for expedited review, *e.g.,* involves more than a minimal risk to human subjects. The Chair shall submit such proposals to the full IRB for action at a convened meeting.

3.3.5. Determine that the proposed research activity is difficult to categorize as exemption status. If this occurs, the Chair may submit such proposals to two IRB members for them to evaluate exemption status.

3.4. Exempt Research Review Process: Upon receipt of the documents submitted in accordance with section 3.1, the IRB Chair shall perform the Exempt Review Process.

3.4.1. Categories of Research Eligible for Exempt Review Process: 45 CFR 46.101(b) sets out those categories of research that may be reviewed using the Exempt Review Process. However, if the IRB Chair determines that any risk to human subjects is posed by research which is otherwise exempt according to 45 CFR 46.101(b), the Chair shall determine the appropriate review status according to the process described in section 3.3. The following categories of research are eligible for the Exempt Review Process if they pose no risk to human subjects:

3.4.1.1. 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.

3.4.1.2. 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.

3.4.1.3. 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.

3.4.1.4. 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.

3.4.1.5. 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.

3.4.1.6. 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.

3.4.2. Categories of Research Not Eligible for Exempt Review Process: Even if a category of research is listed in section 3.4.1, human subjects research under that category is not eligible for the Exempt Review Process if it involves vulnerable populations, such as the following defined by 45 CFR 46 and this policy: "prisoners, mentally disabled persons, economically-deprived persons, pregnant women," and children under the age of eighteen.

3.4.3. Action: A proposed research activity to be reviewed under the Exempt Review Process as described in Section 3.3.

3.4.4. Communication: The Chair shall document the determinations as described in Section 3.3.

3.5. Expedited Review Process: Upon receipt of the electronic documents submitted in accordance with section 3.1, two appointed members of the IRB shall conduct the Expedited Review Process.

3.5.1. Categories of Research Eligible for Expedited Review Process: As authorized by 45 CFR 46.110(a), OHRP sets out the following categories of research which may be reviewed using the Expedited Review Process when no more than minimal risk to human subjects is involved:

3.5.1.1. 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 (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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.

3.5.1.2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3.5.1.3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring

manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3.5.1.4. 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.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

3.5.1.5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

3.5.1.6. Collection of data from voice, video, digital, or image recordings made for research purposes.

3.5.1.7. 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 HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

3.5.1.8. 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.

3.5.1.9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories two (2) through

eight (8) 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. (45 CFR 46).

3.5.2. Action: For the Expedited Review Process, the Chair shall select two members of the IRB (one of whom shall be a member who best represents the area of research contained in the proposal) to review the research proposal. The two members must reach consensus for the proposal to be accepted. The two IRB members shall have the authority to take one or more of the following actions:

3.5.2.1. Approve the proposal for one year or less;

3.5.2.2. Defer the proposal to allow the researcher to modify the proposal as requested before the next evaluation period for resubmission;

3.5.2.3. Submit the proposal to the entire IRB for further review if (a) the two members are unable to reach a consensus; (b) the two members recognize that the proposal poses more than a minimal risk to human subjects; or (c) another issue related to the proposal arises.

3.5.2.4. Communication to IRB: The expedited approval actions shall be provided in electronic form for all IRB members. Also, during the next subsequent meeting of the IRB, the selected reviewers shall discuss their approval actions.

3.5.2.5. Communication to Researchers: The two members of the IRB shall document all actions and any required modifications or clarifications, and shall provide these electronic records and, if applicable, the IRB Approval Form to the researcher. The chair will be included in all communications.

3.5.2.6. The Expedited Review Team is not authorized to reject a proposal (45 CFR 46).

3.6. Full Review Process: All submissions for initial review, continuing review, or review of modifications to previously approved research determined by the IRB Chair to not be eligible for exemption or review by expedited procedures must be reviewed and approved at a fully convened IRB meeting. The IRB follows this process to conduct a thorough review of each protocol, in accordance with federal regulations (45 CFR Part 46 and 21 CFR 50 and 56).

3.6.1. Action: The members must reach consensus for the proposal to be accepted. The IRB members shall have the authority to take one or more of the following actions:

3.6.1.1. Approve the proposal for one year or less;

3.6.1.2. Defer the proposal to allow the researcher to modify the proposal as Requested before the next evaluation period for resubmission;

3.6.1.3. Disapprove the proposal and prepare a statement of action to the investigator and other involved agencies; or

3.6.1.4. Communication to Researchers: The IRB shall document all actions and any required modifications or clarifications, and shall provide these electronic records and, if applicable, the IRB Approval Form to the researcher.

3.6.2. Communication from Researchers: All researchers have the right to respond to any of the IRB decisions.

4. Procedures for Review of Continuing Research: All Human Subjects Research activities that have been approved by the IRB through the Exempt Review, Expedited Review or Full IRB Review Process are subject to continuing review. The Continuing Review shall be performed at

intervals appropriate to the degree of risk involved in the research activity, but not less than once a year, and shall meet the following criteria:

4.1. Continuing IRB review must be substantive and meaningful**.**

4.2. Continuing IRB review may be conducted using the Expedited Review Process if it satisfies the requirement of Section 3.5.1.9. In the case of Expedited Review of Continuing Research, the appointed two members of the IRB shall receive and review all of the information described in section 4.3. The expedited reviewers shall document the specific permissible categories justifying the expedited review and the review and action taken by the two IRB members, and any findings required under federal regulations.

4.3. In conducting continuing review of research not eligible for Expedited Review, all IRB members should receive and review at least a protocol summary and a status report on the progress of the research, including (i) the number of subjects accrued; (ii) a summary of any adverse events or unanticipated problems involving risks to subjects or others and of any withdrawal of subjects from the research or complaints about the research since the last IRB review; (iii) a summary of any relevant recent literature, findings obtained thus far, amendments or modifications to the research since the last review, any relevant multi-center trial reports, and any other relevant information, especially information about risks associated with the research; and (iv) a copy of the current informed consent document.

4.4. The minutes of the IRB meetings must document separate deliberations, actions and votes for each protocol undergoing continuing review by the convened IRB.

5. Procedures for Review of Protocol Changes: A researcher shall not implement any changes to an IRB approved protocol without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects. If after a research proposal is approved and the researcher desires to modify the research process in a way that differs from the approved proposal, the investigator shall obtain approval from the IRB by submitting to the Chair an addendum to the original proposal.

5.1. As required by 45 CFR 46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a Quorum is present, except where expedited review is appropriate under 45 CFR 46.110(b)(2).

5.2. Minor changes in previously approved research may be approved under an expedited process in accordance with 45 CFR 46.110(b)(2). The IRB shall adopt policy describing the types of minor changes in previously approved research by means of an Expedited Review Procedure.

6. Suspension or Termination of IRB Approved Research: The IRB has the authority to suspend or terminate previous approval of research that is not conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

6.1. If the ongoing research is not conducted in the manner described in the approved proposal or if potential or immediate risk of harm is elevated during the approved period, the IRB shall have the right to require the investigator to modify the proposal for an expedited or full review, and or to evaluate the approved proposal for termination of approval.

6.2. Any suspension or termination of approval shall include a statement of the reasons for the IRB's actions and shall be reported promptly to the researcher, the appropriate institutional officials, the Department or Agency Head, and others as appropriate. This statement of action shall be submitted in writing by the IRB.

7. Appeals

7.1. Appeals: If the application is disapproved, a principal investigator may appeal by requesting a second review by the IRB. The principal investigator must submit the request in writing and include a specific response addressing the IRB comments on the Report to Investigator. Every attempt will be made to resolve the identified problem(s). Decisions of the IRB on a second hearing represent the final decision of the IRB and the final decision of OCCC. The principal investigator, however, may appeal to the Vice President for Academic Affairs on procedural irregularities. If on appeal the Vice President of Academic Affairs determines that the IRB failed to follow its procedures, the sole remedy available shall be the return of the proposal to the IRB with a direction that the IRB follow its procedures.

8. Limitations of IRB Approval Authority

8.1. Limitations of IRB Approval Authority: IRB approval only signifies that the research proposal satisfies the human subject protections established by the OHRP. IRB approval does not guarantee access to subjects, facilities or records. The IRB's approval of an application in no way authorizes research which is otherwise prohibited under federal, state, or local law. Additionally, OCCC, through its President, reserves the right to disapprove research approved by the IRB on a scientific and ethical basis if the President deems the research to be harmful to OCCC and/or the community.

9. Institutional Review Board

9.1. Procedural Responsibilities: The IRB shall review and have authority to approve, require modifications to (to secure approval), or disapprove all Human Subject Research activities. The IRB shall evaluate proposed research projects and determine the appropriate level of review in accordance with this policy and 45 CFR Part 46. The IRB will review the proposed research activities to ensure that:

9.1.1. All risks to human subjects and investigators shall be minimized.

9.1.2. Risks to human subject participants shall be reasonable in relation to the anticipated benefits of the human participants, if any, and the knowledge expected to be acquired from the research. (Knowledge, in this example, represents the outcome of the research itself and not implied future knowledge, such as the following: How will this research influence the reduction in poverty?)

9.1.3. The investigators shall select the subjects equitably and impartially.

9.1.4. The investigators protect the rights of participants who are or may be vulnerable to exploitation, coercion or undue influence, such as children under the age of 18, prisoners, mentally disabled persons, pregnant women, and economically- or educationally disadvantaged persons. Where members of these populations are included in the

participants, the research proposal must include additional safeguards to protect the rights and welfare of these participants, satisfying the requirements of 45 CFR Part 46.

9.1.5. The information given to subjects as part of the informed consent process conforms with 45 CFR 46.116 and that the informed consent shall be obtained from each participant, or from the participant's legally authorized representative, to the extent required by 45 CFR 46.116 and 46.117.

9.1.6. Informed consent will be appropriately documented in a writing signed by each participant, or the participant's legally authorized representative, in conformance with and to the extent required by 45 CFR 46.116 and 46.117.

9.1.7. Where appropriate to safeguard the safety of participants, the research proposal sufficiently provides for the monitoring of the data collected.

9.1.8. Where appropriate, the research proposal adequately provides for protection of the privacy of participants and the confidentiality of data.

9.2. Reporting:

9.2.1. IRB action regarding proposed research and any modifications or clarifications required by the IRB as a condition of IRB approval shall be reported to investigators electronically within two weeks after the regularly convened meeting of the IRB by the Chair.

9.2.2. IRB shall review and act upon modifications and clarifications made by the researcher in response to IRB requests within two weeks of the regularly convened meeting of the IRB by the Chair.

9.2.3. The IRB Chair shall notify the following institutional officials of IRB findings and actions annually: the President's Cabinet. Such notification shall be performed electronically.

9.2.4. The Chair of the IRB is responsible for prompt notification of the IRB, appropriate OCCC officials, any supporting Agency or Department Head, and OHRP of any (i) unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval.

9.3. Membership:

9.3.1. The Institutional Review Board shall consist of no fewer than five members, including the chair, and must possess an understanding of the diversity of the people and the programs at OCCC and in the community. Whenever possible, IRB members should possess a terminal degree in their discipline.

9.3.1.1. At all times, the IRB shall have at least one member from a scientific area, at least one member from a non-scientific area, and at least one member from the community at large who is not affiliated with OCCC and not a member of the immediate family of a person who is affiliated with OCCC.

9.3.1.2. At all times, the IRB shall also have a member who is a representative from the Health Professions and a representative from the Social Sciences.

9.3.1.3. The IRB Chair must review each research proposal to determine whether the IRB has the necessary expertise to review the proposal. If the IRB chair determines that the IRB does not have the necessary expertise to review a proposal, the IRB shall obtain the necessary additional expertise from a consultant who is independent of the IRB. The consultant shall not have voting privileges.

9.3.2. Selection Process: IRB members, through their collective experience, knowledge and skills, shall be qualified to ascertain the merits of proposed research, its appropriateness to OCCC and the community, its conduciveness to OCCC's mission, values and goals, and, most importantly, its risk to human subjects.

9.3.2.1. Members shall be recommended by the Executive Director of Strategic Planning and appointed by the President.

9.3.2.2. Members shall serve for a term of four years, except that the terms of the original IRB members may be for a period of less than four years. Terms shall be staggered so that no more than one third of the IRB membership shall be appointed in the same year, in the absence of unusual circumstances.

9.3.3. Conflict of Interest: No IRB member may participate in the IRB's initial or continuing review of a project in which the IRB member has a conflicting interest, except to provide information requested by the IRB. Except when requested to be present to provide information, any IRB members with a conflict of interest shall absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. Such absence shall be noted in the IRB minutes.

9.4. Training: All IRB members shall complete the OHRP Human Subject Assurance Training modules available online at http://ohrp-ed.od.nih.gov/CBTs/Assurance/newuserreg_1.asp. The IRB Chair shall maintain records of completion of the required training.

9.5. Meetings:

9.5.1. Except where the Exempt Review Process or the Expedited Review Process is appropriate, Initial and Continuing Reviews of proposed research requiring full IRB review must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one IRB member whose primary concerns are in non-scientific areas (a quorum).

9.5.2. The Chair shall distribute the proposal and all of the investigator's documents to IRB members at least one week before the meeting.

9.5.3. The IRB shall convene with at least a quorum of its members on the second Friday of every month, and shall discuss new and continuing research proposals that require full IRB review and were submitted for review at least two weeks prior to the meeting. The IRB shall review the merits and risks of each research proposal, and the members shall vote to

approve, disapprove or require the researcher to resubmit the proposal with changes. The Chair shall inform the IRB of any research proposals that were handled administratively (*e.g.*, denied, determined to have exempt status, or handled by expedited review) since the previous meeting.

9.5.4. Approval of research shall be by a majority vote of the members present. Should the quorum fail during a meeting (*e.g.*, loss of a majority through early departure or recusal of member due to conflict of interest, or absence of a nonscientist member), the IRB may not take further actions or votes unless and until the quorum is restored.

9.5.5. Minutes: The Chair will keep a record of the minutes of the IRB meeting and submit them electronically to each IRB member. The minutes must include all the following information:

9.5.5.1. Sufficient detail to show attendance at the meetings, actions taken by the IRB; the vote on those actions including the number of members for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussions of controversial issues and their conclusions.

9.5.5.2. The late arrival, early departure and temporary absence of members;

9.5.5.3. The presence or absence of any member with a conflicting interest in a research proposal;

9.5.5.4. The IRB's determination of which protocols require continuing review more often than annually, as appropriate to the degree of risk, and the approval period determined to be appropriate;

9.5.5.5. A list identifying and verifying that the IRB was informed of all actions handled administratively by the Exempt Review Process and the Expedited Review Process since the last meeting.

9.5.6. The IRB Chair may cancel an IRB meeting if no proposals were timely submitted for full IRB review.

10. Records Retention: The Office of Institutional Effectiveness (Office of Record for IRB records) shall retain all IRB records for at least three years after completion of the research. Records shall include, but shall not be limited to, the full contents of the proposal package, correspondence between the researcher and the IRB, records of continuing review activities, and progress reports concerning the research. IRB records shall include, but shall not be limited to, minutes from IRB meetings reflecting attendance, voting records and summary of actions taken by the IRB. Additionally, the IRB shall retain a list of its members identified by name, earned degrees, area of expertise, licenses, relationship to the institution and record of completion of OHRP Human Subject Assurance training.

Effective: August 6, 2007