OKLAHOMA CITY COMMUNITY COLLEGE

NO. 4500 INSTITUTIONAL REVIEW BOARD

1.0 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 (IRB). The IRB shall evaluate all human subjects research as defined by this policy, established IRB procedures, and the Code of Federal Regulations (CFR) including 45 CFR Part 46. For research involving human subjects, the IRB is responsible for initial reviews, continuing reviews, and provision of oversight.

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

1.3 Definitions:

1.3.A *Human Subject* means a living individual about whom an investigator (whether professional or student) conducting research

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

1.3.B *Human Subjects Research* means a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge and involving one or more human subject(s). 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. Intent to publish or present results usually indicates generalizable knowledge, but this is not the only criterion.

1.3.C *Identifiable Private Information* means Private Information (as defined in federal regulations and definition 1.3.F of this document) in which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

1.3.D *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.E *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.F *Research* means (as defined by federal regulations) a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Federal regulations include examples and exceptions.

2.0 Researcher's Submission and Documentation: Any faculty member, employee or student of OCCC, and any researcher from another institution, who wishes to engage in Human Subjects Research must submit an electronic application to the Chair of the IRB. The application should follow guidelines in the IRB procedures document and include an application form, description of research, information about consent, evidence of investigator training, and any other necessary documents.

3.0 Initial Review of Research: Once the Chair of the IRB receives a complete application, the Chair will determine the status of the proposal, following federal regulations and OCCC IRB procedures. The Chair shall document this determination and provide an electronic notice of decision to the researcher within two weeks of application receipt. The Chair will keep an electronic record of application forms and initial determination decisions, including reasoning.

4.0 Review of Continuing Research: All Human Subjects Research activities that have been approved by the fully convened IRB, and any studies that were approved with a review condition, 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. The review must be substantive and meaningful, and follow the process in the IRB procedures document.

5.0 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. Reviews of protocol changes will follow procedures in the IRB procedures document.

6.0 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 additional review, and/or to evaluate the approved proposal for termination of approval. These rights will be exercised as a review of immediate hazards, as described in the IRB procedures document.

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 federal department or agency head, and others as appropriate. This statement of action shall be submitted in writing by the IRB.

7.0 Appeals: If the application is not approved, an investigator may appeal by requesting a second review by the IRB. The investigator must submit the request in writing and include a specific response addressing the IRB comments on the Report to Investigator. The Chair and members of the IRB will attempt 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 investigator, however, may appeal to the Provost on procedural irregularities. If on appeal the Provost 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 directive that the IRB follow its procedures.

8.0 Limitations of IRB Approval Authority: IRB approval only signifies that the research proposal satisfies the human subject protections established by the Office for Human Research Protections (OHRP) and federal regulations. 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 reject 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.

9.0 Institutional Review Board

9.1 Responsibilities: The IRB shall review and have authority to approve, require modifications to (to secure approval), or disapprove all Human Subjects Research activities. The IRB shall evaluate proposed research projects and conduct the appropriate level of review in accordance with this policy, IRB procedures, and federal regulations..

9.2 Reporting:

> 9.2.A IRB action regarding proposed research and any modifications or clarifications shall be reported to the researchers promptly.
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> 9.2.B The IRB Chair shall annually notify the President of IRB findings and actions. Such notification shall be performed electronically.
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> 9.2.C The Chair of the IRB is responsible for prompt notification of the IRB, appropriate OCCC officials, any supporting federal department or agency head, and OHRP of any (i) unanticipated problems involving risks to subjects or others; (ii) any serious or continuing

noncompliance with federal regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval.

9.3 Membership:

9.3.A Board Composition: 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.A.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.A.2 At all times, the IRB shall also have a member who is a representative from the Health Professions division and a representative from the Social Sciences division.

9.3.A.3 The IRB Chair is considered a voting member. If the position of Chair is vacant, the board member with the longest tenure on the IRB may act as Chair.

9.3.A.4 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.B 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.B.1 Members may be recommended by the Vice President for Academic Affairs, Associate Vice President for Academic Affairs, Vice President for Student Affairs, or Associate Vice President for Student Affairs. Members shall be appointed by the Provost.

9.3.B.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.C 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 or provide evidence of comparable training. The IRB Chair shall maintain records of completion of the required training.

9.5 Meetings:

9.5.A Initial and Continuing Reviews of proposed research requiring full IRB review must be conducted by the IRB at convened meetings at which a quorum is present. A quorum is defined as the majority of the members of the IRB, including at least one IRB member whose primary concerns are in non-scientific areas.

9.5.B 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 of IRB members 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.C Minutes: The Chair will keep a record of the minutes of the IRB meeting, as described in the IRB procedures, and submit them electronically to each IRB member.

10.0 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 appropriate Human Subject Assurance Training.

11.0 Procedures: The IRB shall adopt and regularly review procedures to effectuate this policy and comply with federal regulations and applicable laws.

Effective: August 6, 2007
Revised and Renumbered: April 27, 2022