

**SHAWNEE STATE UNIVERSITY
BOARD OF TRUSTEES**

**Meeting Minutes
January 18, 2013**

Call to Order

Chairperson Mooney called the meeting to order at 1:15 p.m. noting the meeting was in compliance with RC § 121.22(F).

Roll Call

Members Present: Ms. Melissa Higgs-Horwell, Mr. Robert Howarth, Mr. Dan Mooney, Mr. Gary Paine, Ms. Elizabeth Seif and Mr. Christopher Aaron Shaw

Members Absent: Mr. David Lodwick, Ms. Kay Reynolds and Dr. Rita Roberts

Approval of the January 18, 2013 Agenda

Ms. Seif moved and Mr. Paine seconded a motion to approve the January 18, 2013 agenda. Without discussion, the Board unanimously approved said agenda.

Approval of the November 2, 2012 Board Meeting Minutes

Mr. Howarth moved and Mr. Paine seconded a motion to approve the November 2, 2012 Board meeting minutes. Without discussion, the Board unanimously approved said minutes.

Committee Reports

Academic and Student Affairs Committee – Ms. Melissa Higgs-Horwell, Chair

Ms. Higgs-Horwell reported on behalf of the Academic and Student Affairs Committee. Ms. Higgs-Horwell said the Committee did not have a quorum but staff presented information on the two action items to the members present. Other information items were also presented.

Action Items***Resolution ASA01-13, Approval of Graduates***

Ms. Higgs-Horwell, as Chair of the Academic and Student Affairs Committee, moved and Ms. Seif seconded a motion to approve Resolution ASA01-13, Approval of Graduates.

Ayes: Ms. Higgs-Horwell, Mr. Howarth, Mr. Mooney, Mr. Paine, Ms. Seif

Nays: None

Resolution ASA02-13, Approval of Policy 5.25 Revision, Research Involving Human Subjects

Ms. Higgs-Howell, as Chair of the Academic and Student Affairs Committee, moved and Mr. Howarth seconded a motion to approve Resolution ASA02-13, Approval of Policy 5.25 Revision, Research Involving Human Subjects.

Ayes: Ms. Higgs-Horwell, Mr. Howarth, Mr. Mooney, Mr. Paine, Ms. Seif

Nays: None

Information Items**Pre-Med Day**

Dr. Andrew Napper, Professor and Chairperson, Department of Natural Sciences, shared information on Pre-Med Day that was held on December 14, 2012. Pre-Med Day is an annual recruiting event to encourage high school students to choose Shawnee State for their pre-medical education. One-hundred students plus family members attended the event. The day includes visits to the cadaver lab, a panel discussion by Shawnee alumni who have completed medical school, a panel discussion by Shawnee graduates who are currently in medical school, and sessions about the pre-med curriculum, research and other activities, and the medical school admissions process.

Fall Commencement Statistics

Mr. Mark Moore, Registrar, presented fall commencement statistics. The Fall 2012 commencement ceremony was held on December 14, 2012. There were 201 graduates that were awarded degrees compared to 174 for the Fall of 2011. Of the 201 degrees awarded, 22 were Masters, 113 Bachelor and 66 Associate. The ceremony was well attended as the Vern Riffe Center for the Arts was nearly filled to capacity.

Preliminary Spring Semester Statistics

Mr. Moore presented preliminary spring semester statistics. Undergraduate enrollment for Spring 2013 on the first day was 3,943, down 197 students for an overall decrease of 4.8% compared to Spring 2012. Registration activities continued through Friday, January 11th.

Student Programming Board

Mr. Daniel Ondercin, President of the Student Programming Board (SPB) reported that the SPB has collaborated with the Homecoming Committee to initiate new programs and to increase program viability. The activities will be focused on SSU spirit programming. He reported on late night programming which is held on Thursday nights during typical bar hours to offer an alternative for students. Mr. Ondercin reported that there continues to be increased programming for commuter students, e.g. free tax preparation events and "Concessions for Commuters." Attendance of commuter events has increased since the beginning of the Fall semester. Those efforts assist with connecting students to the campus to better enhance a sense of belonging.

Spring Orientation, 2013

Dr. Oling-Sisay reported that 92 students and 45 parents attended the December 13th orientation and 99 students with 40 parents attended the January 3rd orientation. The Student Success Center, the Dean of Student's office and the Student Activities Office phoned all registrants to remind them of their Orientation date.

The Orientation MYSSU page has already gone live for summer orientation, as well as the June dates for fall orientation. Accepted students for summer and fall can now register for their orientation date on MYSSU.

Spring Semester Housing Occupancy

Dr. Oling-Sisay reported that the housing occupancy numbers, current as of January 17, are 832 which is 85.2% occupancy, as compared to the Fall Semester number of 1000, which is 102.5% occupancy. There is typically a decline in occupancy from Fall to Spring.

Education Item

Dr. Oling-Sisay presented on the new Student Conduct Code. She stated that the Conduct Code highlights the values that define our community while providing students with a framework to guide their actions and behaviors. Dr. Oling-Sisay provided an overview of the Conduct Code of behaviors that constitute violations and the processes by which such cases are resolved.

Finance and Administration Committee – Ms. Elizabeth Seif, Chair

Ms. Seif reported on behalf of the Finance and Administration Committee and presented five action items and several information items.

Action Item***Resolution F01-13, Authorization of Lease-Purchase Agreement for IT Infrastructure and VoIP Upgrade Project***

Ms. Seif moved and Mr. Howarth seconded a motion to ratify Resolution F01-13, Authorization of Lease-Purchase Agreement for IT Infrastructure and VoIP Upgrade Project. This action is in response to a request by Key Government Finance, Inc. for a Board of Trustees' resolution as part of the application process for a multiple-year Lease/Purchase Agreement at 0% for the VoIP and IT infrastructure project. .

Ayes: Ms. Higgs-Horwell, Mr. Howarth, Mr. Mooney, Mr. Paine, Ms. Seif

Nays: None

Information Items**FY13 General Operating Budget Update**

An update was given regarding the status of the FY13 general operating budget.

Personnel

The following personnel actions were processed in the Department of Human Resources during the period of October 16, 2012 through December 28, 2012:

- The Division of Academic Affairs had one faculty retirement effective June 1, 2013 and two faculty resignations effective January 4, 2013 and December 18, 2012.
- The Division of Finance and Administration had one administrative promotion effective December 12, 2012.
- The President's Office/Central Administration had one administrative appointment effective January 1, 2013. This position is funded by the SSU Development Foundation.
- The Division of Student Affairs had one administrative resignation effective October 21, 2012.

Investment Report

The University's investment performance report revealed gains in November and December. With an overall positive adjustment, the portfolio has realized a 5.1% gain in the amount of \$711,823 for the reporting period (July 1, 2012 – December 31, 2012).

Capital Status Report

- Administration Building – construction documents are complete and construction is to start the end of February 2013 with a budget of \$1,366,812.
- Founders Plaza Project – revised scope of work and schedule is being developed.
- 310 Chillicothe – construction documents have been submitted for state review and bid documents to be complete mid-January 2013. Additional scope and code compliance issues have delayed the first floor completion until June 2013.

Education Item

Pat Carson, Director of Procurement Services, provided a briefing on SSU's procurement system.

President's Report**Homecoming**

The President reported on the Homecoming activities going on this week and shared the calendar of events with Board members. She highlighted the hard work of the Homecoming committee, led by Mr. Eric Braun, Director of Development, and the contributions of the Alumni Association, Athletics, and Student Affairs.

SSI Formula and Funding for Upcoming Biennium

Dr. Morris updated the Board on the continuing consultation/discussions about changes to the SSI funding formula for the next biennium. She reminded the Board of the Governor's directive given to the university presidents and the Higher Education Funding Commission, outlined the proposal presented to the Governor by the commission, and identified matters still under discussion and of concern for SSU.

Supplement Legislation

President Morris reminded the Board of earlier discussions about a preliminary plan to "step-down" the University from the funding supplement over a 10-year period and the efforts she and Mr. John Carey, Assistant to the President for Government Relations & Strategic Initiatives, had made working with the Board of Regents and the Office of Budget and Management. She informed Board members that in light of the deliberations around the new SSI funding and the

commitment by all University leadership to support and strengthen the new SSI funding priorities, SSU has withdrawn the proposed plan for this session of the General Assembly with the understanding that SSU will resubmit if deliberations about the SSI change dramatically.

314 Chillicothe Street

Dr. Morris reported to the Board that discussions are moving forward to receive a gift of the building and property at 314 Chillicothe Street, immediately adjacent to the building we are currently renovating, from the Schottenstein Property Group. Future purposing of the building is to be determined.

Update on Economic Development

President Morris discussed the efforts being made to reflect the recent change in the University's mission to include a role in the development of the region. Mr. Carey presented an overview of the Economic Development Team, including a new grant for internships in partnership with the University of Cincinnati and Rio Grande University,

Reports, if any, from Board Liaisons with other Organizations

None.

New Business

Chairman Mooney discussed the National Conference on Trusteeship sponsored by the Association of Governing Boards and said that Mr. Howarth and Mr. Paine would be attending the conference this year and asked Mr. Paine to report on the conference at the May Board meeting.

Comments from Constituent Groups (if any) and the Public

None.

Other Business

None.

Executive Session

Ms. Seif moved and Mr. Howarth seconded a motion to enter into Executive Session to review negotiations with public employees concerning their compensation or other terms and conditions of their employment and to confer with the General Counsel concerning a dispute involving the University that is the subject of pending court action.

Ayes: Ms. Higgs-Horwell, Mr. Howarth, Mr. Mooney, Mr. Paine, Ms. Seif

Nays: None

The Board moved into Executive Session at 2:00 p.m. The Board exited Executive Session at 2:42 p.m. and returned to public session.

Adjournment

The Board was adjourned by acclamation at 2:43 p.m.


Chairperson, Board of Trustees


Secretary, Board of Trustees

RESOLUTION E01-13

RESCISSIONS OF BOARD POLICIES

WHEREAS, Policy 5.00REV, Policy on Policies and Procedures, addresses policy subjects appropriate for Board approval and directs the President to establish a process for the regular review of existing Board policies; and

WHEREAS, a systematic review of institutional policies has been undertaken at the direction of the President in order to remove outdated policies, and to modify and update policies; and

WHEREAS, Policy 2.00, Professional Standards of a Faculty Member, Policy 2.01, Faculty Responsibilities, and Policy 2.04, Faculty Development Program, are outdated and address subject-matters that are addressed in the SSU-SEA collective bargaining agreement; and

WHEREAS, Policy 3.05, Student Identification System, Policy 4.74, University Mail Service, and Policy 5.23, Vernal G. Riffe Jr. Founders' Medal, are outdated and address subject-matters that are administrative in nature and not appropriate subjects for board policies; and

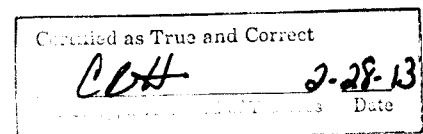
WHEREAS, Policy 5.17, Lobbying Policy, is outdated and addresses a subject-matter that is addressed in the Ohio Revised and administered by the Ohio General Assembly's Joint Legislative Ethics Committee; and

WHEREAS, Policy 5.00REV, requires Board approval for rescission of any Board policy;

THEREFORE BE IT RESOLVED, that the Board of Trustees of Shawnee State University hereby approves rescission of the following University policies: Policy 2.00, Professional Standards of a Faculty Member; Policy 2.01, Faculty Responsibilities; Policy 2.04, Faculty Development Program; Policy 3.05, Student Identification System; Policy 4.74, University Mail Service; Policy 5.17, Lobbying Policy; and Policy 5.23, Vernal G. Riffe J. Founders; Medal; and

THEREFORE BE IT RESOLVED, that the Board of Trustees directs the President to develop guidelines for the awarding of the Vernal G. Riffe Jr. Founders' Medal by the Board of Trustees.

(January 18, 2013)



RESOLUTION ASA 01-13

APPROVAL OF GRADUATES

WHEREAS, it is the role of the Shawnee State University Board of Trustees to award degrees and certificates; and

WHEREAS, annual action approving the granting of degrees and certificates during the year shall be taken by the Board of Trustees (Policy 2.06); and

WHEREAS, candidates for graduation must meet all academic and University requirements in order to be certified as candidates by the Office of the Registrar;

THEREFORE BE IT RESOLVED that the Board of Trustees of Shawnee State University empowers the President to award certificates or degrees at Commencement ceremonies during 2013 to all candidates whose final completion and graduation from the University is confirmed by the Office of the Registrar and whose names are later attached to this resolution as graduates.

(January 18, 2013)

Certified as True and Correct	
<i>CRH</i>	<i>2-28-13</i>
Secretary, SSU Board of Trustees	Date

RESOLUTION ASA 02-13

APPROVAL OF POLICY 5.25 REVISION

RESEARCH INVOLVING HUMAN SUBJECTS

WHEREAS, Shawnee State University must assure appropriate protection of human subjects involved in research at the institution; and

WHEREAS, the current policy must be modified to ensure compliance with all applicable federal, state, and local laws, including the Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (45 CFR 46);

THEREFORE BE IT RESOLVED that the Board of Trustees of Shawnee State University approves revisions to Policy 5.25, Research Involving Human Subjects effective January 18, 2013.

(January 18, 2013)

Certified as True and Correct	
<i>Chitt</i>	2-28-13
Secretary, SSU Board of Trustees	Date

Shawnee State University

SUBJECT: RESEARCH INVOLVING HUMAN SUBJECTS	POLICY NO. :	5.25 REV
	ADMIN CODE:	3362-5-26
	PAGE NO.:	1 of 3
	EFFECTIVE DATE:	01/18/2013
	NEXT REVIEW DATE:	01/18/2018
	RESPONSIBLE OFFICER(S):	Provost
	APPROVED BY:	BOT

1.0 Purpose Statement

1.1 The purpose of this policy is to assure the protection of human subjects for all research projects involving human subjects and to ensure compliance with applicable federal, state, and local laws, including the Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (45 CFR 46). The University will have an Institutional Review Board for Human Subjects (IRB), which will serve to review all research projects involving human subjects. For the purposes of this policy, the definitions and procedures of 45 CFR 46 are incorporated by reference. In cases of conflict between this policy and federal regulations, the federal regulations take precedence.

1.2 The applicable federal regulations will be made available on the University's website.

2.0 Applicability & Ethical Principles

2.1 This policy applies to all activities which, in whole or in part, involve research with human subjects if:

2.1.1 The research is sponsored by the University; or

2.1.2 The research is directed or conducted by University faculty or staff in connection with their institutional responsibilities; or

2.1.3 The research is conducted by University students under the direction of University faculty or staff; or

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- 2.1.4 The research is conducted at the University or involves use of University property.
- 2.2 Research projects that meet the definition of "research," as defined by 45 CFR 46, and are designed for dissemination beyond the classroom are covered by this policy. The University may create a preliminary review process for research projects to determine whether such projects are subject to or exempt from IRB review.
- 2.3 The University IRB and researchers subject to this policy are to be guided by the ethical principles set forth in the "Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (Belmont Report), which is from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report will be made available on the University's website.
- 3.0 Institutional Review Board
- 3.1 IRB membership
- 3.1.1 The IRB will consist of seven voting members from varying and diverse backgrounds with the professional competence and training necessary to review specific research activities. Six members will be University faculty or staff from varying disciplines including scientific and nonscientific backgrounds as well as undergraduate and graduate programs. Consideration will be given to diversity of gender, race and cultural backgrounds of the IRB members. One external member will be appointed and will not have any contractual relationship or otherwise be affiliated with Shawnee State University, and will not be an immediate family member of a person who is affiliated with the University.
- 3.1.2 The term for each member will be three years and will commence at the beginning of the Fall Semester and end at the conclusion of the summer term of the final year of service. Appointments will be proportionately staggered. Members may serve more than one term.
- 3.1.3. A majority of the voting members of the IRB constitutes a quorum.

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3.1.4. Outside Assistance. The IRB may invite other individuals with competence in special areas to assist the IRB in the review of applications. Such individuals are not permitted to vote with the IRB.

3.2 Appointment Process

3.2.1 Members. The Provost and Vice President of Academic Affairs (Provost) will appoint the members of the IRB, in consultation with the University Faculty Senate and the IRB chair. In considering each appointment, the Provost will review the current composition of the IRB in light of the composition requirements of this policy and 45 CFR 46.

3.2.2 Chair and Chair-Elect. The Provost is responsible for appointing a Chair and Chair-Elect from the IRB membership. The Chair should have at least one year of service on an IRB, which may be at another institution. The terms for the Chair and Chair-Elect will be for one year, and both may serve multiple terms.

4.0 Procedures

The Provost is responsible for establishing procedures, subject to the President's approval, to ensure that the IRB and the University's research involving human subjects are in conformance with federal, state and local laws. As part of the process in developing procedures, the Provost may confer with members of the IRB and other University groups or individuals. Procedures will include, but not be limited to, the application process for students and faculty, standards and criteria for the IRB review and approval process, meetings of the IRB, an expedited review process, standards for record-keeping, requirements for informed consent, and other processes to ensure protection of human subjects and legal compliance.

History: Replaces 5.25 (Eff. 06/10/05)

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PROCEDURE TITLE:	RESEARCH INVOLVING HUMAN SUBJECTS
RELATED POLICY:	5.25 REV
PAGE NO.:	1 OF 22
RESPONSIBLE OFFICER(S):	PROVOST
EFFECTIVE DATE:	01/18/2013
NEXT REVIEW DATE:	01/18/2018
APPROVED BY:	PRESIDENT

1.0 PURPOSE

- 1.1 The purpose of these procedures is to support the implementation of SSU Policy 5.25 Rev. Research Involving Human Subjects and the conduct of the University's Institutional Review Board (IRB). These procedures comply with, reference, and incorporate federal law including Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (45 CFR 46) and all its sub-parts and sections.
- 1.2 Shawnee State University may enter into an agreement with other institutions that do not have an IRB to review proposals for research involving human subjects. All applicable policies and procedures established by Shawnee State University will be followed by all investigators as a part of this agreement. See Section 9.5, External Principal Investigators, for more information.
- 1.3 Agreements will be reviewed by the IRB Chair and the Associate Provost prior to final approval signature of the Provost.
- 1.4 Academic units may develop their own procedures related to the development and submission of research proposals that would be in addition to the procedures herein. In situations where conflicts between unit level and university level procedures exist, university level procedures take precedence.

2.0 DEFINITIONS RELATED TO RESEARCH AND THE IRB PROCESS

- 2.1 The University recognizes and utilizes the definitions of federal regulations related to Human Subjects research, specifically 45 CFR 46 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>), in all application and review processes.

3.0 APPOINTMENT AND TERMINATION OF IRB MEMBERS

- 3.1 Appointments

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- 3.1.1 IRB appointments will be made by the Provost in consultation with the University Faculty Senate, the Associate Provost, and the Chair of the IRB. As necessary, the Provost will seek nominations for IRB membership. Self-nominations may be accepted. Federal requirements for membership will be used to determine eligibility for the Provost's appointment of any IRB member with respect to diversity of representation and science and non-science backgrounds of members.
- 3.1.2 The appointment of External IRB members will be made by the Provost in consultation with the IRB Chair and the Associate Provost.
- 3.1.3 Federal requirements for membership will be used to determine eligibility for UFS's recommendation and Provost's appointment of the external member.
- 3.1.4 When appointing an external IRB member, Ohio's Ethics Commission definition of "family" will be used and includes grandparents, parents, spouse, children (dependent or not), grandchildren, brothers and sisters, or any person related by blood or marriage and residing in the same household.
- 3.2 Termination
- 3.2.1 The Provost may terminate the service of any IRB member when the member fails to meet the performance expectations as stated in sections 3.4 and 3.5 or other federal or University policy related to human subjects research.
- 3.3 IRB Chair and Chair-Elect
- 3.3.1 The IRB Chair is a faculty member of the IRB and appointed by the Provost in consultation with the Associate Provost. The IRB Chair will have at least one year of service on an IRB prior to being appointed to this position. This service may be at another institution's IRB. If no experienced faculty are willing to serve in the Chair position, or no faculty meet the qualifications for the position, the Provost may appoint a Chair from all willing members or interested, eligible, University personnel.
- 3.3.2 The Provost will provide the Chair of the IRB with sufficient time, support, and/or compensation to execute the duties of the position.
- 3.3.3 The IRB Chair will report directly to the Associate Provost in all matters related to the IRB. The Office of the Provost will provide administrative and technical support for the functions of the IRB Chair.

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- 3.3.4 The IRB Chair will call meetings of the IRB, plan the agenda for the meetings, determine or approve the appropriate review status of each proposal submitted (exempt, expedited, or full), communicate to investigators the results of all reviews or requests for additional information, and request annual or project completion updates, and other duties as noted in these procedures or required by University policy.
- 3.3.5 The IRB Chair-elect is a faculty member of the IRB and appointed by the Provost in consultation with the Associate Provost.
- 3.3.6 The IRB Chair-elect will assist the Chair in the execution of the duties of the IRB. The Chair-elect will serve as Chair in the absence of the Chair at regular meetings, in cases of conflict of interest research proposals, and any other situation as necessary. The Chair-elect will assume the position of IRB Chair following the completion of the term of the Chair and/or upon appointment as such by the Provost.
- 3.4 IRB University Members
- 3.4.1 All university employees holding full-service appointments are eligible to serve as IRB members providing they meet federal guidelines and university requirements for this service.
- 3.4.2 All university members must complete the human subjects research training as required for membership and other trainings offered by the University to ensure currency of information related to the responsibilities of IRB members. Each IRB member will submit a copy of the human certificate of human subjects research training to the Associate Provost upon initial appointment to the IRB. Current human subjects research training or approved continuing education will be documented every three years or at the beginning of a new term of service, whichever is most recent. Approval of continuing education will be the responsibility of the IRB Chair.
- 3.4.3 IRB members will attend every regular meeting as scheduled, unless excused; read all proposals as provided; solicit information; and offer regular, substantive, and appropriate comments for each proposal prior to the meeting at which the proposal will be reviewed. Each member will be expected to serve as an expedited review proposal reader at least once per year – additional readings may be necessary depending on submission load.

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3.5 IRB External Member

- 3.5.1 The IRB external member is a person not otherwise affiliated with Shawnee State University and not part of the immediate family of a person who is affiliated with the University. See Section 3.1.3 Appointment and Termination of IRB Members, for the definition of "family."
- 3.5.2 All external members must complete the human subjects research training offered by the University and ensure currency of this training by submitting a certificate of training to the Associate Provost. Current human subjects research training or approved continuing education will be documented every three years or at the beginning of a new term of service, whichever is most recent. Approval of continuing education will be the responsibility of the IRB Chair.
- 3.5.3 External IRB members will attend every regular meeting as scheduled, unless excused; read all proposals as provided; solicit information; and provide regular, substantive, and appropriate comments for each proposal prior to the meeting at which the proposal will be reviewed. Each IRB member will be expected to serve as an expedited review proposal reader at least once per year – additional readings may be necessary depending on submission load.

4.0 ADMINISTRATION OF THE INSTITUTIONAL REVIEW BOARD

- 4.1 The Associate Provost has administrative oversight of the IRB's operations and provides administrative and technical support to the IRB process at the University. The Associate Provost serves as the first administrative level of appeal.
- 4.2 The University General Counsel serves in an advisory capacity to the IRB.
- 4.3 The Provost serves in an advisory capacity to the IRB and as the final level of appeal for any decisions of the IRB.
- 4.4 The IRB will report, through the Chair, to the Associate Provost.
- 4.5 The Office of the Provost will provide administrative and technical support for the IRB, including providing for the on-going communication between and among the IRB Chair, the IRB members, Principal Investigators, and others; the regular and ongoing maintenance of the IRB website to ensure accuracy and availability of documents and other IRB resources and information; and the ongoing maintenance of IRB records.

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- 4.6 The Office of the Provost will provide administrative support to the IRB meeting functions including, but not limited to the following:
- 4.6.1 Preparation and distribution of all materials for the consideration of proposals
 - 4.6.2 Meeting minutes and records of IRB actions
 - 4.6.3 Document storage
 - 4.6.4 Update of all electronic notices on the IRB website
 - 4.6.5 Preparation, distribution, and management of all communications of the IRB Chair and investigators with respect to IRB decisions pursuant to 45 CFR 46
 - 4.6.7 Informed consent form storage
- 4.7 Informed consent forms will be maintained by the IRB, Office of the Provost in secure storage for a period of three years for all approved studies. After the three year period, the forms will be destroyed unless otherwise directed by the Principal Investigator or necessitated by the nature of the study.

5.0 IRB MEETINGS

- 5.1 The IRB will hold regular monthly meetings during the academic year and at least one meeting during summer semester to consider all complete proposals submitted according to these procedures.
- 5.2 The IRB meetings will be scheduled by the IRB Chair. Each meeting will be posted on the IRB website. Each meeting will have an agenda that includes each proposal under consideration and any other business items that may be necessary for the operation of the IRB. IRB meetings may be cancelled due to a lack of business to be conducted.

6.0 STANDARDS FOR IRB REVIEW AND APPROVAL OF PROPOSALS

- 6.1 The objective of IRB review is to determine whether the research is subject to Policy 5.25 REV and these procedures, and, if so, to ensure that the rights and welfare of the subjects are adequately protected and that all activities involving human subjects are in compliance with University policies and federal regulations to assure that:
- 6.1.1 Selection of research subjects is equitable

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- 6.1.2 Informed consent is obtained and documented where appropriate
 - 6.1.3 Risks to subjects are minimized
 - 6.1.4 Risks are reasonable in relation to anticipated benefits to subjects and others
 - 6.1.5 Privacy and confidentiality are protected
 - 6.1.6 Data handling and safety monitoring provisions are adequate
 - 6.1.7 Vulnerable subjects are provided special safeguards against undue influence or coercion to participate in the research.
- 6.2 Approval of research under these policies and procedures is for a one year period, unless the IRB determines the risk is sufficiently high to require more frequent review.
- 6.3 Any research project that lasts for more than one year must submit the IRB Continuing Project Form for review (Section 16.0).
- 6.4 If, after the initiation of research, it appears that an unapproved project should have had prior IRB review, the investigator(s) or anyone with information about the project should contact the IRB Chair to determine ways to maximize human subjects protection for any aspects of the study that are still in process and to maintain confidentiality of existing data. Refer to Policy 5.25, U.S. Department of Health and Human Services regulations for the Protection of Human Research Subjects, 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>), and each section for definitions of research that requires IRB approval.
- 7.0 CRITERIA FOR IRB APPROVAL OF RESEARCH (45 CFR 46)
- 7.1 According to federal guidelines (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>), the IRB shall determine that all of the following requirements are satisfied:
- 7.1.1 Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - 7.1.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as

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IRB Board of Trustees

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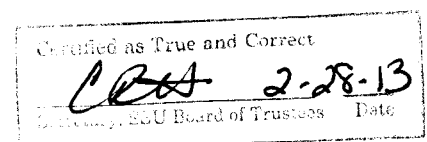
distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- 7.1.3 Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- 7.1.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- 7.1.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- 7.1.6 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7.1.7 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 7.1.8 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

8.0 TYPES OF RESEARCH REVIEW AND REVIEW PROCESSES

- 8.1 The type of review that a research project undergoes is determined by the level of risks to the participants and the types of participants involved in the research. There are three types of reviews for research: exempt, expedited, and full. The investigator must evaluate risk and type of participants to determine which type of review, and, therefore, which application may be appropriate for the project. The "What Type of IRB Review?" flowchart is helpful in determining the type of review required. Click here for the chart:

http://www.shawnee.edu/com/irb/pdf/Type_of_Review_Flow_Chart_8-30-12.pdf



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8.2 Level of Risk

The IRB will evaluate the risk and determine if the risks are reasonable in relationship to the anticipated benefits of the research to the subjects, if any, or the knowledge that may reasonably be expected to result. There are, generally, three levels of risk associated with human subjects research. Brief descriptions of each are below. Investigators should make every effort to minimize the level of risk involved in the research design. Additional information may be found at the website for Policy 5.25, U.S. Department of Health and Human Services regulations for the Protection of Human Research Subjects, 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>).

8.2.1 Less-than-Minimal-Risk

Less-than-Minimal-Risk is research in which there is no known physical, emotional, psychological, or economic risk. This research may qualify as exempt if it does not involve a vulnerable population and falls in an exempt category.

8.2.2 Minimal-Risk

Minimal-risk includes research that presents only the kind of risks encountered in daily life by most people (e.g., moderate exercise testing, minor stress from psychological tests, or surveys involving sensitive topics). This research may qualify as expedited if it does not involve a vulnerable population and falls in an expedited category.

8.2.3 Greater-than-Minimal-Risk

Greater-than-minimal-risk is research procedures that may include risk beyond that ordinarily encountered by subjects (e.g., maximal exercise testing, stressful psychological testing, questions about illegal activities). This type of research requires a full review.

8.3 Description of Participants

8.3.1 Principal Investigators are required to consider the population from which their study's subjects will be drawn. Protection of the subjects must be commensurate with the vulnerability of the population. Vulnerable populations require a higher level of protection, thus a higher level of scrutiny for the research procedures. Research considered to be less-than-minimal-risk for non-vulnerable adults is considered as minimal-risk for vulnerable populations.

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- 8.3.2 Prisoners, mentally disabled persons, and children are considered vulnerable because their ability to give truly voluntary and informed consent may be limited.
- 8.3.3 Pregnant women are considered vulnerable in the case of research procedures that pose any hazard to the fetus.

9.0 PRINCIPAL INVESTIGATORS SUBJECT TO IRB REVIEW PROCESS

9.1 Principal Investigators are those individuals engaged in a formal research study. Investigators may include any full or part-time employee or student of the University as well as individuals from outside the University who wish to conduct a research study utilizing University personnel, students, or facilities.

9.2 Principal Investigators shall obtain approval for proposed human subjects research prior to recruiting subjects or collecting data from subjects. This applies to preliminary and pilot studies which are developing or testing instruments and procedures, as well as the full study.

9.3 University Personnel as Principal Investigators

University personnel conducting a research study will follow all federal and University policies and procedures which are appropriate to the nature of the study.

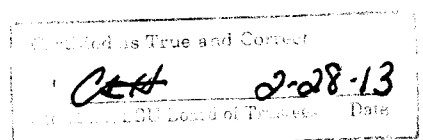
9.4 IRB Chair Serving as Principal Investigator

If the IRB Chair is the Principal Investigator of a study submitted for any review, s/he will not be involved in the direct review. The Chair-elect will assume the duties of the Chair for that proposal only.

9.5 External Principal Investigators

9.5.1 Individuals from other institutions who wish to conduct research using Shawnee State University students or personnel as subjects must provide proof of IRB approval from their home institution to the IRB Chair. If the IRB Chair is satisfied with the proposal materials and the home institution's IRB approval, she or he may grant permission for the research to begin. The IRB Chair may request additional information or require the use of Shawnee State University's IRB procedures.

9.5.2 If the external investigator's institution does not have an IRB, the investigator must submit to the Shawnee State University IRB according to the procedures herein. The decision of the Shawnee State University IRB is final.



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- 9.5.3 Standard appeal procedures are available to external Principal Investigators. Unless a formal agreement between the University and another institution exists, a memorandum of understanding (MOU) will be developed and signed by the institution's chief research officer or Provost/Vice-President for Academic Affairs, as appropriate for that institution.
- 9.5.4 University personnel may, at their discretion, participate in research studies as representatives of their professional fields or members of their profession when their affiliation with Shawnee State University is not the primary condition of their selection as a study participant. When University affiliation is a condition for selection to be a subject in a study, the IRB Chair should be consulted for a determination as to whether IRB review is necessary.
- 9.6 Student Investigators
- 9.6.1 Student research projects designed to add to generalizable knowledge through dissemination of results in publications or presentations beyond the classroom are covered by the policy and procedures on human subjects research. All student research meeting this definition must be supervised by a University faculty who assumes responsibility for the conduct of the research.
- 9.6.2 Faculty members who assign or supervise research conducted by students are responsible for ensuring that the proposed research is reviewed and conducted in accordance with University policy and the student is qualified to adequately safeguard the well-being of the subjects.
- 9.6.3 Class projects designed to provide hands-on experience or research training to students are not treated as research projects in accordance with this policy and do not require formal IRB review. Projects in this category are expected to be confined to the specific class and end at the termination of that class.
- 9.6.4 If it is anticipated that the research project will be used in other classes, published, or presented beyond the classroom, the project should be submitted to the IRB for review.
- 9.6.5 Faculty members who assign research learning experiences are responsible for assuring that people used in such projects are treated ethically.
- 9.6.6 Faculty members must provide information to students on University policies and guidelines on human subjects research and develop class

as True and Correct
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SAC Board of Trustees Date