BYLAWS OF THE CENTRAL STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

Article I. NAME

The name of the board is the Central State University Institutional Review Board (hereinafter called "CSU-IRB").

Article II. OBJECT

The CSU-IRB is to ensure observance of the Federal Policy for the Protection of Human Subjects, published in the Federal Register, Vol. 56, No. 117, June 18, 1991, beginning at 28001 (the "Regulations"). The CSU-IRB will review all research conducted on the CSU campuses by CSU faculty, students, or staff as well as qualified researchers from outside Central State University, that directly, or indirectly, involves human subjects.

Article III. AUTHORITY

CSU-IRB is empowered to:

1) Review all funded and unfunded research by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
2) Determine the type of review (exempt, expedited, or full board) the research requires.
3) Disapprove, modify, or approve research protocols based upon consideration of the protection of human subjects.
4) Suspend or terminate a research project if it violates the federal policies for the protection of humans or if it does not follow the protocols and agreement in the submitted petition to the committee.

Article IV. RELATIONSHIP TO THE UNIVERSITY

CSU-IRB shall be directly responsible to the CSU Provost and Vice President for Academic Affairs. CSU-IRB shall coordinate its actions and policies with the Office of Sponsored Programs and Research which in turn supports the CSU-IRB committee and house all submitted petitions as well as letters of approvals. The Chairperson and committee members shall be selected from CSU faculty and staff as well as one or more external member.

The Office of Sponsored Programs and Research shall provide the needed clerical support, files, copying facilities and supplies for CSU–IRB.

Article V. MEMBERS

CSU-IRB's membership, appointed by the CSU Provost and Vice President for Academic Affairs, shall consist of:

1) Individuals with expertise in all research fields from all colleges and departments.
2) An individual with primary concerns in spiritual areas outside Central State University.
3) An individual not affiliated with the University.

In making appointments to the CSU-IRB, the appointing authority shall take such reasonable

steps as necessary to achieve a membership with diversity in race, gender, cultural backgrounds, and professional qualifications.

Members shall be removed only for stated cause, non participation and/or attendance. Failure to attend four (4) consecutive meetings may constitute cause for removal and replacement by another individual designated by the CSU Provost and Vice President for Academic Affairs.

Members shall be appointed for an initial three year term and may serve multiple terms. CSU members will receive no compensation. External members may receive token compensation to include reimbursement for travel expenses. The University shall provide liability coverage under its umbrella coverage. CSU-IRB shall consist of no fewer than five members. The Director of the Office of Sponsored Programs and Research who is the CSU-IRB Administrator will not serve as a voting member of the committee.

Membership Documentation

A current roster of all CSI-IRB members, in addition to the curriculum vitae of each member, is kept in the files in the IRB office, and contains the following information:

a. Name

b. Degrees earned (if any)

c. Gender

d. Representational capacity (scientist; non-scientist)

e. Relationship to the institution (affiliated; non-affiliated)

f. Identification of specific role, if any, e.g., chair, vice-chair, specified alternate

g. Representative of specific entity (i.e., psychiatry, VA, radiation safety committee)

h. Advocate role, or other specific role

If a member resigns prior to the expiration of the term of membership, the CSU Provost and Vice President for Academic Affairs shall, with all due speed, appoint a new member to complete the term of membership. Consideration shall be given to current alternate members and to any special expertise required among IRB membership.

Training

All members and all alternates must complete the demonstration of knowledge of human research protection. Currently this training is provided through the Collaborative Institutional Training Institute (CITI) on-line course. The IRB Coordinator will maintain a log of training completion dates. Retraining will be done every three years. A newly appointed member must complete an orientation in human subjects protection and IRB procedures prior to casting a

vote at a convened IRB meeting. The CSU-IRB Chair and Administrator are responsible for delivering new member orientation.

Article VI. OFFICERS

CSU Provost and Vice President for Academic shall appoint a chairperson of the CSU-IRB for a three year term. The chairperson shall be a voting member of CSU-IRB. The chairperson may appoint an acting chairperson to function in his or her absence. Other officers may be appointed to carry out activities of the board. Any individual appointed as Chair of the IRB shall have served as an IRB member prior to the appointment as Chair and shall demonstrate knowledge of human subjects' protections. The CSU-IRB Chair is a voting member of the IRB and presides over all convened IRB meetings. The CSU-IRB Chair has authority to sign all IRB action items.

The CSU-IRB Chair will be evaluated every three years by the CSU Provost and Vice President for Academic Affairs. The CSU Provost and Vice President for Academic Affairs will seek input from the IRB members serving under the chair and will also consult with the CSU-IRB coordinator during the annual evaluation. The CSU-IRB Chair may serve multiple terms.

Article VII. MEETINGS

The IRB committee will meet on the fourth Wednesday of each month. All applications must be submitted two weeks prior to the scheduled meetings. Notification will be given within one month from the date of application submission. Signed applications must be submitted to irb@centralstate.edu or hand delivered to Office of Sponsored Programs and Research.

Notice of time and place shall be given at least one week in advance. The chairperson may call a special meeting upon five working days by written or telephone notice. Minutes of each meeting shall be kept by the CSU-IRB Administrator. A quorum shall consist of a simple majority, including at least one external member. Members who leave the meeting cannot be counted for determination of a quorum.

Article VIII. DECISIONS OF THE IRB

Full review by CSU-IRB shall consist of all members, or alternates, that will be attending the meeting reviewing each protocol.

CSU-IRB shall be empowered to approve or disapprove a protocol, and to give conditional approval. It may also table protocols whose review requires more information. In the review process CSU-IRB shall have as its primary criteria: the degrees of physical, social, and psychological risk; the need for and degree of confidentiality; the presence, absence, or adequacy of informed consent; and the protection of particularly vulnerable subjects.

CSU-IRB shall not concern itself with the quality of the protocol or its methodology unless more than minimal risk is involved, in which case quality and methodology are appropriately considered in assessing the risk-benefit ratio.

A majority vote will decide whether a protocol shall be approved, disapproved, tabled, or conditionally approved. If a member has conflicting interest in the petition reviewed, she/he shall not vote on that matter and will be absent from the room during the deliberation and vote.

Each CSU-IRB member shall have one vote. Voting shall proceed openly, after an opportunity for full discussion and debate has been afforded. Individuals whose protocols have been reviewed shall be notified of the CSU-IRB decision in writing within one week.

An investigator may re-submit a protocol for re-review once it has been modified in such a way as to remove the previous CSU-IRB's objections. There shall be no mechanism for appeal by investigators beyond the IRB.

Article IX. SUBCOMMITTEES
The chairperson shall, if necessary, appoint subcommittees from CSU-IRB membership to execute various duties related to the objectives and policies of the IRB.

Article X. EXEMPT AND EXPEDITED REVIEW
In accordance with §46.101b and §46.110 of the Regulations, the chairperson, or some other members of the CSU-IRB designated by the chairperson, shall be empowered to perform exempt and expedited reviews: approving protocols which appear to present no more than minimal risk.

CSU-IRB and CSU Provost and Vice President of Academic Affairs will terminate any project where the Principal Investigator (PI) proceeds to collect data without IRB approval.

Article XI. MONITORING
CSU-IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. In some circumstances, a shorter review interval may be required. The IRB will require review more frequently than annually for those studies deemed “high-risk.” If a study is inadvertently terminated by the investigator, it may be reactivated within 60 days without having to submit a newly completed application to CSU- IRB as a new study.

In the event that CSU-IRB becomes aware of any serious or continuing non- compliance with the regulations or the policies of CSU-IRB, a written notice of such noncompliance, suspension, or termination will be given to the Researcher by way of the Office of Sponsored Programs and Research and CSU Provost and Vice President for Academic, who will decide on the appropriate disciplinary actions.

Article XII. RECORDS
The CSU-IRB Chair and Administrator shall see that proper records are maintained, specifically:

Minutes

- Complete minutes of all convened IRB meetings are taken by the CSU- IRB Coordinator or designee.
- Minutes are provided to all committee members prior to the subsequent meeting for their review prior to the meeting.
- Minutes are approved by the committee at the subsequent meeting. Once approved, they may not be altered by anyone, including any higher institutional authorities

Minutes include the following elements:

1) Member attendance at the meeting, including when an alternate member has replaced a primary member, and (if both are present) which is being counted for purposes of establishing a quorum.

    - Note – although members do not routinely participate via teleconference, this option is allowable under OHRP guidelines. If members do participate by teleconference, the minutes need to document this, as well as document that these members received pertinent material prior to the meeting, and were able to actively and equally participate in discussions.

2) Visitor attendance at the meeting.

3) Roles (e.g. community representative, representative of vulnerable populations, VA representative) of each person present at meeting, including any alternate members who are replacing primary members at the meeting.

4) Any changes in attendance for each action taken by the committee (e.g. changes due to members who have left or joined during the meeting). Names of members will be recorded as changes in attendance occur. If members have absented or recused themselves due to a conflict of interest, the member name and this reason are recorded in the minutes.

5) A summary of any controversial issues and their resolution.

6) For any protocol requiring revision prior to approval, a complete summary and justification of all items requiring modification in sufficient depth to allow the researcher to address the areas of concern to the committee.

7) For any protocol that is disapproved, the basis for disapproving research will be clearly recorded.

8) If applicable, a justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

9) If applicable, the rationale for significant risk/non-risk device determinations.

10) A determination of the level of risk.

11) Specific determinations, as required by the regulations, and protocol-specific findings justifying those determinations for:

- Waiver or alteration of the consent process or documentation of consent;
- Waiver or alteration of the HIPAA authorization requirements for use of protected health information; and
- Research involving prisoners, pregnant women, human fetuses and neonates, and children.

12) A decision on the protocol (approval, approval with restrictions, disapproval, table pending clarification from the principal investigator) and the length of the approval period. This will include the specific number of votes for each protocol as numbers for, against, abstaining, and recusal (and reason for recusal).

13) A decision on the body responsible for reviewing the principal investigator's response to a protocol which has been approved with restrictions by the CSU-IRB.

14) Review and approval may be granted by the CSU-IRB Chair or designee.

15) Review and approval will be granted only following full board review of the modified protocol.

16) A record of approval of all actions taken by the IRB chair or designee on exempt or expedited research. This will also include the specific category used to determine exemption for protocols categorized as exempt.

17) A record of all protocols that were contingently-approved at a prior meeting and that have since fulfilled the requirements for approval as specified by the CSU-IRB.

18) Reports of significant adverse events or unanticipated problems and a determination if these are serious, unanticipated and research-related (for adverse events) or (for unanticipated problems) if these involve noncompliance, and/or are serious and continuing in nature.

19) Reports of emergency use of investigational drugs, biologics or devices.

The minutes shall be kept in perpetuity; all protocols shall be kept for three years after completion of the research.

Records Retention

1) All materials required by regulatory authorities will be maintained for at least three years.

2) All records relating to research that is conducted shall be retained for at least three years after completion of the research.

3) At a minimum, the following regulatory-required materials will be maintained for at least

three years:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the CSU-IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- Records of continuing review activities (see below).
- For a protocol's initial and continuing review, documentation will include the frequency of the next continuing review.
- For initial and continuing review of research by the expedited procedure, documentation will be maintained indicating:
- The specific permissible category.
- Description of action taken by the reviewer.
- Any findings required under the regulations.
- Copies of all correspondence between the IRB and the investigators.
- A list of CSU-IRB members in the same detail as described in §46.103(b)(3).
- Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

Article XIII. CSU-IRB REQUIREMENTS OF THE INVESTIGATOR

For protocols requiring full review CSU-IRB shall require:

Application Form

1) Informed consent forms.
2) Surveys, Questionnaires, Instruments.
3) Contact letters, Flyers, advertisements etc., if used to recruit subjects.
4) Letter from the external supervisor/collaborator expressing willingness to advise/collaborate with the principal investigator, purpose of collaboration and duration.

5) Letter from the supervisor of the principal investigator at CSU expressing no conflict of interest.

6) Three (3) copies of the grant application, if seeking extra-mural funding.

CSU-IRB will not review any applications unless the required items are included in the submission. Also if the study is conducted outside CSU facility, CSU-IRB approval from the study site may be required. If the site does not maintain an IRB, then a letter of compliance signed by the Institutional official and written on signed letter head must be forwarded to the committee. The letter must explicitly state the IRB number, study title, name of the Principal Investigator, and the assurance that the site will abide by and comply with the procedures approved by the CSU-IRB.

APPENDIX

IRB Member Conflict of Interest Form

1) As an CSU-IRB member/alternate member, do you have a vested interest in any actual or potential commercial enterprise/business, other than patents, which may be germane to conducting research protocol reviews?

   ☐ Yes ☐ No

   If yes, fully explain and identify the safeguards taken to prevent bias in review.

2) Are there financial issues that may be of concern to conducting an impartial review? If no, please certify this by checking the following boxes to indicate that you, as an IRB reviewer/ committee member:

   ☐ Do not have ownership interest, stock options or other financial interest related to any proposed research whose value, when aggregated for immediate family, represents >5% interest in any one single entity.

   ☐ Will not receive compensation related to the research whose amount is affected by the outcome of the research.

   ☐ Have no equity interests in the sponsor of studies greater than $10,000 (when aggregated for the immediate family), or do not have ownership interest, stock options, or other financial interest related to the proposed research of any value whose value could not be determined through reference to publicly available prices.

   ☐ Do not have Board or executive relationship related to proposed research, regardless of compensation.

   ☐ Will receive no payments by research sponsors directly to the investigator(s), their spouses or dependent children.

   ☐ Have no financial interests (other than patents) in any non-sponsored research.

If all boxes above cannot be checked, please describe below (or in a separate attachment) how such financial arrangements will not adversely affect the interests of the research subjects, and how subjects will be given any information which may be material to potential subjects' decision-making process.

3) Do you agree to excuse (recuse) yourself on a case-by-case basis, in any matter coming before the CSU-IRB committee in which you may have a potential or real conflict of interest?

☐ Yes ☐ No

Committee member: _____ Date: _____
(Print Name)

Signature _____

The above should be filled out yearly, as applicable, and submitted to the CSU-IRB Chair.