MEMO

Date: March 18, 2018

To: Veena Prabhu
   Chair, Academic Senate

From: Sharon H. Ulanoff, Chair
       Faculty Policy Committee

Copies: M. Caldwell, J. Lazo-Uy, R. Roquemore, V. Salcido, H. Riggio, J. Underwood, J. Shiotsugu

Subject: Recommendation for Proposed Policy Changes for Chapter II of the Faculty Handbook

FPC 17-9: Institutional Review Board—Human Subjects

On February 2, 2018 Faculty Policy Committee was charged with reviewing FPC 17-9: Institutional Review Board—Human Subjects (IRB), proposed changes recommended by the IRB in order to update the policy to be in compliance with federal regulations. The charge included existing policy, which was recommended for deletion as well as replacement policy language. FPC reviewed FPC 17-9, which included information compiled by ORSCA that provides the rationale for replacing existing policy with new policy language. FPC reviewed the proposed policy deletion and proposed new policy in light of the provided information and met with Dr. Jeffrey Underwood, Associate Vice President for Research (AVP-R) and Institutional Official responsible for the IRB at its meeting on February 19, 2018. Dr. Underwood discussed the need for the changes based on regulations related to the membership, selection and appointment of members, training, and member responsibilities and further clarified that ORSCA and the IRB are seeking Senate support for the recommended changes. The main focus of FPC’s discussion was eligibility for membership and selection/appointment to the IRB. We further discussed the need for member training for compliance and member responsibilities. After review and considerable deliberation FPC voted to support the recommendations in FPC 17-9: Institutional Review Board—Human Subjects, recommending deletion of existing policy and replacing it the new policy language that was proposed. FPC concluded that debating/amending the language of the policy falls under the purview of ORSCA, the IRB, and the institutional official to ensure compliance with federal regulations and therefore did not modify any of the proposed language. It should be noted that two FPC members also serve on the IRB.

Lines 41-70: This language updates the membership of the existing policy to align the policy with federal regulations, specifically to exclude those who are not eligible (e.g., students) and include two IRB staff members per pending changes to federal regulations. Federal regulations specific state the requirements for IRB membership: 45 CRF 46.107 states “the IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding...”
the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

45 CRF 46.107 further states that each IRB shall include at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. It further allows for consultants to be added as necessary.

Lines 71-83: This language addresses selection/appointment to the IRB. The Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections under the auspices of the Office for Human Research Protections (OHRP) and the NIH Human Research Protection Program provide guidance for member appointment to the IRB. Both indicate that the institutional official is in charge of making sure that members meet the qualifications indicated under 45 CRF 46.107. The language in lines 71-83 indicate that the IRB chair and IRB administrator identify membership needs for the following year, make and solicit recommendations for potential membership, and forward those recommendations to the institutional official, the AVP-R.

Lines 84-90: This language on member training is aligned with 45 CRF 46. This has been an ongoing issue with new IRB members who do not complete the training and therefore are unable to conduct expedited reviews, the main responsibility of IRB members.

Lines 101-110: This language lays out the considerable responsibilities for IRB members, which previously was not included in the policy.

Lines 121-133: This language addresses committee member removal, which falls under the purview of the institutional official. This responsibility is not addressed in the existing policy and recently has fallen to the IRB chair when a committee member was not fulfilling membership obligations regarding training and reviews.
Regulations related to oversight of IRB

1. Office for Human Research Protections (OHRP). "Secretary's Advisory Committee on Human Research Protections (SACHRP)-draft guidance on institutional official responsibilities."

The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.

The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federal-wide Assurance (FWA).

What are some responsibilities that may be delegated by the IO to a designee?

The IO may delegate the performance of certain oversight and operational duties to one or more individuals. Any delegation of duty must be in writing. Upon designation of a new IO, all delegation letters must be reviewed and renewed by the new IO if the new IO chooses to maintain delegation.

- Appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;
- Appointing the IRB chair or co-chairs. Suspending or terminating the appointment of any chair or co-chair who is fulfilling his/her responsibilities and or obligations;
- Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;
- Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an educational plan for IRB members, staff and investigators;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Performing periodic evaluation of the performance of the IRB members and administrative staff;
- Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRB;
- Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;
- Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.

2. From the NIH Human Research Protection Program IRB member manual

A. Identifying members: The Institute CD [Clinical Director] or CDs (in the case of multi-Institute IRBs), the IRB Chair, and, at the discretion of each IC [Institute Director], the SD [Scientific Director], recommend the appointment of the IRB Chair, the IRB Vice Chair and IRB members (including alternate members). In making such recommendations, consideration will be given to the requirements above for IRB membership and representation. The designated IRB will provide the prospective nominee with the IRB Member Survey to ensure that they satisfy the IRB’s composition and representative capacity requirements.
   a. Nominees and their supervisors should agree to the nomination.

   For our campus, Jason would be either CD or SD and Jeff is Institute Director.

3. From 45 CRF 46. 46.107. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

   The institutional officer is in charge of making sure that members meet the qualifications.
The Institutional Review Board - Human Subjects

(Senate: 1/5/82, 3/6/90, 4/13/93, 2/15/94, 5/3/94, 8/17/99, 2/19/02, 5/20/03; President: 1/18/82, 4/5/90, 5/14/93, 6/6/94, 6/29/94, 9/17/99, 3/21/02; 9/5/03; Editorial Amendment: 9/00, 8/01, 1/27/16 [EA])

Charge. The Institutional Review Board - Human Subjects reviews proposed biomedical and behavioral research projects involving human subjects in order to protect their rights, in compliance with federal regulations. Both funded and unfunded research projects, whether they are conducted by faculty, staff or students of the University, or by researchers not affiliated with the University but whose research involves campus personnel, shall be subject to review, except those unfunded projects for which adequate review procedures exist within a department/division/school. This review must determine whether the subjects will be placed at risk and, if risk is involved, whether:

1. The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant the committee’s decision to allow the subject to accept the risks.
2. The rights and welfare of any such subjects will be adequately protected.
3. Legally effective informed consent will be obtained by adequate and appropriate methods.

Where the committee finds risk is involved and an activity is approved, the committee must review the conduct of the activity at timely intervals.

Membership. The membership of this committee shall be composed of the following:

1. Eight faculty members from at least two different colleges having expertise in medical, physical, psychological, social or legal risks nominated and elected for staggered four-year terms by the Nominations Committee. At least three faculty members shall be practicing scientists experienced in research involving human subjects. The primary concerns of at least three other faculty members shall be in a nonscientific area (e.g., ethicist, lawyer, clergy).
2. The University Physician or designee.
3. One public member and one alternate public member who are not affiliated with the University, appointed by the President for a specified term, subject to approval by the Nominations Committee.
4. One upper division, classified graduate or postbaccalaureate student member who is knowledgeable regarding medical, physical, psychological, social or legal risks selected annually by the Board of Directors of the Associated Students, Inc. Criteria for the student member are the same as those specified for student members of the Academic Senate (Constitution of the Faculty, Section 3h, Appendix C of the Faculty Handbook).
5. The Provost and Vice President for Academic Affairs or designee who serves ex officio as executive secretary, non-voting, and in consultation with the committee chair, will be
responsible for establishing the agenda and promoting efficient and effective committee
action.

All members will attend an annual orientation meeting.

**Quorum.** A quorum shall be a majority of the voting members of the committee.

**Officers and Duties.**

1. The officers of this committee are chair and vice chair who shall be elected annually at the
last meeting of the spring quarter by the members of the following year’s committee.
2. The chair shall call regularly scheduled meetings of the committee and shall set the
agenda.
3. The chair shall determine by the second week of the spring quarter the faculty
replacement needs for the following year and shall notify the Nominations Committee to
conduct necessary elections.

**Meeting Time.** The Institutional Review Board - Human Subjects meets the even weeks of the
semester from 12:30 p.m. to 2:35 p.m.
THE INSTITUTIONAL REVIEW BOARD - HUMAN SUBJECTS


THE IRB REVIEWS RESEARCH WHEN PROCEDURES ARE PROPOSED TO OBTAIN INFORMATION ABOUT A LIVING INDIVIDUAL THROUGH INTERACTION OR INTERVENTION SUCH AS THE USE OF A SURVEY, INTERVIEW, OBSERVATION, EXPERIMENTATION, OR THE ANALYSIS OF HUMAN TISSUES, RECORDS, SAMPLES OR OTHER DATA PREVIOUSLY COLLECTED FROM HUMAN SUBJECTS. ALL RESEARCH INVOLVING HUMAN SUBJECTS MUST BE REVIEWED AND APPROVED BY THE IRB IN ADVANCE OF STUDY INITIATION (45 CFR 46.109).

BOTH FUNDED AND UNFUNDED RESEARCH PROJECTS CONDUCTED BY FACULTY, STAFF OR STUDENTS OF THE UNIVERSITY SHALL BE SUBJECT TO IRB REVIEW. THIS REVIEW MUST DETERMINE WHETHER THE SUBJECTS WILL BE PLACED AT RISK AND, IF RISK IS INVOLVED, WHETHER:

1. THE RISKS TO THE SUBJECT ARE SO OUTWEIGHED BY THE SUM OF THE BENEFIT TO THE SUBJECT AND THE IMPORTANCE OF THE KNOWLEDGE TO BE GAINED AS TO WARRANT THE COMMITTEE'S DECISION TO ALLOW THE SUBJECT TO ACCEPT THE RISKS.
2. THE RIGHTS AND WELFARE OF ANY SUCH SUBJECTS WILL BE ADEQUATELY PROTECTED.
3. LEGALLY EFFECTIVE INFORMED CONSENT WILL BE OBTAINED BY ADEQUATE AND APPROPRIATE METHODS.

THE IRB REVIEWS RESEARCH PROTOCOLS AND MAY REQUIRE MODIFICATIONS TO THE PROTOCOL TO SECURE APPROVAL TO CONDUCT THE RESEARCH. THE IRB MAY ALSO DISAPPROVE RESEARCH. DECISIONS MADE BY THE IRB ARE COMMUNICATED IN WRITING TO THE INVESTIGATOR (45 CFR 46.109). THE IRB MAY SUSPEND OR TERMINATE APPROVAL OF RESEARCH THAT IS NOT CONDUCTED IN ACCORDANCE WITH THE APPROVED PROTOCOL OR THAT HAS BEEN ASSOCIATED WITH UNEXPECTED SERIOUS HARM TO SUBJECTS (45 CFR 46.113). ACTIONS TAKEN BY THE IRB TO SUSPEND OR TERMINATE APPROVAL WILL BE DOCUMENTED IN WRITING AND REPORTED TO THE INVESTIGATOR, INSTITUTIONAL OFFICIALS, AND TO THE FEDERAL OFFICE FOR HUMAN RESEARCH PROTECTIONS.

RESEARCH THAT IS APPROVED BY THE IRB MAY BE SUBJECT TO FURTHER REVIEW BY THE OFFICIALS OF THE INSTITUTION. AUTHORIZED INSTITUTIONAL OFFICIALS MAY APPROVE OR
The institutional officials may not approve research involving human subjects that has not been approved by the IRB (45 CFR 46.112).

**MEMBERSHIP.** IRB members are appointed for renewable four-year terms by the associate vice president for research in accordance with federal requirements (45 CFR 46.107). The IRB is composed of members representing the university faculty, staff, and local community. Membership includes at least one individual whose primary concerns are in nonscientific areas and at least one member not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution. The faculty members on the IRB are from a variety of disciplines representative of the research reviewed.

The membership of this committee shall be composed of the following:

1. Eight faculty members from at least two different colleges having expertise in medical, physical, psychological, social or legal risks. At least one faculty member shall be a practicing scientist experienced in research involving human subjects. The primary concerns of at least one other faculty member shall be in a nonscientific area (e.g., ethics, law, religion).
2. The university physician or designee.
3. One public member.
4. Two IRB staff members.
5. The associate vice president for research or designee who serves ex officio as executive secretary and is a non-voting member.

**ALTERNATE MEMBERS.** Up to three alternate members shall be appointed to the IRB to serve in the absence of a regular voting member. Alternates are selected based on the expertise and perspectives they bring to the review process. Alternate member may be scientists, nonscientists, or community members and are required to complete the same training as IRB members. Alternate members attend IRB meetings but only vote when taking the place of a voting member.

**CONSULTANTS.** The IRB recognizes that additional expertise may be necessary when reviewing a protocol. The IRB may request consultation from subject matter expert when issues relevant to a protocol require outside expertise. Consultants are not IRB members and may not vote.

**SELECTION/APPOINTMENT.** The IRB chair or IRB administrator will confirm that IRB membership is in compliance with regulations (46.107). If an additional member(s) is needed, several methods are used to identify candidates. The existing members may be asked to provide recommendations to the chair. Department chairs may be contacted to suggest faculty who are available and interested. Faculty who
ARE ACTIVE IN THE RESEARCH COMMUNITY MAY BE CONTACTED DIRECTLY TO DISCUSS
SERVICE TO THE COMMITTEE. THE CHAIR AND THE IRB ADMINISTRATOR FORWARD
RECOMMENDATIONS TO THE ASSOCIATE VICE PRESIDENT FOR RESEARCH. APPOINTMENT TO
THE IRB IS MADE BY THE ASSOCIATE VICE PRESIDENT FOR RESEARCH. REAPPOINTMENT MAY
OCUR PROVIDED THE MEMBER DEMONSTRATES AN INTEREST IN RESEARCH ETHICS,
KNOWLEDGE OF REGULATIONS AND ETHICAL STANDARDS IN ASCERTAINING THE
ACCEPTABILITY OF PROPOSED RESEARCH, COMPLIANCE WITH REQUIRED TRAINING, AND HAS
THE TIME TO DEVOTE TO ASSOCIATED RESPONSIBILITIES.

MEMBER TRAINING. IRB MEMBERS PARTICIPATE IN INITIAL AND CONTINUING EDUCATION BY
REVIEWING RELEVANT MATERIALS ON ISSUES, REGULATIONS AND GUIDANCE CONCERNING
HUMAN SUBJECTS PROTECTIONS (45 CFR 46.107). SUCCESSFUL COMPLETION OF THE IRB
MEMBER TUTORIAL TRAINING IS A MECHANISM FOR THE CAL STATE LA IRB MEMBERSHIP TO
DEMONSTRATE A BASIC UNDERSTANDING OF BOTH FEDERAL AND CAL STATE LA-SPECIFIC
ETHICAL PRINCIPLES AND REGULATORY COMPLIANCE PRACTICES. IN ADDITION TO THE IRB
MEMBER TUTORIAL, ALL IRB MEMBERS WILL ATTEND AN ANNUAL ORIENTATION MEETING.

QUORUM AND VOTING. TO CONVENE A MEETING OF THE IRB, A MAJORITY OF THE VOTING
MEMBERS (OR DESIGNATED ALTERNATES) OF THE IRB MUST BE PRESENT. THE COMMITTEE
MAY NOT CONVENE WITHOUT A MEMBER WHOSE PRIMARY CONCERNS ARE NONSCIENTIFIC. IF
THE QUORUM FAILS DURING THE MEETING (EARLY DEPARTURES, LOSS OF NONSCIENTIST,
EXCUSED FOR CONFLICT) THE MEETING WILL BE TERMINATED UNTIL THE QUORUM CAN BE
RESTORED. ANY ACTION TAKEN WITHOUT A QUORUM PRESENT IS CONSIDERED INVALID.

INDIVIDUALS DESIGNATED AS NON-VOTING MEMBERS MAY CONTRIBUTE TO DISCUSSION;
HOWEVER, MAY NOT SERVE AS A PRIMARY REVIEWER, PROPOSE A MOTION OR VOTE ON A
MOTION. IN ORDER FOR A MOTION TO PASS, IT MUST RECEIVE THE APPROVAL OF A MAJORITY
OF VOTING MEMBERS PRESENT AT THE MEETING.

IRB MEMBER DUTIES/RESPONSIBILITIES

1. ATTEND IRB MEETINGS.
2. COMPLETE IRB MEMBER TRAINING.
3. CONDUCT REVIEW OF RESEARCH PROTOCOLS (FULL BOARD PROTOCOLS) AT CONVENED
   MEETINGS AT WHICH A QUORUM OF THE MEMBERS OF THE IRB ARE PRESENT.
4. CONDUCT INITIAL AND CONTINUING REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS
   (EXPEDITED PROTOCOLS).
5. REVIEW PROPOSED CHANGES IN RESEARCH ACTIVITIES TO INSURE THAT CHANGES IN
   APPROVED RESEARCH, DURING THE PERIOD FOR WHICH IRB APPROVAL HAS BEEN GIVEN,
   HAVE NOT BEEN INITIATED WITHOUT IRB REVIEW AND APPROVAL.
111  **OFFICER DUTIES/RESPONSIBILITIES**

112  1. THE OFFICERS OF THIS COMMITTEE ARE CHAIR AND VICE CHAIR WHO SHALL BE ELECTED
113     ANNUALLY AT THE LAST MEETING OF THE SPRING SEMESTER BY THE MEMBERS OF THE
114     FOLLOWING YEAR’S COMMITTEE.
115  2. THE CHAIR SHALL CALL REGULARLY SCHEDULED MEETINGS OF THE COMMITTEE AND
116     SHALL SET THE AGENDA.
117  3. OFFICERS ARE RESPONSIBLE FOR ALL IRB MEMBER DUTIES.
118  4. THE CHAIR SHALL DETERMINE BY THE SECOND WEEK OF THE SPRING SEMESTER THE
119     FACULTY REPLACEMENT NEEDS FOR THE FOLLOWING YEAR AND SHALL NOTIFY THE
120     ASSOCIATE VICE PRESIDENT FOR RESEARCH.

121  **IRB MEMBER REMOVAL**

122  THE ASSOCIATE VICE PRESIDENT FOR RESEARCH MAY REMOVE A MEMBER FROM THE IRB
123  BEFORE THE END OF HIS/HER APPOINTED TERM. THE IRB CHAIR, IN CONSULTATION WITH THE
124  DIRECTOR OF RESEARCH, MAY SUBMIT A REQUEST FOR REMOVAL TO THE ASSOCIATE VICE
125  PRESIDENT FOR RESEARCH BASED ON THE MEMBER’S FAILURE TO CARRY OUT THE
126  RESPONSIBILITIES OF AN IRB MEMBER (E.G. FAILURE TO ATTEND MEETINGS REGULARLY,
127  FAILURE TO COMPLY WITH REGULATIONS AND POLICIES, FAILURE TO CONDUCT EXPEDITED
128  REVIEWS). THE ASSOCIATE VICE PRESIDENT FOR RESEARCH MAKES THE FINAL DECISION ON
129  REMOVALS. IF REMOVED, PROMPT NOTIFICATION WILL BE PROVIDED TO THE MEMBER. IRB
130  MEMBERS MAY REQUEST TO BE REMOVED FROM THE IRB WITHOUT PROVIDING A REASON
131  (E.G., TIME COMMITMENT, PERSONAL REASONS) AND WILL BE REMOVED WITH NOTIFICATION
132  TO THE ASSOCIATE VICE PRESIDENT FOR RESEARCH. EFFORTS WILL BE MADE WHEN POSSIBLE
133  TO RETAIN THE IRB MEMBER SO THAT THE FOUR-YEAR TERM MAY BE COMPLETED.

134  **MEETING TIME.** THE INSTITUTIONAL REVIEW BOARD - HUMAN SUBJECTS MEETS THE EVEN
135  NUMBERED WEEKS OF THE SEMESTER FROM 12:30 P.M. TO 2:35 PM.