TO: Executive Committee & Academic Senate
FROM: The Committee on Research (CR) & Faculty Affairs Committee (FAC)
SUBJECT: 15-16 CR 3: Response to referral to review the appointment procedures for membership on the Institutional Review Board (IRB). Appointment procedures for the Institutional Animal Care and Use Committee (IACUC) are also discussed.

ACTION REQUESTED: Information to the Executive Committee of the Academic Senate

ACTION REQUESTED: Review and discussion of this information item.

BACKGROUND:

CR and FAC received a referral from Ex Com (15-16 BEC 6) to review and clarify the appointment procedures for the Institutional Review Board (IRB). Per the US Department of Health and Human Services (HHS), The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. (From: http://www.hhs.gov/ohrp/archive/irb/irb_chapter1.htm)

CR and FAC contributed to, reviewed, and approved this document. CR approved it on 2/25/16 and FAC approved it on 3/2/16.

Given that CR is requesting to update the Animal Care and Use Policy (15-16 CR-2), this document also briefly covers appointment procedures for the Institutional Animal Care and Use Committee (IACUC).

The HHS requirements for IRB membership are quoted below from http://www.hhs.gov/ohrp/policy/faq/irb-registration/requirements-for-irb-membership.html:

The requirements for IRB membership are addressed in the HHS regulations at 45 CFR 46.107 [Note: 45 CFR 46.304 requires a specialized IRB composition when research involving prisoners is being reviewed, including the presence of a prisoner representative].
An IRB must:

1) have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
2) make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
3) include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
4) include 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; and
5) not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Please see the regulations at 45 CFR 46.107 for complete information on all of the required qualifications to properly compose an IRB.

Point 1) is described in more detail here (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/cfrsearch.cfm?fr=56.107):

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. 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 IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The CSUEB Policy on Research with Human Subjects stipulates some additional requirements regarding membership:

5.1 Membership
California State University, East Bay's IRB shall be a standing subcommittee of the Committee on Research. Its membership shall consist of eleven or more members of varying backgrounds to assure complete and adequate review of research and related activities commonly conducted by the University. The membership shall vary in discipline, profession, racial background, and sex. One member of the IRB must be a community representative and, as such, may not be
an employee or related to an employee of the University. The AVP or his/her
designee will serve as the IRB Coordinator and an ex officio member of the IRB.
The Medical Director of Student Health Services or the Medical Director's
designee, and the Chair of the Committee on Research shall be ex officio
members of the IRB. The remaining members shall serve by appointment. One
shall be a faculty or staff member who has current skills in, and is licensed to
provide, psychological counseling. There shall be an equal number of alternate
members to serve when a regular member is absent from a meeting. Alternate
members will meet the same criteria, and have the same qualifications to serve as
do the regular members. All members shall undergo appropriate training as well
as periodic updates to that training as specified by the AVP.

In an email exchange to assist in preparation of this response to the referral, Dr. Kevin Brown,
Chair of the CSUEB IRB noted:

As required above, one would choose members who have experience in the types
of research being reviewed. The main departments we get research protocols
from are Teacher Education, Educational Psychology, Nursing, Social Work,
Communicative Sciences and Disorders, Psychology, and Kinesiology. I like to
try to have 2 members from each of these departments on the board so that we
have one expert available even if the other faculty member from the same
department submits an application. Beyond that, and the above federal
requirements, I try to recruit members who have submitted protocols in the past,
and hence are familiar with the IRB processes and with human subjects research
in general.

I believe that the standard CSUEB procedure for committee membership could
not ensure that federal regulations would be followed, nor would it provide the
most qualified set of members to complete the reviews.

The appointment procedures for IRB are also noted in the CSUEB Policy on Research with
Human Subjects:

5.2
Appointment Procedures
When appropriate, the Committee on Research shall select nominees for the IRB
and forward them to the Executive Committee of the Academic Senate. The
Executive Committee shall review the nominees, add additional names if it
wishes, and forward all nominations to the AVP of Research and Sponsored
Programs. The AVP shall select the appointed members of the IRB from among
these nominees, except in those instances in which he or she finds the list
inadequate in any respect. In such cases, the AVP shall ask the Committee on
Research to forward, through the Executive Committee, the names of additional
nominees. The AVP shall also have the authority to appoint special members to
the IRB in those instances when the Board is considering cases in which Federal
regulation requires unique expertise, e.g. experiments with new drugs or research
with prisoners. All appointments to and changes in IRB membership shall be
reported to the Department of Health and Human Services (hereinafter referred to as DHHS).

These appointment procedures are currently being followed. On January 5, 2016, Ex Com approved 15-16 CR 1 Nominees to fill vacancies on the Institutional Review Board.

Given this information regarding federal and other guidelines for IRB it is the recommendation of CR and FAC that we continue the current practice. A regular election might not allow for selection of members that fit the criteria, and the length of time an election requires could mean that we are out of compliance with federal guidelines for a significant period of time while waiting for an election to be completed.

CR and FAC would like to make an additional recommendation that whenever it is feasible, vacancies for IRB and IACUC be announced to all faculty via the Academic Affairs newsletter or other appropriate means (depending on the specific opening that needs to be filled) so that faculty who meet the criteria and are interested in serving on these committees may apply.

Though CR and FAC were not specifically asked in 15-16 BEC 6 to address membership and appointment procedures for the CSUEB Institutional Animal Care and Use Committee (IACUC), the membership requirements are similarly detailed in that members must have specific backgrounds and training. Additionally, the IACUC may not conduct official business if a vacancy exists. In view of these realities, and given the fact that responsibilities for compliance ultimately rests with the President of the University or the Institutional Official that has been delegated the authority for animal care matters, it is the recommendation of CR and FAC to continue the current practice of having members recommended by the chair of IACUC and appointed by the Institutional Official.

The CSUEB Policy on Research with Human Subjects was last updated in 2008. On March 10, 2016, Dr. Kevin Brown will meet with CR to review the IRB policy and to update it if necessary. If changes are recommended, they will be brought to Ex Com and the Academic Senate for review and approval.