TO: The Executive Committee and Academic Senate
FROM: The Committee on Research
PURPOSE: Provided to the Academic Senate as Information

BACKGROUND INFORMATION:
The following attached document is the 2017-2018 Institutional Review Board Annual Report as submitted by Kevin Brown, Chair of the Institutional Review Board.
Institutional Review Board Annual Report
June 16, 2017 – June 15, 2018

As stated in 80-81 BEC 2, the Assurance of Compliance with Department of Health and Human Services Regulations on Protection of Human Subjects, the Chair of the Institutional Review Board (IRB) shall report annually to the AVP of the Office of Research and Sponsored Programs, and through the Chair of the Committee on Research to the Chair of the Academic Senate.

80-81 BEC 2 states that the annual report must contain six elements:

1) The dates of all IRB meetings and the attendance.

Most human subjects research conducted at CSUEB is of minimal risk and is evaluated via administrative or expedited review, which is coordinated via campus mail and email. No full board meetings were held in academic year 2017-2018.

2) The total number of projects and activities reviewed, including statistics on expedited reviews, approvals, rejections, and deferred protocols.

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Faculty/Staff-Initiated</th>
<th>Student-Initiated</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>5</td>
<td>39</td>
<td>44</td>
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<tr>
<td>Continuation Review</td>
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<td>3</td>
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<tr>
<td>Modification Review</td>
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<td>5</td>
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<tr>
<td>Exempt Protocols</td>
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<td>165</td>
<td>208</td>
</tr>
<tr>
<td>Incomplete</td>
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<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Not HSR</td>
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<td>4</td>
<td>7</td>
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<tr>
<td>Withdrawn</td>
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<td>1</td>
<td>2</td>
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<tr>
<td>Rejected</td>
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<td>0</td>
</tr>
<tr>
<td>Reliance Agreement</td>
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<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Total: 80 projects, 219 activities, 299 protocols.

The categories above reflect those used in the federal regulations governing IRB operations. Protocols undergoing full board review are reviewed by a quorum of board members at an in-person board meeting. Protocols undergoing expedited review are reviewed by the IRB chair and a subset of the board, typically using email correspondence. Protocols undergoing exempt review are reviewed by the IRB chair alone. 288 of the 299 protocols submitted to the IRB were approved, either via full board, expedited or exempt review of new, modified, or renewed research protocols. Two (2) of the remaining protocols require additional information for review. The information was requested but had not been received at the time of this report. Seven (7) of the protocols submitted were found not to be considered human subjects research. Such research does not require the approval of the IRB. Two (2) of the protocols were withdrawn by the investigator. In one case, a student-initiated protocol described a class
project where class projects do not require IRB review. The second was determined to be a Quality Improvement (QI) project, also which do not require IRB review.

Compared to last year, the number of faculty/staff-initiated protocols was somewhat lower (80 vs. 104) while the number of student-initiated protocols was similar (219 vs. 230.) The total number of submitted protocols was somewhat lower (299 vs. 334).

Note that the Departments of Teacher Education, Educational Psychology, and Educational Leadership submit their students’ Master’s theses projects for Board approval. Four sections of these students account for approximately 60 of the above student-initiated protocols. Protocols from Master’s of Social Work students accounted for another 5-10 protocols.

The board instituted a training policy for investigators conducting research using human subjects which was approved by the Academic Senate on June 3, 2008. The training program was implemented by subscribing to the CITI Human Subjects Research Training program, an online training program hosted by the University of Miami. Compliance with the training requirement was required for investigators submitting protocols and all IRB members from Spring quarter 2009 onward. The ORSP maintains a database of investigators who have completed the training. During the year covered by this report, faculty, staff, and student investigators completed 584 training programs.

3) The current membership of the Board with terms of appointment indicated.

The board is made up of eleven (11) members and an equal number of alternates. Both members and alternates participate equally in reviewing protocols. A distinction is only made during full board meetings as required by federal regulation.

**Members:**

1. Jeffra Bussmann, Chair, Committee on Research  
   Term Ends: Fall 2019  
   Ex-officio
2. Kevin Brown, Chair, Computer Science  
   Term Ends: Fall 2019
3. Anne Wing, IRB Coordinator, ORSP  
   Term Ends: Fall 2019  
   Ex-officio
4. Ann Halvorsen, Educational Psychology  
   Term Ends: Fall 2019
5. Kimberly Kim, Nursing and Health Sciences  
   Term Ends: Fall 2019
6. Elana Dukhovny, Communicative Sciences and Disorders  
   Term Ends: Fall 2019
7. Leonardo R. Arriola, Community Representative  
   Term Ends: Fall 2019
8. Toni Naccarato, Social Work  
   Term Ends: Fall 2019
9. Richard Sprott, Human Development  
   Term Ends: Fall 2019
10. Jessica Weiss, History  
    Term Ends: Fall 2019
11. Andrea Wilson, Director, Student Health Service  
    Term Ends: Fall 2019  
    Ex-officio

**Alternates:**

1. John Eros, Music  
   Term Ends: Fall 2019
2. David Fencsik, Psychology  
   Term Ends: Fall 2019
3. Silvina Ituarte, Criminal Justice Administration  
   Term Ends: Fall 2019
4. Will Johnson, Sociology and Social Services  
   Term Ends: Fall 2019
5. Marvin Lamb, Psychology          Fall 2018  
6. Denise Liu, Nursing and Health Sciences  Fall 2020  
7. Mari Gray, Educational Leadership    Fall 2019  
8. Vanessa Yingling, Kinesiology        Fall 2020  
9. Terry Soo-Hoo, Educational Psychology  Fall 2018  
10. Elizabeth Wilson, Community Representative  Fall 2020  
11. Pradeep Ramanathan, Communicative Sciences and Disorders Fall 2018

4) **A citation of current, relevant legislation and regulatory requirements which govern the actions of the IRB.**


5) **Notes on developments at the national, state, local community and university levels that may require policy revisions to provide assurance as defined by Federal regulations, changes, or addenda or other administrative attention or action.**

The U.S Department of Health and Human Services (DHHS) and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). These revisions were approved by the Obama administration and most provisions were to take effect January 19, 2018. The effective date of the Revised Common Rule has been delayed two times. The current date that they will take effect is January 21, 2019.

When the changes do become effective, CSUEB policy must be updated to conform to the new regulations. Most of the changes concern handling of bio-specimens, a new limited review process, and the requirement for single-IRB approval of multi-site projects. CSUEB has seen little or no research using bio-specimens, allowing for straight-forward implementation of the new requirements in that regard. Limited review will need to be defined for our campus, and may affect current policies and procedures. Single-site review policies and documents will also need to be developed. Due to the complexity involved, single-site review provisions of the revised Common rule are not to take effect until January 20, 2020.

The Council on Governmental Regulations (COGR) has engaged in conversations with the Human Subjects Research Protection Officer, National Science Foundation, regarding applications and proposals lacking definite plans for involvement of human subjects. Per 45 CFR 690.118, applications lacking definite plans for involvement of human subjects, such as “projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds,” need not be reviewed by an IRB before an award is made. NSF has indicated that for studies that meet these criteria, IRBs may use a “Preliminary Approval” notice for NSF projects and that this approval is consistent with the Proposal and Award Policies and Procedures Guide. The draft letter provides a limited approval period and indicates that the investigator must submit an amendment or new IRB
application for full IRB approval of the project prior to the expiration date. It also emphasizes that no work with human subjects, including recruitment, may be conducted under the determination. Establishing a time limit, whether it is 3 or 6 months, requires investigators to return to the IRB and establishes accountability. The CSUEB ORSP and IRB are aware of this policy and will comply when reviewing new NSF grant applications.

6) Recommendations for administrative or Academic Senate actions for maintaining an effective institutional review function for the purpose of protecting the rights and welfare of human subjects.

The Office of Research and Sponsored Programs is continuing to evaluate potential grant management software packages that include electronic IRB components. Such a system would allow investigators to submit research protocols and accompanying materials electronically, and to track their submissions as they go through the review process. Results of the evaluation will be presented to the Committee on Research for further action.

A discussion was begun this year in the CSU-IRB group, made up of IRB chairs and coordinators throughout the CSU system, regarding the appropriate oversight to the respective campus IRBs. Some campus IRBs are overseen through a senate committee and others are overseen through administrative offices such as the Office of Research and Sponsored Programs. It may be fruitful to start a discussion at CSUEB to determine which mode of oversight is most appropriate and efficient.

Respectfully submitted,

Kevin Brown
Chair, Institutional Review Board