COMMITTEE ON RESEARCH

DESIGNATION CODE: 2013-2014 CR 5
DATE SUBMITTED: September 30, 2014

TO: The Academic Senate
FROM: The Committee on Research

PURPOSE: Provided to the Academic Senate as Information

BACKGROUND INFORMATION:
The following attached document is the Institutional Review Board Annual Report as submitted by Kevin Brown, Chair of the Institutional Review Board.
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 expedited review, which is coordinated via campus mail and email. No full board meetings were required this year.

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>8</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>Continuation Review</td>
<td>13</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Modification Review</td>
<td>13</td>
<td>9</td>
<td>22</td>
</tr>
<tr>
<td>Exempt Protocols</td>
<td>52</td>
<td>165</td>
<td>217</td>
</tr>
<tr>
<td>Incomplete</td>
<td>4</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Not HSR</td>
<td>5</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>0</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Rejected</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Total 95 198 293

The categories above reflect those used in the federal regulations governing IRB operations. Protocols undergoing expedited review are reviewed by the IRB chair and a subset of the board. Protocols undergoing exempt review are reviewed by the IRB chair alone. 268 of the 293 protocols submitted to the IRB were approved, either via expedited or exempt review of new, modified, or renewed research protocols. Five (5) of the remaining protocols required additional information for review. The information was requested but had not been received at the time of this report. Twelve (12) of the protocols were withdrawn by the investigator. Eight (8) of the protocols submitted were found not to be considered human subjects research. Such research does not require the approval of the IRB.
Compared to last year, the number of faculty/staff-initiated protocols increased from 86 to 95 (+10%) and the number of student-initiated protocols decreased from 236 to 198 (-16%). The total number of submitted protocols increased from 322 to 293 (-9%).

Note that the Departments of Teacher Education, Educational Psychology, and Educational Leadership submit their students’ master’s theses projects for Board approval. Five cohorts of these students account for 68 of the above student-initiated protocols. The EdD program also generated 20 student-initiated research protocols for review. The Communications program also submitted protocols from cohorts of students with 20 and 7 protocols respectively.

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, 510 faculty, staff, and student investigators completed the training.

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. Sarah Taylor, Chair, Committee on Research  
   Ex-officio
2. Kevin Brown, **Chair**, Math and Computer Science 
   Fall 2016
3. Anne Wing, IRB Coordinator, ORSP  
   Ex-officio
4. Ann Halvorsen, Educational Psychology 
   Fall 2015
5. Kimberly Kim, Nursing and Health Sciences 
   Fall 2016
6. Elana Dukhovny, Communicative Sciences and Disorders 
   Fall 2015
7. Mary Jane Pabalan, Community Representative 
   Fall 2014
8. Mavis Braxton-Newby, Social Work 
   Fall 2016
9. David Sandberg, Psychology 
   Fall 2014
10. Jessica Weiss, History 
    Fall 2015
11. Andrea Wilson, Director, Student Health Service  
    Ex-officio

**Alternates:**

1. John Eros, Music  
   Fall 2014
2. David Fencsik, Psychology  
   Fall 2014
3. Silvina Ituarte, Criminal Justice Administration  
   Fall 2014
4. Will Johnson, Sociology and Social Services  
   Fall 2014
5. Marvin Lamb, Psychology  
   Fall 2015
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 federal government is considering making changes to the regulations which govern the conduct of human subjects research. On July 22, 2011, the Department of Health and Human Services (DHHS) issued an Advance Notice of Proposed Rulemaking (ANPRM) requesting comments on current regulations and suggestions for modifications. Comments were accepted through October 26, 2011. “Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences” was published in 2014, but there is no current timeline for approval or adoption of these proposals by the federal government.

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.

Currently, the board uses an Excel spreadsheet to accept, maintain, and track IRB applications, modifications, renewals, and closures. With the large number of protocols submitted each year, and the need for short turn-around time for student protocols in particular, an automated protocol submission and review system would be very helpful to the board and office staff as well as providing additional features to investigators. San Diego State University has implemented such a package in-house, and other CSU campuses have purchased commercial software. Based on a presentation comparing various options at the CSU IRB conference in January 2013, I suggest that the university consider purchasing the IRBNet service.

Respectfully submitted,

Kevin Brown
Chair, Institutional Review Board