CALIFORNIA STATE UNIVERSITY, LONG BEACH

VICE PROVOST FOR ACADEMIC PROGRAMS

Memorandum of Understanding

This MOU has been read and approved by:

Chair of Institutional Review Board: Paul Ratanasiripong, Ph.D. Date: 2/7/2023
Paul Ratanasiripong

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Institutional Review Board (IRB)
Office of Research and Economic Development (ORED)
February 6, 2023

This Memorandum of Understanding outlines the consensus reached by the Institutional Review Board (IRB), the Office of Research and Economic Development (ORED), and the Division of Academic Affairs, based on the recently conducted program review (Self-study in October 2022, with an internal and external review site visit in November 2022). It describes the goals to be achieved, and the actions to be undertaken by all parties to this MOU to achieve these goals, during the next program review cycle. Progress toward goals is to be addressed in an annual report. This is the first review for this academic support program, therefore there is no previous MOU. Information for the report below is directly from the self-study and the external review report.

Background

The aim of the Institutional Review Board (IRB) is to ensure that ethical research is being conducted. Processes for the IRB are delineated by CSU Chancellor Office Executive Order 0890, Section 3.4.2 (effective 01/07/2004, last revised 02/22/2021) and Academic Senate Policy 00-03 Protection of Human Subjects, (effective 01/28/2000). Currently, the IRB staff includes the Director for Research Integrity and Compliance (DRIC) Dr. Jason Wang, Research Compliance Specialist Mandie Claussen (almost full-time for IRB), and Research Compliance Specialist Dr. Mary Walker (30-40% time/effort for IRB). They are in the process of recruiting a Senior Research Compliance Specialist to provide high-level services to the IRB (such as independently conducting Exempt Protocol Reviews, etc.) and other components of research compliance.

Per campus policy, IRB Board membership includes a total of 14 voting members, including Dr. Dina Perrone, ex officio voting member as the Designee for Vice Provost for Academic Programs and Dean of Graduate Students, the DRIC, one community/non-science member, and 11 faculty voting members. Drs. Paul Ratanasiripong and Connie Ireland serve as the Chair and Vice-Chair, respectively.

Starting in 2012, IRB protocol submission/review documents are managed via the online management platform, IRBNet. The CSULB IRB Website provides important and useful information to the research community regarding FWA/IRB Registration, IRB regulation policies and procedures, regulation updates, guidance, IRB board member roster, IRB meeting dates, submission deadlines, submission instructions, forms to use (including accessible PDF versions), IRB contact information, methods to report non-compliance cases, etc.

A number of strengths were identified by the self-study and the review team:

- The IRB stringently adheres to relevant federal, state, and CSU CO IRB regulations, thus no significant violations have been reported.
- The IRB board is well constituted with dedicated and collaborative members.
- Researchers, IRB members, and staff are provided with sufficient training on IRB regulations to ensure their qualifications prior to taking on their responsibilities.
- IRB support staff presented a deep commitment to serving the campus community. They are eager to innovate new processes and implement updated technology to increase the efficiency of IRB reviews. The IRB staff provides proactive outreach presentations to educate the researchers, especially those who are first-time submitters.

Concerns and Opportunities for Development were noted by the self-study and the review team:

The overwhelming consensus of the review team and faculty and students that were interviewed was that the IRB procedures on campus lacked efficiency and timeliness, due in part to a challenging, rigid, and risk-averse process with inconsistent feedback as well as slow and unreliable timelines. Many of the faculty interviewed perceived the process as an obstacle to their success and their students' success.

Delays in Processing

- The most significant and consistent complaint from faculty and students was the lengthy
  delay and variability in review timelines that hinder the advancement of research projects, the securing of research funds, and impedes (sometimes catastrophically) student graduation and faculty promotion.

- The IRB typically handles an average of 340 submissions per year, with the most recent data from 2021-22 much lower at 278 submissions (Table 1). A large majority of the proposals are submitted as Exempt or Expedited reviews, with an expected shorter timeframe for review. Table 2 reveals that CHHS and CLA consistently have the most applications, followed by CED. These Colleges in particular have reported delays in approvals that have negatively impacted students' progress to graduation.

- Although the external review points to anecdotal evidence of some protocols taking from 4 months to a year (with one instance of 21 months) to approve, data from IRB Table 1 shows average business days to process protocols ranging from 29-57, which is an average of 6 weeks to 11.4 weeks.

	AY 2017/2018	AY 2018/2019	AY 2019/2020	AY2020/2021	AY 2021/2022
New Submissions					
Number of Submissions	348	334	343	336	278
Average Business Days to Process	29	44	39	57	44

Number of Admin/Exempt Review	130	237	264	277	218
Number of Expedited Review	49	92	78	49	56
Number of Full Board Review	1	5	1	3	2
Number of Unassigned/Withdrawn	151			7	2

Table 1. Annual account of Number of submissions and time to review.

Initial Submission by College	AY 2017/2018	AY 2018/2019	AY 2019/2020	AY2020/2021	AY 2021/2022
College of Business		12	15	20	12
College of Education		57	67	54	51
College of Engineering		9	7	6	2
College of Health and Human Services		108	116	107	86
College of Liberal Arts		109	77	102	94
College of Natural Sciences and Mathematics		9	14	13	9
College of the Arts		9	6	15	8
External Investigators		6	15	8	8
University Centers		15	26	11	8
TOTAL	0	334	343	336	278

Table 2. Submissions by College

- There is a lack of transparency of where the proposal is in the approval process. IRB Net does not provide a transparent workflow for submitters to gauge the progress of their proposal.

- Stakeholders expressed concern about the inordinate time spent on the pre-review process, which can take several weeks and impedes getting applications to board members for review. Table 3 reveals a pre-review range of 1-19 days. In total, the protocol is with the IRB an average of 44 days from June to September, and 21 days from October to June. This also demonstrates the lack of responsiveness from the IRB over summer months.

Month	# of days for Pre-Review	# of days for PI Revision	# of days to assign	# of days for Board member Review	# of days for IRB Office processing	# of days for PI Modification	# of days for Final Approval	Total # of days (initial submission to final approval)		Total Days with PI	Total Days with IRB	Total Completed Protocols	Total Number of Protocols	Percentage of Protocols Completed
YEARLY AVERAGE	7	13	6	4	5	12	11	45		16	28	22	23	94%
Jun-21	19	14	12	3	9	8	18	76		19	57	20	20	100%
Jul-21	15	19	9	2	8	19	16	81		32	47	22	22	100%
Aug-21	11	5	10	3	9	5	6	43		8	34	13	13	100%
Sep-21	9	14	10	6	4	5	15	54		13	40	23	23	100%
Oct-21	2	14	9	5	5	25	13	52		24	31	24	26	92%
Nov-21	2	15	6	6	3	15	20	52		18	31	41	41	100%
Dec-21	3	9	4	4	1	19	18	41		16	22	17	18	94%
Jan-22	7	15	4	3	8	11	11	37		17	25	18	21	86%
Feb-22	2	7	5	3	6	5	14	36		10	26	21	25	84%
Mar-22	3	10	3	5	1	11	6	31		14	16	22	23	96%
Apr-22	12	23	2	3	1	8	4	36		19	20	24	28	86%
May-22	1	11	1	4	1	8	3	21		8	6	14	15	93%
Jun-22	4	9	4	3	3	11	4	30		13	16	21	22	95%

Table 3. Time for Processing at each level of the review (2021-22)

Processes:

- The feedback from the IRB is inconsistent, and at times inappropriate. Stakeholders reported inconsistencies on identical applications; multiple rounds of review with new (and often minor) points to address each time; reviewer preoccupations with typographical errors that could hold up a project for months at a time; and the IRB board members at times overreaching in their reviews by critiquing the quality or necessity of the research project rather than identifying the risk to human subjects. In one case, multiple identical applications were submitted and received

varied and inconsistent feedback from reviewers.

- A comprehensive CSULB Human Research Protection Program (HRPP) has yet to be established.
- Risk-aversion was identified as a significant problem throughout the review process. Having such a low tolerance for risk not only holds up the review process but it affects how staff and IRB board members comprehend what the research is. Examples included difficulty getting approval for K-12 classroom observations; prior history of an inability to get blanket protocols for a lab (faculty having to get individual clearance for each student as opposed to one clearance for the entire class); prior history of an inability to get blanket protocols and needing release forms and to post a flyer; peculiar procedures being implemented for simple surveys and collection of de-identified student data. Reviewers also noted the need to separate considerations of risk, with some risks related to human subjects (for the Board to consider) and other risks related to institutional risk (for the administrators to consider.)

Staffing:

- The IRB self-study attributed delays in processing due to being short-staffed. More specifically, to a lack of an experienced IRB Administrator to provide more qualified services, such as conducting exempt protocol reviews, processing complicated protocols, etc. In addition, the self-study reflects that the importance of the role that the IRB administrator(s) play is not well recognized/rewarded, thus the staff turnover rate is high. The external review report also notes that staff turnover was mentioned frequently as a significant challenge and barrier to overall effectiveness. The IRB has lost 4 staff members in the last 3 years.

- The Director of Research Integrity and Compliance (DRIC)'s portfolio of responsibilities appears too large to allow for adequate guidance of the IRB process. The DRIC's responsibilities also include overseeing the operations of IACUC, IBC, RCR, FCOI, HSCI Vivarium, etc. Reviewers heard reports that, together with staff shortages, the fact that the DRIC is stretched too thinly contributed to tensions with the support staff and to the related problem of frequent staff turnover.

- Board members reported inadequate reassigned time to review the number of applications. While the current expectation is for members to review during the summer months, it was not clear that all understood this expectation and/or felt more time was needed. Effective and timely review of proposals in the summer months would greatly help offset the delays in processing reviews.

Technology:

- IRBNet lacks key features that other online IRB management systems currently offers:
    - A customizable online smart form
    - Meaningful protocol review status tracking, reporting, and communicating tools to promptly generate review metrics, and inform the investigators about their protocol review status. The limited tracking capacity in IRBNet leads to an overreliance on Excel—at any given time support staff are working with eight

different Excel sheets, which makes the process more error-prone.
- The technology is difficult to work with, inefficient, and causes delays because paperwork (digital or otherwise) gets lost. The IRB Application templates are too rigid, especially for the MAC users.
- Some disciplines, such as the Nursing Program, Physical Therapy, etc. need board members with THE relevant expertise

It is therefore agreed that the ORED and IRB will work together to address the following issues:

1. Delays in Processing/Processes: Streamline the entire IRB process. Goal to reduce the full process for Expedited and Exempt reviews to no more than 4 weeks, and Full Board reviews to no more than 8 weeks. These timeframes are based on the assumption that the PI takes no longer than 2 weeks to complete any requested revisions.
   a. Consider training a faculty member (perhaps in a liaison role) or a graduate student assistant to conduct the pre-reviews rather than support staff, looking only for technical issues that represent an incomplete or incorrect application.
   b. A class/project specific guidelines and umbrella protocols has recently been implemented with a set of standardized guidelines/expectations with a goal of streamline the process for review and approval of blanket protocols. It is recommended to engage with faculty to ensure that they are aware of how to request approvals under these protocols. It is also recommended that the DRIC evaluate the effectiveness of this new protocol.
   c. Engage in an institution-wide discussion of acceptable risks for human subjects research activities on the campus and set guidelines for appropriate institutional oversight. Doing so will contribute to effective risk management and ideally reduce the extreme risk-aversion practices currently in place.
   d. Establish systems to reduce or eliminate inconsistencies in reviewer feedback. To this end, consideration of reviewer expertise, number of reviewers, and the archival process of protocols should be examined. Discussions among IRB members, staff, and researchers that identifies common concerns and issues of the protocol review process should be held regularly.
   e. Address issues of accessibility and outfacing communication.
      i. Update the IRB website to be more accessible and user-friendly. This can include a short video (rather than the lengthy one currently available); clearer guidelines; and information about the nature of risk—and how to remediate it—that might be useful in applications.
      ii. Implement afterhours contacts to serve students who work full-time and cannot meet with support staff until after 5:00pm.

2. Staffing: ORED will examine the roles of Research Integrity and Compliance staff.
   a. Consider reducing the DRIC's portfolio, which is too large and unwieldy to allow for effective oversight of IRB-related activities which include protocol review processes and informative and timely communication to researchers.
   b. Reconsider the DRIC's role as an IRB voting board member. This will alleviate the heavy workload associated with the review of proposed research study protocols.

c. Redirect the ethical review (protections for human subjects) of proposed research activities to IRB faculty members and encourage better communication strategies with the Research Director when needed (for risk aversion or policy confirmation). With a fully-staffed office led by a Senior Research Compliance Specialist, the DRIC should not need to routinely review applications that are already being reviewed by the board and the board's chair, but the DRIC will still need to help with the review, especially urgent ones since this person has the authority to both review and approve protocols quickly.

d. Explore the possibility of IRB Board liaisons with the Colleges

e. Examine staff retention strategies.

i. Examine ways to increase support staff pay and job classifications to attract and retain highly qualified professionals.

ii. As a result of the complexity of managing and supporting an IRB, consider biannual or annual plans for staff training and education to encourage a sense of value, growth, and team building.

iii. Foster a more encouraging work environment with opportunities and rewards for self-initiated continued training, innovation, and above-and-beyond contributions.

3. <u>Technology:</u> Fast-track technological solutions to immediately address inefficiencies.

a. Transition from IRB Net to IRBManager (or other desired system) as soon as possible to alleviate the burden on support staff. The chosen platform should allow for:

i. a customizable online smart form with improved ease of use. including for MAC users

ii. immediate consolidation of reviewer comments

iii. an outward-facing tracking system and communication tools

4. Explore the possibility of IRB Board liaisons with the Colleges. These liaisons would improve the quality of submissions by providing pre-submission feedback and offering discipline-specific suggestions (technical language, formatting, research method strategies, etc.) that could help move the applications through the review process more quickly.

<u>It is therefore agreed that ORED and the CSULB Administration will</u>:

1. Provide support and professional development for the DRIC in leadership and management to assist in becoming more effective in managing his staff, becoming more productive in his position, increasingemployee engagement to reduce staff turnover, improving relationships with IRB support staff, and offset micromanagement.

2. Examine reassigned time or stipends for summer work for IRB Board members.

Please see the attached "Response to IRB External Review Report_Draft_01-25-2023.doc" with details of the Action Plan.