

# **Provost Committee on IRB Review**

## **Recommendation Report**

**April 8, 2015**

### **Committee Roster:**

Kelly Cukrowicz

Associate Professor

Department of Psychological Sciences

Member of the IRB

Angela Eaton, Committee Reporter

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The committee on IRB Review was created by Provost Schovanec. Dr. Farmer, President of the Faculty Senate, invited faculty members. Dr. Cukrowicz was invited as an IRB member. Dr. Eaton was invited as an IRB member and the IRB Liaison to the Faculty Senate. Dr. Taylor was invited as a representative from Faculty Senate. Drs. Steele and Kahl were invited as faculty members.

The committee met on February 16th. Dr. Farmer distributed the group charge:

1. History of this committee and confidentiality of charge.
2. Appoint a reporter.
3. Review history of adaptation by IRB to increased volume.
4. What are specific problems, if any; and what are initial recommendations?
5. Special attention to management of exempt or expedited proposals
6. Is there a need for a more focused, subsequent management process? If so, what are the recommendations for its structure.
7. Arrange a time for a second meeting. Inform senate president of time and the appointed reporter.
8. Summary report to senate president. Next senate meeting March 11, but you have all the time you need.

Dr. Farmer excused himself. Committee members discussed concerns of their own and their colleagues. They divided up topics to research for the next meeting. Dr. Eaton volunteered to be the committee reporter, as she teaches report writing. She contacted Dr. Farmer with the time and place of the next meeting.

The second meeting was scheduled for February 27th at 12:30 p.m., but was rescheduled due to terrible winter driving conditions. The second meeting took place in the Department of English on March 9th, 2015. A follow-up meeting took place at Dr. Eaton's home during spring break.

The committee drew on the Protection of Human Subjects Institutional Review Board/Human Research Protections Program 2014 Annual Report and a document compiled by the IRB for the Faculty Senate as part of their research. Information was also gathered by Dr. Cukrowicz in an IRB full board meeting on February 24th. Dr. Steele did research on IRBs at comparable universities, to determine staffing and reviewer rates.

Based on our research, we make the following recommendations. Please note that the IRB, while consulted for source material, was not consulted on these solutions, and have not in any way committed to them. Whenever possible, this committee tried to provide a low-tech and a high-tech option, so if an idea is impossible to implement in Cayuse (the online submission system), there's an option that would work.

## Increase Number of Staff Members and Reviewers

One of our first concerns about the IRB is its staffing levels. Every problem that might be experienced will be affected by the number of staff members and reviewers available to deal with it. Therefore, we will begin this report by comparing our IRB to four other similar institutions' IRBs.

University	Protocols Processed Yearly	IRB Members	Protocols per IRB Member Average	Staff	Protocols per Staff Member Average
University of Iowa	~1000	18	55	17	58
West Virginia	300-400	14	29 (used 400 as number)	4	100
Iowa State	200-400	12	33	4	100
University of Oklahoma	700-800	15	53 (used 800 as number)	5	160
Texas Tech	1458	18	81	3	486

When looking at number of proposals per reviewer, Texas Tech has the worst rates of the five universities compared. There are 18 members on TTU's IRB; eleven of them typically review during a long semester. If we assume that the other universities included people who are actively reviewing and not in their member count, like our 18 does, then we have 81 proposals per reviewer (this is what the table shows). Other schools have 29, 33, 53, and 55—and those numbers use the higher end of their range of proposals for the year. We have 53% more proposals per reviewer than the University of Oklahoma, the next highest rate. We have 279% more proposals than West Virginia.

To bring our number of proposals per reviewer down to the average of the other four schools, or 42.5 proposals per reviewer, we need 34 reviewers—16 more than we have now, nearly double. The IRB planned to add four this year (as predicted in their annual report).

Most notable from these results are the protocols per staff member. As a rough guideline of amount of work per staff person, we calculated number of proposals per staff member. TTU had the worst rate of proposals per staff person of the five universities compared: 486 proposals per staff member. Other schools had only 58, 100, or 160 proposals per staff member. TTU's IRB's staff's workload is 8 times heavier than the University of Iowa's: 486 proposals per staff member compared to only 58. It is approximately *three times heavier* than the next lowest number.

To bring our numbers even down to the next highest rate, or 160 proposals per staff member, we need nine staff members, triple what we have now. (To bring it to the lowest rate, we'd need 25 staff members instead of our 3, but that does not seem feasible.)

**This is serious understaffing.** Pair that with the move to the online submission system Cayuse, along with the continued increased emphasis on research by the university administration, and we fear that the IRB will only be increasingly strained. In light of this, we recommend the following:

1. **Provide at least two additional staff members.** Six are necessary to bring our numbers down to the next highest rate. Increasing the research infrastructure should be an intrinsic part of our university plans for increasing research conducted, and therefore adding six staff members should be the ultimate goal.
2. **Train eight new reviewers instead of four.** Ideally, 16 are necessary to bring our numbers down to other institutions' rates, but 8 is a beginning. Note: training new reviewers is an intense nine-month effort on the part of the IRB staff, so the two additional staff members are key in also helping train more reviewers.
3. **Offer a summer stipend to ensure a steady flow of approvals.** During the summer, there was an average of 75 reviews performed each month. Following these numbers, we would need 2 reviewers per month. If the IRB doesn't have 2 available in the summer, the Provost should offer a summer stipend to ensure a steady flow of approvals.
4. **Provide an Associate IRB Chair.** This will provide for help with the workload and for continuity for the IRB Chair's job. This position was also specifically requested in the 2014 IRB Annual Report.

## Individual Problems and Proposed Solutions

In this section we present problems that were reported during our research and possible solutions; the problems are in blue text and the proposed solutions are bulleted. Many of the solutions would be simple to implement. Others are more effort intensive. The IRB should be consulted on which to implement and in what order.

**The main concern we have heard or have personally experienced is that reviews sometimes take longer than is stated on the forms. IRB has notes on these specifics. There were two major delays caused by problems in the proposals that involved another department to fix; others may not actually be delayed, but part of the review process may be invisible to the PI, so it seems delayed.**

- Have Cayuse, the online submission system, show exactly where the proposal is in the process—being assigned, pre-screened, under review, etc. This screen would also show how long each step should take, which will help set accurate expectations in the PIs.
- Check all submission forms and webpages to make sure dates stated are accurate to current statistics and include all of the stages. For example, the Claim for Exemption form currently has "allow ten working days for processing"; however, when looking at all of the stages, including assigning the proposal to a reviewer and possibly pre-screening, more than 10 days are typically needed. It is better for PIs to have a longer estimate that the IRB completes faster than a shorter one that is thought to be delayed (when really some of the stages are just not visible to the PI).
- If the proposal is delayed beyond the stated time, Cayuse could have a "nudge" button so that PIs under time pressure could push the proposal along.
- Determine if Cayuse can send emails to the PIs of all recent proposals, so that if a major problem occurs that affects their proposal they can be easily alerted. Also, if there is a slowdown in which the IRB can't hold to its typical timeline, Cayuse should send an email. If Cayuse can't send mass emails, then a slowdown alert should be placed on the HRPP website.

**Proposals are not reviewed during breaks—winter, spring break, and the last two weeks of August, weekends, plus any university holidays.**

- Make PIs more aware of this:
  - Cayuse should display a special warning dialog box when anyone submits a proposal near a major break, pointing out that proposals aren't reviewed during breaks.
  - All cover forms and webpages should have language added that points out that proposals are not reviewed during major breaks. As part of this, change "business days" in the time estimates to "faculty working days" to emphasize the difference.
- We also recommend the Provost pay a summer stipend to two reviewers to increase the number of proposals that can be approved. The other breaks, such as winter break, would be more difficult to fix.

**PIs complained of being told that they are required to change language to a specific wording, of having their language being changed in their proposal by a reviewer (not as a suggestion, but a change), and of staff members stating methodological suggestions as requirements.**

- All reviewers can be informed that they can make suggestions, but can't require exact language unless warranted by federal guidelines.
- When a change is required by federal guidelines, the guidelines should be cited so that the researchers can familiarize themselves with them.

**Faculty question the extent to which IRB staff and members should evaluate personal liability and to what extent to which research is prevented or changed based on those assessments.**

- Review IRB parameters and educate staff and members on the limitations on what qualifies as sufficient personal safety protocols.

**Faculty members are occasionally annoyed when they submit very similar proposals and get very different feedback.** Examples found during our research include having wording be acceptable one month and then the same wording in the next proposal, not long later, needing to be changed. Some of this is the nature of different humans reviewing guidelines: interpretations of these regulations change and the regulations themselves can change. However, keeping close track of differing feedback would put an undue burden on the IRB. Instead, we suggest that if a faculty member points out a perceived inconsistency to the IRB, that the IRB makes note of it and determines if there is any pattern. We suggest they only keep track of what faculty members specifically point out. This in addition to the previous suggestion about pointing out regulations ought to help solve the situation.

**Questions submitted to the website don't get answered quickly.**

- Simply remove the generic HRPP email address from the website, and replace it with the name, title, and address of whichever staff member is assigned to answer questions.

**Graduate students sometimes bypass the PI and deal directly with the IRB; often the PI has no idea the student has done this.**

- The IRB will only email the PI on correspondence, so that the PI must interact with the co-PI and the IRB.

**Colleges can have questions that relate to their research methods; creating special resources by college must be very time consuming for the IRB.**

- The IRB can offer a special liaison to individual colleges, an IRB member (or two) who specifically deal only with that college. This won't cost anything, but it will promote better relationships between certain colleges and the IRB.
- Each college should create a template for exempt and expedited proposals (full proposals would be too complicated for a template) that fits expectations of their fields. The IRB would look it over and ensure it's accurate.

**Faculty members can have inaccurate ideas about who makes up the IRB and who actually reviews their proposals.** We think these inaccurate perceptions make the relationships between these faculty members and the IRB more difficult than they need to be.

- Introduce the IRB at new faculty orientation, and emphasize that the reviewers are faculty members (might also mention that some proposals are reviewed by staff members).
- Mention who the reviewers are on the website by using terms like "faculty reviewers." (We know the list of members appears on the website.)
- When recruiting new reviewers, make an announcement to the Faculty Senate, Deans and Department Chairs, and current users of the IRB (we are hoping there is a way within Cayuse to

easily email all those with proposals in the system) and invite faculty members to join. We are hoping this will emphasize who the reviewers are, make the work involved in the IRB more concrete to faculty, and help us find reviewers who wouldn't normally have thought of joining.

**When a faculty member wants to do IRB proposals as part of a research class, it can be confusing for them and a lot of work for the IRB.**

- The IRB should create a handout to explain the options available for the faculty member, posted on the webpage.
- As not every project from the class will actually be published, the IRB should see if there is a workaround, like the "existing documents" clause, that could be used to ethically process IRB approvals for classroom projects after the class is over, so that the IRB doesn't have to be completed during the semester. If this is possible, it should be added to the handout.

**Frustrations can build up on both sides, with faculty and IRB members.**

To cut down on frustration, we suggest having the Senate subcommittee on the IRB gather satisfaction information through Cayuse and evaluate it once per long semester, in April and November. They can create a short survey that appears after a proposal is approved in Cayuse, with such questions as satisfaction with the overall process, interaction with faculty and staff, and time the process took. It should be anonymous, with an option for the researcher to submit their name if they want follow-up.

The subcommittee can examine the data for recurrent patterns, and if any are found, can alert the IRB to them and possibly make recommendations of how to fix them. Also, the subcommittee should report on the statistics to the Senate. This will help everyone involved have a clear, data-driven (not anecdote-driven) picture of current IRB performance. This will put in place a regular check on faculty perceptions, but it will not add to the work overload the IRB is experiencing.