PURDUE
UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH, REGULATORY AFFAIRS

Date: September 15, 2017

To: Associate Deans of Research

cc: Suresh V. Garimella, Executive Vice President for Research and Partnerships
Jay T. Akridge, Interim Provost and Executive Vice President for Academic Affairs and Diversity

From: Christopher R. Agnew, Associate Vice President for Research, Regulatory Affairs

I write to share with you results obtained from a recent survey distributed to faculty, graduate students, and staff regarding Institutional Review Board (IRB) processes at Purdue. The results suggest the need for immediate and sustained actions to improve processing of research protocols involving human participants. Please distribute this memo to your faculty, graduate students, and research staff.

Background

During the Spring 2017 semester, following pilot testing, an anonymous online Qualtrics survey was distributed to faculty, graduate students, and staff regarding their experiences with IRB processes at Purdue, including the use of the online human subject protocol submission system, Coeus. The survey was developed by the Associate Deans of Research and the Office of the Executive Vice President for Research and Partnerships. It included input from campus faculty with expertise in preparation and analyses of surveys. The survey, which contained both closed-ended and open-ended questions, was administered between February 16 and March 10, 2017.

Survey Results

A total of 714 recorded responses to the survey were received. Of these 714 responders, 201 indicated at the start that they had not been involved with the submission of IRB protocols at Purdue. The remaining 513 indicated that they had been involved and this group was asked to respond to detailed questions about their IRB experiences.

Distribution of Responders, by Rank and Type of Research:

Rank:

Graduate and Post docs:	29.0%
Assistant Professor:	19.1%
Associate Professor:	19.7%
Full Professor:	16.1%
Staff	16.1%

Research Type:

Social/Behavioral Science	86.6%
Biomedical	13.4%

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Key Findings:

Complete results, including frequencies of responses for each closed-ended survey question, are appended to this memo. Overall, the survey results reflected a mixture of opinions, with general satisfaction expressed regarding personal interaction with IRB staff and general displeasure expressed regarding current IRB protocol processing procedures. Major take-away points:

1. Overall, the staff were viewed as being both professional and helpful.
2. Most respondents reported significant issues with IRB processing of protocols, including:
    a. Reviews were not timely, even for low risk protocols and small changes in already approved protocols.
    b. Responses to email questions and phone inquiries were not always prompt.
    c. Lack of perceived understanding by IRB staff of some types of research.
    d. Inconsistent feedback from different analysts and with different submissions for similar research.
    e. Information/directions on the IRB website were seen as inadequate.
3. Overwhelmingly, the Coeus system is considered very difficult to use, cumbersome, and unreliable.

In addition to responses to the closed-ended survey questions, over 400 written comments were submitted which were consistent with the key findings described above. To maintain anonymity, these responses, many of which detail specific experiences with specific people, are not included here.

Fixing Identified Problems in the Long-Term (beginning January 19, 2018)

The Federal regulations governing human subject research are known collectively as "The Common Rule" and have been in place since 1991. After years of effort by the research community to streamline these regulations, to both focus on improving review of more risky protocols and reduce administrative burden regarding the review of less risky protocols, significant changes to the Common Rule have been approved by the Federal government and will become effective on January 19, 2018. We will embrace these changes at Purdue. You can expect to hear more on the specifics in the months ahead, but we expect a significant decrease in what will be required by many Purdue researchers working with human subjects, with no reduction in protection of human research participants. We are also reviewing various options to replacing Coeus for online protocol submissions. In addition, we intend to pursue accreditation by AAHRPP (Association for the Accreditation of Human Research Protection Programs), a step taken by the vast majority of our peer and aspirational-peer institutions, which will help ensure that we maintain an appropriate infrastructure in ongoing efforts to protect human research participants.

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Fixing Identified Problems in the Short-Term (i.e., between now and January 19, 2018)

The Office of EVPRP is fully committed to addressing the problems with IRB processing that have been clearly identified from the survey. Our IRB staff is also very committed to enhancing the services they provide. To that end, we will be making the following changes to procedures, effective September 30:

1. Principal investigators (PIs) will no longer be required to interact directly with Coeus. PIs will be able to submit new protocols, amendments to approved protocols, protocol renewals, and requests for exemption determinations via a new simple IRB web portal as MS Word attachments. IRB staff will then handle uploading submitted materials to Coeus and PIs will have access, should they wish, to all their protocol materials within Coeus (as they do currently). Clear directions on web portal submission of protocol materials will be available on the IRB website.
2. We will institute "Fast Lane" processing of exemption determinations, procedural amendments to approved protocols and renewals of protocols. The goal will be 72-hour turnaround (between Monday and Friday) on these types of protocol submissions when submitted via the new IRB web portal and in accordance with specific "Fast Lane" directions posted on the web portal page.
3. Those PIs seeking immediate turnaround for processing of exemption determinations can schedule an appointment (by calling the IRB at 765-494-5942 and following the voice prompts) to meet with an IRB analyst in the IRB offices on the 10th Floor of Young Hall and have your exemption request application reviewed and, assuming the application meets exemption criteria, approved as exempt at the meeting.
4. IRB analysts will be designated as being specialized in one of the broad types of research that distinguish our two IRBs (biomedical vs. social/behavioral), thus providing greater continuity of input across protocols of a given type.
5. Pre-approved wording for commonly-used procedures (e.g., for blood draws; use of Amazon's MTurk) will be available on the IRB website for use by researchers in crafting their protocols.
6. We will form a faculty advisory committee, composed of faculty from across colleges of the university who conduct research with human subjects, to provide ongoing input to our IRB staff on processes of particular concern.

For those who took the time to complete the survey, I offer my sincere thanks. I very much appreciate having access to this very helpful feedback as I begin my new role and look forward to working with you to improve IRB processing in the days ahead.

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Summary of Results from Spring 2017 Purdue IRB Survey

(Prepared by Dr. Zhao Ma, Department of Forestry and Natural Resources)

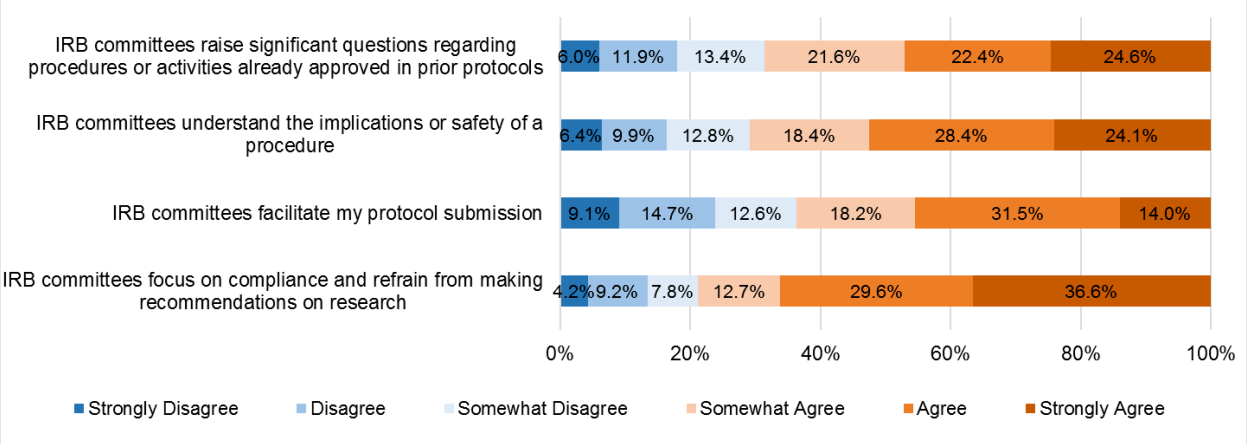
How many IRB protocols at Purdue have you been involved in before?

	Freq.	Percent
1-5	296	59.8
6-10	88	17.78
11-15	32	6.46
>15	79	15.96
Total	495	100

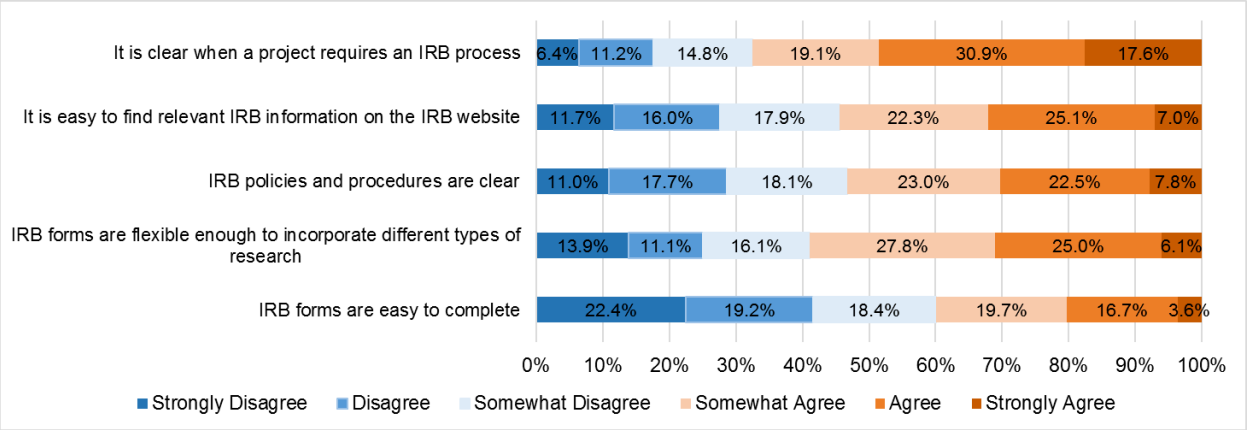
What level of IRB have you applied for? Please check all that apply.

	Freq.	Percent
Exempt Review	392	76.41
Expedited Review	320	62.38
Full Board Review (Behavioral or Social Science)	118	23.00
Full Board Review (Biomedical)	44	8.58
Missing	21	4.09
Total	495	100

Please rate your experience with the Purdue IRB committees (This question was only displayed to those who checked at least one of the Full Board Review options above.)



Please rate your experience with the IRB policies and procedures at Purdue on the following statements



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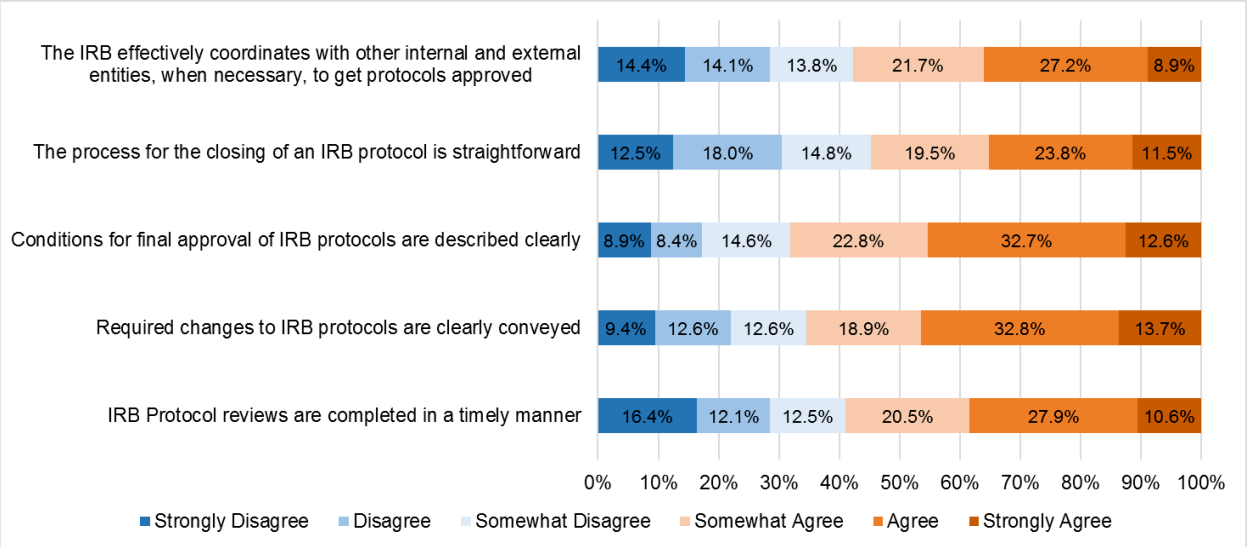
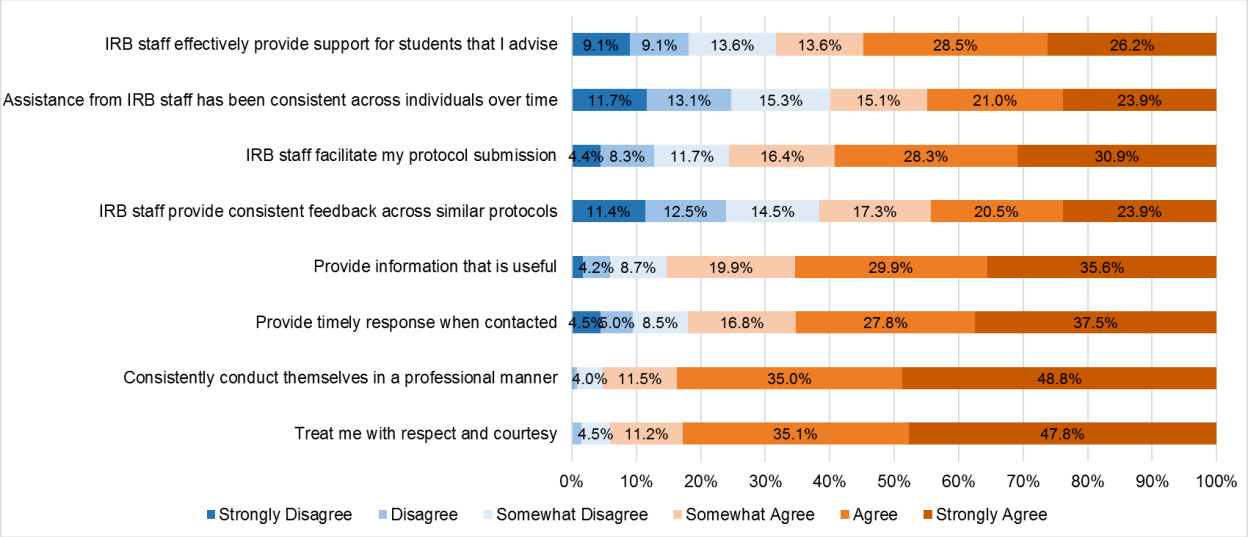


Have you previously interacted with Purdue IRB staff?

	Freq.	Percent
Yes	406	79.14
No	66	12.87
Missing	41	7.99
Total	513	100

Please rate your experience with IRB staff at Purdue on the following statements (This question was only displayed to those who indicated yes to the above question.)



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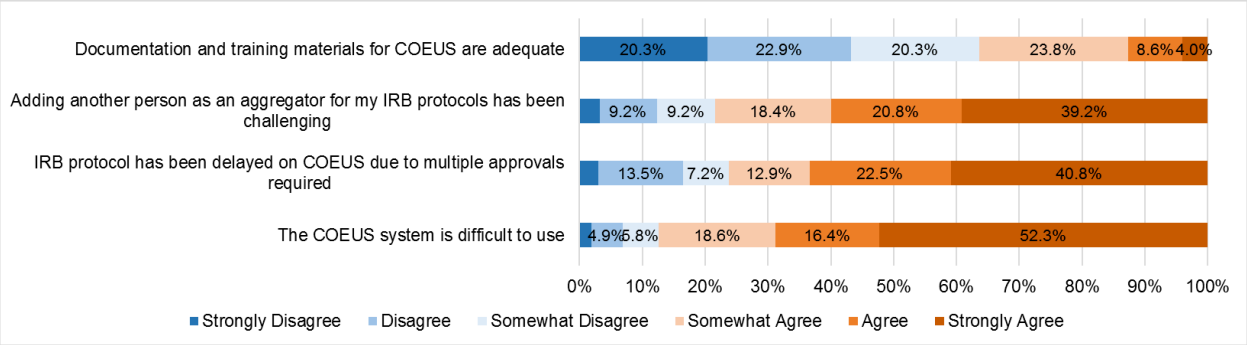
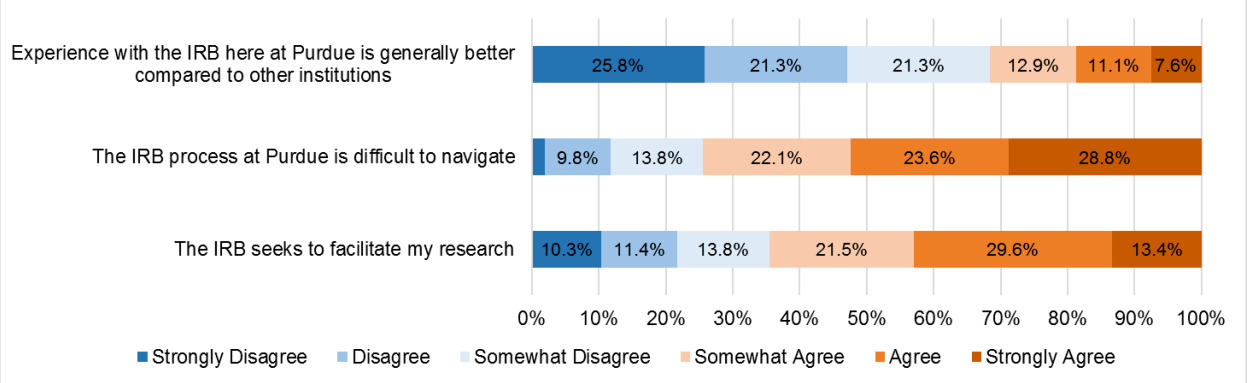
Have you used the online COEUS system for submitting an IRB protocol before?

	Freq.	Percent
Yes	366	71.35
No	104	20.27
Missing	43	8.38
Total	513	100

Please rate your experience with the COEUS system on the following statements (This question was only displayed to those who indicated yes to the above question.)



Please rate your overall impression of the IRB on the following statements



Do you have any experiences with the Purdue IRB (good or bad) to share?
236 written comments provided

Do you have any specific suggestions to improve the IRB process?
207 written comments provided