

Faculty Senate/All University Committee Report (2014-2015)

Committee:	Research & Scholarship	Prepared By:	Gail Pyne-Geithman	Date: March 26 th , 2015
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Committee Members at the Meeting:	<p>Present: Sally Moomaw (<i>Proxy chair</i>); Gail Pyne-Geithman; Rachel Frankel; Kevin Li; Daria Narmoneva.</p> <p>Guests from IRB: John Holden (<i>Vice Chair, IRB Board</i>); Angela Braggs-Brown (<i>Director, Human Protections Research Program</i>); Kareemah Mills (<i>Assistant Director, Research Compliance & Regulatory Affairs</i>).</p> <p>Not in attendance: Sarah Stitzlein; Arlene Johnson; Lilit Yeghiazarian</p>
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Topics Discussed: provide a brief description of each	<p>In response to comments made at the FSM regarding the Institutional Review Board (IRB), our committee had gathered comments and specific incidents from colleagues to discuss with invited representatives of the Human Protections Research Program (HSPP), Research Compliance and Regulatory Affairs and the IRB board. Dr. Moomaw summarized the comments, which came from faculty both in the social and medical sciences, and we addressed each point with the members. Attached to this report is the summary upon which our discussions were based.</p>
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Action Items: List item and attach supporting document if action requires such background	<p>There was much productive discussion, the major points of which are summarized here.</p> <ol style="list-style-type: none"> 1. Implementation of catalyst will not interfere with the ePAS system, as it is hosted on a server outside of the UC intranet. 2. Most of the problems seem to stem from the user interface, called ePAS. <ul style="list-style-type: none"> (i) UC is “piggybacking” on the ePAS licensure, which is held by CCHMC. When the CCHMC administrator makes changes, it also affects the UC interface and can unnecessarily complicate UC submissions, especially in the social sciences. This includes triggers and frequency of application progress through the review system. (ii) UC does not have a dedicated ePAS administrator, which would be needed in order to optimize the UC interface for the types of research that we do. (iii) PI’s need to understand what kind of review they are requesting to make sure their proposal is not routed incorrectly and therefore delayed. Many social science studies are in fact exempt, and do not require a full board meeting for approval. 3. Many of the issues can be resolved with better IRB outreach and communication between PI’s and IRB prior to submission to determine the correct mechanism for their protocol submission. We agreed that, as PI’s, we will do what we need to do, but there is a lack of clear instruction in this regard. <ul style="list-style-type: none"> (i) The HSPP has recently revised and clarified their website: many forms are provided as templates and there are clearer instructions about whom to contact regarding your application. The website is under continuous improvement. (ii) Self-educational ePAS instructions and tutorials are available here also. (iii) Claudia Norman is available for Departmental/Divisional outreach sessions to help PI’s understand the IRB process. (iv) Delays in review of protocols can be mitigated by contacting IRB ahead of submission to clarify the appropriate mechanism. This is particularly important for multi-institutional applications, because there is a special mechanism that must be followed, depending on which institution initiates the protocol. <p>Overall, the meeting was most productive and it is clear the IRB is already aware of, and actively addressing, the concerns raised by the faculty.</p>
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Describe action needed on items above (discussion and input, vote, etc):	By Whom:
The R&S committee will discuss at our next meeting what, if any, actions we can perform to facilitate the IRB’s effort in faculty outreach and training.	<input type="checkbox"/> By Faculty Senate <input type="checkbox"/> By Cabinet <input type="checkbox"/> Others (List-)

Next Meeting: Thursday, April 16, 2015 from 3:00-5:00 in room 401 Teachers College	

Summary of Faculty Comments (prepared by S. Moomaw).

1. Numerous problems with ePAS
 - a. Will this change under Catalyst?
2. Process too slow
 - a. Entire IRB protocol goes unreviewed until last person completes CITI.
 - b. Much delay prior to review, including for studies expected to be exempt.
 - c. Collaboration with other Universities is delayed because their IRBs are much faster.
 - i. Example: 1 week for ASU vs. 3 months for UC.
3. Directions on UC website are unclear.
4. Use of unfunded reviewers.
5. Researchers are not notified of status changes (and don't know this).
6. Researchers don't know that they have to notify IRB when a response is submitted. They assume this is automatic.
7. Questions about statistical design and analysis seem outside the purview of the IRB.
8. Proactive responses would help- do this, this and this.