

RESEARCH AFFAIRS COMMITTEE REPORT 2011-2012

Committee Members 2011-2012

Members with Term Expiring June 30, 2012

Bigatti, Silvia (Public Health)
Burrage, Joe (Nursing)
Galli, Dominique (Dentistry)
Laskey, Toni (Medicine)
Marrs, James (Science)
Mayo, Lindsey (Medicine: Peds)
McDaniel, Anna (Nursing) (**Chair**)
Petrache, Horia (Science)
Rubart, Michael (Medicine)
Wilson, Jeremy (SLA)

Members with Term Expiring June 30, 2013

Agha, Anila (Herron)
Atkinson, Simon (Science)
Boehm, Stephen (Science)
Bruzzaniti, Angela (Dentistry)
Chen, Hsin-Liang (SLIS)
Corson, Tim (Medicine)
Koskie, Sarah (Engineering and Technology)
Maxcy, Brendan (Education)
Song, Fengyu (Dentistry)
Staten, Lisa (Public Health)
Wang, Yang (Medicine)

Liaisons for 2011-2013 (or Ex Officio)

Varahramyan, Kody (Vice Chancellor for Research) (**Administrative Liaison**)
Windsor, Jack (**Executive Committee Liaison**)

Chair - Anna McDaniel (Interim Chair Spring Semester, Simon Atkinson)

The committee met regularly throughout the fall and spring semesters. Vice Chancellor Varahramyan attended most meetings and reported on developments in the OVCR. The combined IUPUI and IUB Research Affairs Committees met with Vice President José and staff from the VPR at Bradford Woods in October. The committee benefited from close cooperation with Steve Burns and other members of the IUB Research Affairs Committee throughout the year. The main issues addressed by the committee are outlined below, and action taken by the committee is noted where appropriate.

1. Human Subjects Research.

By late summer 2011 delays in processing approvals for human subjects research, particularly in social and behavioral sciences had reached crisis levels. These delays impacted exempt and expedited studies and were the result of delays in administrative processing, not IRB review. Processing of exempt studies took well over 70 days through much of the fall semester. Faculty research and student course requirements were seriously impacted. The committee immediately raised the issue with the VPR and this was a major topic of discussion at the meeting in October, reflecting major problems at both IUPUI and IUB. The committee was highly dissatisfied with the initial response to the crisis, brought the issue to the UFC and

also passed the following resolution, which was subsequently adopted by the IFC and brought to the attention of the Trustees by the UFC Co-Secretaries.

Resolution to Address Unacceptable Delays in IRB Reviews at IUPUI

October 31, 2011

Whereas the average time to receive IRB approval of human subject research protocols is excessive,

Whereas these delays have a significant negative impact on the ability of faculty and visiting scientists to initiate and complete research projects in a reasonable time frame,

Whereas delays in research hinder timely publication of findings, threaten junior faculty progress toward tenure, and affect future funding potential,

Whereas a wide range of constituents across Indiana University experience these delays as the most pressing obstacle to their research endeavors,

Whereas these delays are prohibitive to student achievement, such that the quality of the educational experience at Indiana University is jeopardized,

Whereas if these delays are not addressed, they will impact not only the current but future academic standing of Indiana University,

Whereas these delays are likely to have significant financial consequences to the university due to loss of grant funding, delayed release of grant funds, and potential legal liability resulting from postponement of student graduation due to IRB delays,

Whereas the efficiency of the IRB approval process has markedly deteriorated since the move to centralize IRB administrative operations, despite good faith efforts of the Office of the Vice President for Research,

The IUPUI Faculty Council urges the Administration, President, and Board of Trustees of Indiana University to deploy the appropriate resources, including the use of external services (e.g., WIRB) to eliminate the IRB approval backlog immediately,

Furthermore, the IFC calls on the President to immediately initiate an independent, external review of the current administrative structure and practices of the IRB to examine potential long-term solutions, including restoring campus-based administrative operations, to sustain future research productivity.

Subsequently, significant changes were made in the organization of the office and John Baumann was appointed as Executive Director of the Human Research Protection program in January 2012. The changes appear to have dealt effectively with the immediate backlog. There is also a new culture of open dialogue with faculty researchers and some processes have been effectively streamlined. ***The 2012-13 committee should continue to carefully monitor the situation to ensure that processing of applications is completed within an acceptable time period and without unnecessarily burdensome paperwork.*** The committee deeply appreciates the heroic efforts of the staff in the Human Subjects Protection Program in addressing the problems.

2. New NIH Financial Conflicts of Interest in Research Requirements.

The committee reviewed the new NIH requirements and recommended revisions to the IU Financial Conflicts of Interest in Research policy. These changes were adopted by the UFC in April.

3. Revisions to IU Policy on Responsible Conduct of Research.

The committee concurred with revisions to the above policy recommended by the IUB RAC that bring IUB and the regional campuses in line with IUPUI practice. These changes were passed by the UFC in April.

4. Other Topics

The committee also discussed limited submission competitions, research components of the reaccreditation self-study, searches in the OVCR.

5. Issues for 2012-2013

The committee discussed issues that should be monitored by the committee next academic year. These include

- Human subjects research - monitoring progress in the timeliness and efficiency of study approval and review.
- Other study approvals – especially biosafety approvals (an area where there appears to be at least anecdotal reports of delays and errors) and IACUC as centralization of oversight continues.
- Signature Centers – review of the program to coincide with new EVC and uncertainty over funding for new centers.
- Center designation process - inventory of active/inactive centers as a first fact-finding step.
- IUCRG Program - faculty input into future directions/funding priorities if the program continues.