

**IUPUI Faculty Council Committee
Annual Report 2018-2019**

Committee Name: IUPUI Research Affairs

Chair: Victoria Champion

Members:

Members with Term Expiring June 30, 2020

Bhatwadekar, Ashay (Medicine)
 Carter-Harris, Lisa (Nursing)
 Chu, Tien-Men (Gabe) (Dentistry)
 Goodlett, Charles (Science)
 Guiliano, Jennifer (Liberal Arts)
 Mosley, Amber (Medicine)
 Odell, Jere (University Library)
 Organ, Jason (Medicine)
 Vemuri, Gautam (Science)

Members with Term Expiring June 30, 2019

Burr, David (Medicine) through December 2018.
 Champion, Vickie (Nursing) (**Chair**)
 Ellsworth, Susannah (Medicine)
 Foster, Erin (Medicine Library)
 Goff, Philip (Liberal Arts)
 Konrath, Sara (Philanthropy)
 Massie, Crystal (Health & Human Sciences)
 Mendonca, Marc (Medicine)
 Miller, Steven (Medicine)
 Nan, Hongmei (Public Health)
 Tanaka, Hiromi (Medicine)
 Warden, Stuart (Health & Human Sciences)
 Yokota, Hiroki (E&T)

Liaisons for 2018-2019 (or Ex Officio)

Atkinson, Simon (Vice Chancellor for Research) (Administrative Liaison)
 Mendonca, Marc (Medicine) (Executive Committee Liaison)

Action Items:

Action Item(s)	Status
Strategic Direction Initiative	Simon Atkinson discussed the Strategic Direction Initiative for 2018-2019. The Strategic Plan does not accurately describe the way in which research is done within the schools. Additionally, some schools have a process to do strategic plans and some do not. The Office of Research would like to understand what is going on within each school as it relates to research. The Associate Deans for Research and the Deans of each school will be responsible for developing a strategic plan. Simon is developing a draft template which will be reviewed by the Research Affairs Committee and will be used as a benchmark by schools to look at their trajectory. It will not be used to compare across schools but only within schools. The IU Foundation thinks that this is appropriate for the transformative growth potential that is identifying donors who may be willing to give in excess of \$20 million. This type of gift is usually done in coordination with research. David Burr indicated that the strategic plan should include research training money. The summit on February 11, 2019 will be in Hine Hall from 8:30 AM – 2:00 PM and is an important step in strategic direction dialogue.
Travel Reimbursement	Amber Mosley asked if there were mechanisms for travel reimbursement to be paid ahead so that disadvantaged students would not have to pay well in advance. This was discussed but with Resource Center budgeting it is incumbent upon each department to provide a strategy to pay for student’s expenses in advance. Some departments currently do this with the department card.

<p>Percentage of Clinical to Tenured Faculty</p>	<p>The Board of Trustees sets a 60% tenured to 40% clinical faculty yardstick, however, each school does this differently. Marc Mendonca indicated that one of the major problems was identifying who is eligible to vote in University or IUPUI Faculty Council. Currently the School of Medicine has 37% tenured faculty.</p>
<p>Description of Effort on Funded Studies to Promote Promotion and Tenure</p>	<p>The Council of Associate Deans for Research discussed an email from Rachel Applegate on Friday (9/5), There were two options; 1) 100% of a grant was counted which was unilaterally discarded. The second option was that the person would only count the funded effort. After discussion it was decided that although there are many issues to be considered, putting down the percent of funded effort is the most direct way for recording Digital Measures Activity.</p>
<p>Conflict of Interest Policy</p>	<p>Jere Odell reported on revisions for the Conflict of Interest (COI) policy. Everyone agreed that the COI policy as revised was acceptable. Discussion ensued about convergence of COI and conflicts of commitment which are now one form sent annually to faculty.</p>
<p>Monetary Gifts to Indiana University</p>	<p>Fred discussed the idea that the IU Foundation thinks there are potential people eligible for large gifts. This giving may cut across schools and information should be garnered and submitted to the foundation.</p>
<p>Classified Research</p>	<p>Fred Cate talked about classified research even being research on underground water or oil. It is obviously expensive to do classified research. In order to do this the University could set up a separate entity, which would make it possible. Fred has gotten a research consultant to discuss this and the Department of Defense and the consultant recommended this. It would be something like an LLC or shell entity and would have 1.5 staff and hold allowances to do research. The office would reside outside of any area of students. There are obviously bureaucratic problems. The space would be part of UITS on the Bloomington campus and would be funded from the President's office. An area would be set up in which all computers and conversation was secure and no laptops would leave. This would not include biological research or weapons research. The only people who could get clearance would be a US citizen or those holding a green card from European speaking countries. The oversight would go through the research office. Prior to establishing this, the Research Affairs Committee of IUPUI and Bloomington would have to agree. This would be done after it was approved by the Trustees. Many questions followed including what the cost would be to the University if the need for services would be excelleated. Although there were many questions, there was not strong opposition.</p>

<p>New Common Rule</p>	<ul style="list-style-type: none"> • Overriding principle behind the new common rule is to align oversight to level of risk For instance, at one time, they required IRB approval at time of application to go to a study section and then realized – we are only funding 15% that means 85% may not go anywhere. Idea was why are we doing this, it does not make sense. The New Common Rule follows the same idea-match risk to oversight. • Major change in minimal risk-negligible change in more than minimal risk. • Definition of Human subjects research-A living individual about whom an investigator conducting research <ul style="list-style-type: none"> • Obtains information or <u>biospecimens</u> through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or The word identifiable was not there in previous versions of the common rule. It was any biospecimen. Identifiable is name, address, etc. and it does not change what we do now. • Specifically excluded as not Human Subjects Research certain activities. Only thing new is Oral History. Many instances of oral history do not require IRB-only if generalizable knowledge. • Exemptions <ul style="list-style-type: none"> ▪ Application would come to Human subjects office to determine if exempt by office-not IRB. ▪ Research is defined as a systematic investigation designed to contribute to generalizable knowledge. ▪ Expedited review if subjects can be identified but expedited is simplified. ▪ Many benign behavioral interventions now exempt. If the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts limited IRB review to make the determination required. Benign behavioral intervention is brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact and researcher has no reason to think subjects will find it offensive or embarrassing. ▪ A limited IRB review is a type of Expedited review. When you have a minimal risk research project that does not qualify for an exemption, it can go through Expedited review. A study that goes through Expedited review has to meet the 7 criteria for study approval; risks are minimized, benefits and risks are in balance, selection of subjects is equitable; etc. ▪ The introduction of a limited IRB review says, the IRB review will be limited to one criteria of approval, privacy and confidentiality. ▪ Exemption-research conducted with already collected data, not for research purposes as long as the researcher records the data in a way that subjects cannot be identified. New plan eliminates those words and talks about secondary research. It does not matter whether or not it is retrospective or prospective it could still qualify. ▪ Basic elements of informed consent: concise and focused presentation of the information most likely to assist a subject in deciding whether to participate or the entire consent form is considered concise and focused. Must have a 3 page summary if longer than 3 pages. ▪ Additional elements of informed consent – statement that the subject’s biospecimens may be used for commercial profit and whether the subject will/will not share in those profits. ▪ For federal-funded research, statement regarding whether clinically relevant research results will be disclosed to subjects and, if so, under what conditions. ▪ Elimination of continuing review’s dilemma for minimal risk research is no longer required or presumed to be required by local IRB however, the institution remain responsible for overseeing the conduct of such minimal risk research. Oversight is to require an Annual Certification from researchers. ▪ Single IRB review – is importantly different than the NIH requirement that went into effect a year ago. The NIH requirement is only for NIH funded and it is for protocols funded by the NIH that are carried out at more than one site at the United States. The new Common Rule talks about cooperative research projects are those projects covered by this policy that involve more than one institution. ▪ Not automatically transitioning research studies.
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Action Items to be carried over to 2019-2020: None

Action Item(s)	Status

Suggested new action items for 2019-2020:

Action Item(s)	Status

Please attach any completed documents, minutes, or recommendations made by your committee during this report year. One copy of this report and supporting documents will be sent to the IUPUI University Archives.

Report due: June 30, 2019

Submit to: Karen Lee
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