

University Senate Research Committee Meeting

3 May 2019

1:00 PM

156 CL

In Attendance: C. Bonneau, E. Chasens, D. Harall, G. Huber, R. Melhem, P. Morel, R. Rutenbar, D. Salcido, S. Sant, B. Yates

No comments or corrections were received for the minutes of the March 29 meeting, so the minutes were approved as posted.

Discussion of new COI web-based form

R. Rutenbar described the process for the new COI web-based form, which is anticipated to be ready for April 2020. The purpose of this is to allow integration of all of the regulatory requirements in one centralized database that can be accessed by individual investigators. This form is being coordinated with UPMC, and PIs will fill out a different form based on whether their primary appointment is Pitt or UPMC. A committee has been formed that includes faculty participation (P Smolinski will be on this committee) to finalize the format and questions to be asked.

The goal is to simplify the experience through a series of questions concerning each “entity” a PI is associated with. The PIs will be asked to define all activities with entities outside Pitt that they are involved with and to provide certain information concerning these activities. This will include whether payment is received (< or > than \$5000) and how much time, in days/year, is spent on these activities. The form will be paperless and will be sent to the PIs Department Chair for approval. If there is a concern about an activity (in terms of money received or time commitment) the Chair could ask for more information and a management plan may need to be put into place in coordination with the COI office.

Pitt has an External Activities policy, that can be found on the COI website, and while external activities are encouraged it is important that all be disclosed in order to avoid any potential institutional liability.

B. Yates commented that the approval route for outside activities still needs to be worked out. There was some discussion about how best to categorize time commitment since activities, such as editorial board responsibilities, may be time-consuming but faculty may be doing these at weekends or outside of regular hours. It is not clear how this will be incorporated into the COI form.

R. Rutenbar noted that there may be increased scrutiny of any consulting for foreign companies, since it appears likely that Federal rules may change. More requirements may be added by the federal Government, but the new form will be flexible to allow for any such additions.

D. Salcido asked if the data collected as a result of this form will be stored in a central database. R. Rutenbar answered that it would. D. Salcido further asked if there was a policy on how these data would be used. R. Rutenbar stated that there was no detailed policy on this, but mentioned that it may be used to tailor communications to individuals who are engaged in certain, similar activities.

P. Morel raised the question about the security of the database and R. Rutenbar stated that the data would be secure and only the PI and select administrators could access their data and a few select individuals in the administration (e.g. Jennifer Woodward) would have access to the database as a whole. It was pointed out that the Federal Government may ask for some of these data and it would appear to be wise to have a policy for how such requests would be handled.

#### Changes to rDNA rules

B. Yates announced that the recombinant DNA rules related to human gene therapy have changed. The NIH Recombinant DNA Advisory Committee (RAC) has been replaced and will no longer approve human gene therapy protocols. This will now fall under the purview of local IBCs. This is creating a problem since there has been an explosion of new protocols, relating to some of the novel immunotherapy of cancer protocols. B. Yates stated that it is proving difficult to find sufficient expert physicians to serve on the IBC to review these protocols.

B Yates also mentioned that the USDA conducted a surprise visit of Pitt's animal facilities and that no deficiencies were identified.

#### Update on Foreign Influence Policy

R. Rutenbar stated that it is likely that new regulations from the Federal Government concerning interactions with foreign entities and scientists will be forthcoming. Pitt is involved in several nationwide committees, represented by Allen DiPalma, that are working behind the scenes to inform the government of the impact of potential changes, so as to minimize their impact on the mission of the Universities.

#### Indirect rates for foundation grants

E. Chasens asked about the procedure for providing waivers on the payment of indirect costs to Foundations that provide small grants to faculty. R. Rutenbar noted that Deans have the authority to provide such waivers if a grant is <\$50,000. However, he was concerned that some PIs have put the Office of Research in awkward situations when they may have promised a foundation not to charge indirect costs in order to get a grant. He stated that the policy of Pitt is that indirect costs should be paid and he noted that many Foundations state the indirect rate they will pay on their websites. He urged investigators to use the indirect rate published by Foundations when preparing their budgets

The meeting was adjourned at 2:25 pm.

The last meeting of the year will be May 31, 2019 in **CL 817 – Note room change**

Minutes submitted by P. Morel