

MINUTES

University of Minnesota Medical School Faculty Advisory Council

January 5, 2016

The meeting of the Medical School Faculty Advisory Council (FAC) was held on Tuesday, January 5, 2016 at 4:00 p.m. in Room B646 Mayo Memorial Building and 112 School of Medicine Duluth (via ITV). Dr. Paul Bohjanen, Chair of the FAC, presided.

Members Present: Drs. Ionna Apostolidou, Robert Bache, Paul Bohjanen, Ben Bornsztein, Rachel Dahms, Dana Davis, Marna Ericson, Deborah Ferrington, Jerry Froelich, Dan Garry, David Ingbar, Hyun Kim, Mojca Konia, Linda McLoon, Steven McLoon, Kristin Nichol, Becky Olson-Kellogg, James Pacala, Marc Pritzker, Michel Sanders, Kiki Sarafoglou, Joseph Schuster, Andrea Shields, Sara Shumway, Robert Sorenson, Jakub Tolar, Gregory Vercellotti

Dean's Office Staff Present: Brooks Jackson, MD, Dean
Mark Paller, MD, Senior Associate Dean
Cliff Steer, MD, Associate Dean for Faculty Affairs

AGENDA

1. Approval of December 1, 2015 Minutes (Draft attached)
2. DRAFT COI Policy (updated) - see attached (Zentner, Guden, Durfee)
3. Fetal Tissue Research (LeBien, Shiels)
4. Non-tenure Faculty Tracks (McLoon, Ingbar)
5. Update on integration workgroups

Call to Order and Welcome

The meeting was called to order at 4:04 pm by Chair, Dr. Paul Bohjanen

1. Approval of December 1, 2015 Minutes

MOTION by the Chair to approve the November 3, 2015 minutes as circulated. The motion was made by Drs. Linda McLoon (First) and Deborah Ferrington (seconded). No corrections being heard the minutes were approved as circulated.

2. DRAFT COI Policy (updated) - (Zentner, Guden, Durfee)

William Durfee, Johnathan Guden, and Lynn Zentner presented to FAC members the updates to the draft COI policy. They started by saying that the document is reviewed and updated every three-four years, and the two main updates that were: 1. Employees (investigators and any individuals who enroll or consent participants) are prohibited from receiving personal remuneration or equity from a business entity while participating in a human participant study that: is sponsored by that business entity, or involves the development or evaluation of that business entity's product, device, or other technology; 2.

Unless an exception is approved by a Conflict Review Panel, employees may not receive personal remuneration or equity from a business entity while serving as an investigator on a human participant study that is sponsored by that business entity, or involves the development or evaluation of that business entity's product, device, or other technology. Questions surrounding the updates and the timing of the vote were discussed. It was asked why that provision came about as many researchers would be affected.

S. McLoon asked if there were specific examples that came about that caused the need for the update. L. Zentner stated that they have only had three problems arise over the past seven years and that the changes didn't arise because of past problems, but as a statement of the values of the institution. Dean Jackson stated that there is no evidence that relationships are detrimental to patients – the issue is perception. If there is a bad outcome and you are paid by the group it looks bad to the public. P. Bohjanen asked why the term "business entity" was changed to "company". J. Guden stated that business entity was too broad. Dean Jackson asked if there were any other institutions with a similar policy? L. Zentner stated that Mayo and UCSF have similar policies.

One member asked how many faculty would be affected, and J. Guden stated it would be hard to measure. It was also asked if this applied to clinical research only and was basic science is okay? W. Durfee stated that no, anything that has human subjects and must go to IRB would be affected. M. Pritzker noted that there have been many revisions to the document, but that the most significant edits only affect a certain type of faculty; if changes are going to be enacted then it should be applied to industry research across all faculty, regardless of whether or not human subjects are involved (including \$0 reporting). L. Zentner reiterated that all faculty must disclose relationships with industry; there are various levels. D. Davis pointed out that the changes really only effect the AHC, and it does not read as a university-wide policy. It was pointed out that while public perception is an issue [regarding human subject trials], from faculty perspective, this is a very negative policy, and it feels like a lawyer is needed in order to understand what it means. The indirect the message is don't do it. It was also pointed out that industry views the U of MN as difficult to work with already, and this makes it a lot worse.

It was asked if the draft policy statement will be voted on in the March senate meeting and how would the FAC be able to have impact on the wording of the document to be voted upon. A follow-up question asked if there would be additional opportunity for discussion in the senate. W. Durfee stated that at this time there is no additional discussion planned and it is slated for a vote in March. Dr. Ingbar made a friendly suggestion to the senate that the vote be delayed; the document has evolved so much that the senate should not vote on in March without further discussion. W. Durfee stated that they want to take the time to get it right, and if it's not ready for a vote, then they won't vote in March. It was asked if there are federal or state mandates to make this policy change and Dean Jackson pointed out that this came about due to the issues with the Dan Markingson case to improve public perception about human subject research at the University. The University has been criticized by legislature and we are trying to set the bar for a high ethical standard.

Action Item: It was decided that the Office of Faculty Affairs would send out contact information for the presenters and additional feedback could be sent directly to them.

3. Fetal Tissue Research (LeBien, Shiels, McArther)

Tucker LeBien (Vice Dean for Research), Angela McArther (Director, Anatomy Bequest Program), and Barbara Shiels (Senior Associate General Counsel) presented a discussion on the Human Fetal Tissue

(HFT) item that is on the Board of Regents docket for the February meeting because the Regents received a letter from 37 state legislators wanting to ban this type of research.

Dr. LeBien stated that human HFT research is legal and millions of federal dollars are given out across the country to support it; many areas use HFT research including developmental biology, infectious disease and neuroscience. B. Shiels stated that eight individuals in medical school have used HFT in their research; seven who have used it recently, and one who has potential to use. The use is across several different departments, through several NIH grants. All researchers have been following policy and guidelines.

B. Shiels stated that we currently have administrative policies on embryos and transplantation, and HFT research that will be updated. The updates will focus on management around supervising the use of HFT including: a more comprehensive tracking system; implementing review, approval and oversight; implementing a centralized process for procuring and disposal of HFT. The requirements of the “final” policy will include: Researchers must obtain approval from stem cell research oversight panel if it does not meet criteria for IRB; Anatomy Bequest Program will procure the samples, or approve the source of the HFT from 3rd party vendor (there will be no acquisition from within MN); disposition of unused fetal tissue will be done using the Anatomy Bequest Program.

Given the potential for legislative action, members of the FAC said they wanted to consider making a motion as a faculty to support. It’s important to the regents to know what the faculty support.

Action item: P. Bohjanan asked that B. Shiels and T. LeBien forward the final updated policies to Office of Faculty Affairs staff, and then the FAC will discuss in the February meeting and decide if they want to vote.

4. Non-tenure Faculty Tracks (McLoon, Ingbar)

Dr. Linda McLoon handed out copies of the faculty survey regarding non-tenure track and asked committee members to email her and Dr. Ingbar with updates/suggestions. It was suggested in the meeting that links to the tracks be provided in the survey. Dr. James Pacala also noted that Vice Dean for Education Mark Rosenberg had put together a committee to look at educational scholarship (lead by James Nixon) and that could inform the survey. Dr. McLoon indicated she would follow up with Dr. Nixon.

5. Update on integration workgroups

Brief updates were provided by the various workgroup members that were present. The question of how the basic scientists fit into the integration was brought up, and the importance of transparency in hiring and funds flow was noted. It was also noted that recommendations were being made to the leadership in the coming week and if there were any major concerns for the workgroups they should be communicated quickly.

Adjournment:

The meeting was adjourned at 5:35 pm by MOTION of Drs. Pritzker and Davis (first, seconded). The next meeting will take place on February 2, 2016 at 4:00pm.

Respectfully submitted,

Kerri M. Miller
Staff to the FAC