

**Medical Affairs Advisory Committee Meeting
November 20, 2019**

Members Present: Jawad Al-Khafaji, John Allen, Ajjai Alva, Stephanie Chervin, Sami Malek, Suomya Rangarajan, Rishindra Reddy (Chair), John Tranfaglia

Guests Present: Joy Beatty (U of M Faculty Senate Chair) & Ben McCoy (Compliance Specialist)

Presenters: Ray Hutchinson, MS, MD
Associate Dean for Regulatory Affairs
Professor of Pediatrics and Communicable Diseases

Topic of Discussion: Conflict of Interest: Memorial Sloan Kettering in the News—What lessons can we learn?

Dr. Reddy opened the meeting and welcomed everyone.

MSK's Response to findings:

- They have barred top executives from serving on boards of directors (BOD) of health or life-science related companies. (CEO, CMO & CFO)
- OTT will assess if MSK will have a role on start-up BOD's – each time.
- MSK plans to disclose financial interests of faculty members & researchers on its site – Cleveland Clinic does this too.
- MSK is forming a 'Board-Level' COI committee to oversee COI of all employees, board members and MSK as an institution – Michigan Medicine has such a committee in place.

University of Michigan Checkpoints – Committees:

- **UMMS MEDCOI Board** (1990's) Look at individual conflicts of interests, some faculty have stepped away from outside interests, so they can continue research

Question about how are employees' data analysis protected? 1. Pre-clinical, they shy away from analysis data, because it has to be replicated. 2. In human trials, they ask an independent CO to take role to review data.

Any data going out should go out with a Data Use Agreement & Tech Agreement.

Dr. Runge: Most companies will not look at data w/o release.

Dr. Hutchinson: We don't have control of the companies use of data.

- **UM Institutional COI Committee** (2010). Prior to MSK the focus was narrow, only on clinical trials spin-offs 7-8 years. It has been expanded to include all research and institution executives.
- **UMMS Human Data and Biospecimen Release Committee.** The committee is made up of: Steve Kunkel, Ray Hutchinson, Erin Kaleba, Sachin Kheterpal, Judy Birk, Teri Grieb, Sheryl Flanagan, Victoria Blanc, Craig Reynolds, Drew Bennett, Kayte Spector-Bagdady, Patrick Woods, Michael Ranella and Tara Bradshaw

Fast Forward reviews requests to share info.

The language is specific and consistent with our mission – why doing it is relevant to our mission.

Dr. Runge thought that there was a problem. Premise: data is institutional (no one owns it), it is not theirs to give/share without consent. The consent protects the patient information. In the past

2 years', they have worked through many examples. Most universities do not have these safe guards.

Dr. Hutchinson, speak to what is right, he referenced an article from the NE Medical Journal. Harry Greenberg, MD, from Stanford has reached out to Dr. Hutchinson in regards to safe guards that Michigan Medicine has put in place. Their COI, has no committee process.

Dr. Runge's concerns with conflicts, for example genetics companies, current & former faculty of U of M. Result was to do RFP to address that situation. The RFP protects us with 'fair market value', Fast Forward helps in this regard.

Dr. Malek asks 'who is the custodian of information?' Large amounts of \$ & people are useless to ethically protect.

Dr. Hutchinson's response, the committee has high value, COI look, and what happened at MSK, would not happen here. We do not do exclusives.

Dr. Runge, companies doing research or spin offs with side business with data. What they do is sell the data. Google & Ascension Health, that patient data could be ID'd, so the project died. Each step along the way, things can be identified.

Someone asked with the Apple study being done here. The line is blurred with tech companies, 'How do you ensure data, not just health information?

Dr. Hutchinson, people are trying to hack our systems. There are 10,000 hits/attempts a day.

Dr. Allen, there is no idea how data will be aggregated in the future.

Dr. Reddy, how do you share clinical trial studies? It is not very time effective, have to streamline the process. He's working on a robotics project with 16 institutions, and it took 16 months to get through our process, it was the second slowest. When working with industry, we are not that nimble to work with.

Dr. Hutchinson, the committee working along with Dr. Runge are trying to get faster. Call or email them.

HITS contract took 9 months to process. Dr. Allen is okay with being careful.

- ***Questions for the Future/additional measures:***

Dr. Malek commented that the NIH Policy on Assets, typically follow the grantees. If the PI moves on to another institution, policy 'would not stand in the way', there are checks and balances. Dr. Runge shared that they did 'hold the truck up' in one instance, because the data/work was funded by the university and not NIH.

- ***UMMS Response***

Dr. Malek commented that a topic was missing that of 'Culture of Organizations'. Why it happened, 'top down' not challenged – MSK & MD Anderson. He commented that we have good culture – COI policies.