

Consulting Management Committee  
February 18, 2014  
2:00- 3:00 p.m.

Present: M. Breland, A. De Blas, K. Fearney, S. Spiggle, T. Van Hoof

Staff: B. Murray, E. Passan, S. Reis, S. Wetstone

**Actions:**

- The minutes of September 17, 2013, were approved: motion by S. Spiggle, seconded by A. De Blas, passed unanimously.
- S. Wetstone outlined a confidential scenario, where a faculty member at the UConn Health Center has been asked to provide answers to questions, pertaining – perhaps – to a single drug, and the answers provided by the faculty member will be recorded. The faculty member's answers will be edited when discussing off-label use of the drug, and the faculty member will have the opportunity to review the edits, per email correspondence between the faculty member and the potential contracting entity.
- Members of the Committee raised concerns regarding the possible one-sided nature of the final video, the editing process, and the leading nature of potential questions.
- S. Wetstone and T. Van Hoof confirmed that off-label concerns uses for a product that are not within the specific designated scope of the FDA.
- The Committee agreed that S. Wetstone will summarize their concerns and engage the faculty member by email. Pending the responses of the faculty member, the Committee expressed its willingness to hold a subsequent email meeting in order to formally vote on its approval of the activity. The following was provided to the Committee for review the day after the meeting:
  - 1) We all share a concern that the activity might be a promotional presentation (i.e. it represents marketing without a fair and balanced presentation of the treatment options). We are particularly aware that the final educational product will be posted on a general web site. With that said, we understand that the activity may not be promotional and want to give the requestor an opportunity to provide more information which could then lead to a positive vote by the CMC.
  - 2) The requestor must maintain control of her presentation and the educational materials associated with it.
  - 3) The editing of the video is of concern. While we understand the need to remove any off label remarks, the faculty member must be in a position to review and agree both such revisions as well as any other editing. We need assurances this will be the case.
  - 4) The choice of questions asked in the interview can be self-serving towards a promotional end. We need to review these questions to ensure they are not. We also need to know whether the requestor has the right to add questions to this list.

5) The interview clearly focuses on a single drug for the treatment of MS. Usually, this is a flag for a promotional presentation, but in certain circumstances it might not be. We need to understand more from the requestor why it might be appropriate to focus on one drug rather than a class a drug and/or provide a balanced discussion of all the treatment modalities.

- Open Payments

S. Wetstone has been appointed to develop the Health Center's response to Open Payments. The UCHC Executive Compliance Committee has convened an advisory committee to assist him.

- a. Data collection began on August 1, 2013 and the first reports to the Federal government will be through December 31, 2013. The government will post these data on a web site at about the end of the summer of 2014.
- b. This applies to any of the following types of professionals that have an national provider identification number:
  - i. Doctor of Medicine
  - ii. Doctor of Osteopathy
  - iii. Doctor of Dentistry
  - iv. Doctor of Dental Surgery
  - v. Doctor of Podiatry
  - vi. Doctor of Optometry
  - vii. Doctor of Chiropractic Medicine
- c. Pharmacists and Nurses are not included in this legislation.
- d. Providers will have a 45 day window prior to the public posting of the data to dispute its accuracy..
- e. Possible Risks when the payment information is made public:
  - i. Reputational (i.e. perception of CoI by patients, the media or the public)
  - ii. Increased allegations of abust through "bounty hunter" associated laws including the False Claims Act, Stark, and similar laws
  - iii. Demonstrated non-compliance with the University's consulting, financial CoI in research, and IRB policies and rules.
- f.

- High-Risk Consulting

- a. K. Fearney, S. Reis, and S. Wetstone are developing procedures for deans and department heads regarding high-risk conflict of interest and commitment. K. Fearney is attempting to find models policies and/or information materials about CoI from other Universities.

- OFCAS Version 3

- a. B. Murray provided an update on OFCAS 3, which will hopefully launch during summer 2014. The new version will be independent from the Kualu Rice routing system.

- b. The Consulting Oversight Committee gave permission in early February to the following proposals:
- i. Accelerated requests (this is based on the current definitions) will become 'FINAL' after department head approval. They will not route automatically to the Dean, FCO, or Provost. Accelerated-Requests from a department head would route to the Dean, then become 'FINAL'.
  - ii. If a faculty member reaches a certain maximum number of consulting during normal work days during a fiscal year, future requests will route through the system as they currently do (we can establish this number at a future date – we don't believe it will be a heavily used feature as only 1 faculty member consulted more than 39 days in fiscal year 13).
  - iii. Department Heads will always have the option to route a request to the Faculty Consulting Office for further review, and FCO may involve the dean in discussions, or, if easier, we can instruct the department heads to contact the FCO with any questions, instead of the alternate routing.
  - iv. The FCO will continue to review all reconciliation forms.
  - v. FCO will manually randomly audit 10% of accelerated requests.

Respectfully submitted,

Brandon L. Murray