



Office of Research and Sponsored Programs

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Notes from Faculty Advisory Committee Meeting September 30, 2013

Attendees: John McGrath, Kevin Cunningham, Mary Montoye, Ed Simpson, Sivaram Narayan, Steve Roberts, Mary Senter, Adam Epstein, Elina Erzikova, Jamie Johansen, Ed McKee, Crina Tarasi

Absent: Rachel Caspari, Janet Sturm, Ksenia Ustinova, Megan Goodwin

1. McGrath welcomed the Committee and had individual members introduce themselves. He indicated that two of the Committee members have schedule conflicts during the normally scheduled meeting time. He is working with them to try to work out a solution.
2. McGrath indicated that the Committee met three times during the last academic year. The Committee meetings are scheduled every two weeks on Mondays from 4 – 5. If there are no agenda items, the meetings will be cancelled. McGrath will provide draft notes from the committee meeting. If anyone has changes, please let Montoye know. Formal approval will be sought at a subsequent Committee meeting. McGrath indicated that ORSP met with five college's faculty last year. A summary of their recommendations was provided with this meeting agenda. McGrath hopes to spend time at a future Committee meeting reviewing the recommendations.
3. McGrath indicated it was his intent to spend today's meeting discuss research compliance issues. During the summer ORSP worked with three consulting firms (HPP, Huron and Maximus.) Some of their suggestions were that ORSP should engage the faculty in discussion of some of the compliance issues that CMU is facing. Last year this Committee helped McGrath navigate some compliance issues related to the IRB. McGrath reviewed a PowerPoint presentation with the Committee.
4. There are several matters pending from last years' notes from the Committee meetings. They include the following:
 - Strategic planning status update
 - ORSP proposal deadline
 - ORSP staffing levels
 - ORSP guidelines status
 - ORSP to provide copy/editing service

- Statistics support
 - Post early career support by providing course reassignment
 - IRB-SOPs
 - ORSP website
5. McGrath provided an executive summary of major accomplishments for ORSP for 2012 – 13. They included the following:
 - Standard Operating Procedures (SOPs) for the conduct of human subject research at CMU were formally released after several years of delays.
 - ORSP hired the HRP consulting firm. Major issues concerning significant non-compliance associated with human subject research at CMU were identified and initial steps to address the issues have been taken.
 - ORSP hired the Huron consulting firm. The current status of the CMU research infrastructure has been defined. Gaps and opportunities have been identified. Recommendations for action have been made.
 - ORSP hired the MAXIMUS consulting firm. Final advice is expected soon related to faculty supplemental and summer compensation that has kept the Article 7 Subcommittee occupied since April 2012.
 6. McGrath shared a copy of the current ORSP organizational chart, along with a proposed organizational chart resulting from recommendations from the consultants. They have recommended six additional positions in ORSP. They have also recommended that there be two IRB's, one for social and behavioral protocols, and one for health professions and college of medicine protocols. They have further recommended that both committees be chaired by tenured faculty and that a co-chair be considered for each committee. They have also recommended that consideration be given to compensation for IRB committee members due to the significant work load.
 7. McGrath indicated that the previous ad hoc committee had worked with HRP to assist in the development of IRB SOP's. ORSP recently brought HRP back to help review processes in light of recent research compliance concerns. They have identified a number of non-compliance issues related to the IRB, many of which appear to be technical non-compliance. Some of these appear to be related to not having the SOP's in place and lack of training for IB and faculty members. HRP is conducting a full IRB protocol audit and will work with ORSP on a plan to resolve the non-compliance issues they identify. HRP has provided a time line to have IRB compliance issues resolved by January 2014.
 8. Huron was hired to assess research infrastructure of the university to align resources with CMED initiatives. They have confirmed that ORSP is understaffed. .
 9. Maximus was hired to help identify solutions to the summer salary and supplemental pay issues that ORSP has been working with the FA on. ORSP is waiting for their final recommendations.
 10. McGrath provided information about why research compliance is important at CMU and how to best engage faculty in the process.

- Faculty and students are conducting or may conduct research using: chemicals, pathogenic and lethal agents, genetically-engineered molecules or organisms (recombinant DNA), lasers, radio-isotopes, animals, humans, sensitive data, controlled substances, etc.
- Protect students, staff and faculty conducting the research
- Protect the community
- Protect human and animal subjects of the research
- Protect CMU
- Aspects of research compliance
 - Ethical, legal, regulatory, financial, health and welfare, reputation
 - Essential component at all universities conducting research

11. McGrath shared information on the kinds of research compliance at CMU.

ORSP

- Human subjects
 - Institutional Review Board (IRB); Office for Human Research Protection (OHRP)
- Animals
 - Institutional Animal Care and Use Committee (IACUC); Office of Laboratory Animal Welfare (OLAW)
- Animal Handler Occupational Health and Safety
 - Michigan Occupational Safety & Health Administration (MIOSHA) & Office of Laboratory Animal Welfare (OLAW)
- Recombinant DNA
 - Institutional Biosafety Committee (IBC); NIH

Risk Management/Environmental Health & Safety

- Bio-safety [Bio-hazardous waste, infectious agents, and blood-borne pathogens]
 - Biosafety Committee; Michigan Occupational Safety & Health Administration (MIOSHA), Michigan Department of Environmental Quality (MDEQ) and Department of Health and Human Services (DHHS)
- Chemical Safety
 - Lab Safety Committee; Michigan Occupational Safety & Health Administration (MIOSHA)
- Radiation Safety
 - Radiation Safety Committee; Nuclear Regulatory Commission (NRC)
- Laser Safety
 - Laser Safety Committee; Michigan Occupational Safety & Health Administration (MIOSHA)
- Field Safety
 - Under consideration

CMU Information Technology

- Data security
 - CMU IT; NIH and other entities possessing the sensitive data

CMU General Counsel

- Export control
 - Department of Commerce, Department of State, Treasury Department
- **Finance and Administrative Services/Internal Audit**
- Effort Reporting, Cost Sharing, Cost Transfers, Expense Allocability and Allowability, Credit card expense allocation, payroll appointment and processing
 - Federal and state auditors

12. McGrath indicated that all of the major components are in place at CMU. He is working on a comprehensive assessment of all compliance areas. Additional information:

IRB

- HRP audit underway. Major aspects to be complete by Jan 2014
- ORHP notified of CMU proactive assessment of HRPP
- Potential and actual non-compliance reports sent to OHRP
- Other possible and actual non-compliances will be reported to OHRP, NIH, etc. as required
- Membership under review. Two IRBs being considered
- SOPs require tailoring for CMU
- AAHRPP or Alion accreditation to be considered

IACUC

- HRP audit to be initiated soon. Expected to be complete by Oct/Nov 2013
- AAALAC accreditation to be considered

Chemical & Environmental Safety

- ORSP working with CMU Risk Management/Environmental Health & Safety to engage consultants to conduct audit

13. McGrath is interested in faculty engagement during these processes. There is a new committee being established "Research Compliance Review Committee. This Committee will be comprised of one faculty representation from each college. In addition, he will seek input from the current ORSP Faculty Advisory Committee which is comprised of two faculty representative from each college along with one FA representative. He will also be working with the compliance committees (IRB, IACUC, IBC, Biosafety, Lab Safety, Laser Safety, and Radiation Safety). In addition, there have been e-mail communications sent to the university community, and meetings with some colleges and departments. A presentation will be made to Academic Senate, informational flyers will be distributed and information will be added within IRB net. If anyone has additional suggestions for faculty engagement, please let McGrath know.