I. Introduction

HRP Consulting Group (HRP) was engaged by the University of Southern Maine (USM) to assist in the evaluation of the USM research compliance program. The following is a report on the results of evaluation and HRP’s recommendations with regard to the USM compliance program.

II. HRP’s activities in the engagement

1) HRP reviewed the documentation for the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC).

2) Dr. Cohen and Ms. Savini conducted a two-day site visit to USM on November 22-23, 2010. During this site visit, Dr. Cohen and Ms. Savini met with representatives from the IRB, IACUC, IBC, institutional officials, investigators and faculty members.

III. Observations

Strengths

1) There is a strong commitment to the responsible conduct of research throughout the institution, including institutional officials, ORIO staff, reviewers and investigators.

2) HRP was extremely impressed with the expertise and dedication of Ross Hickey and Sarah Gilliam.

3) The USM research compliance program plays a leadership role among Maine research institutions. USM has hosted an educational program open to other research institutions and the USM IRB reviews research for other organizations.
**Weaknesses**

1) The research compliance program at USM is significantly under-resourced. Although Ross Hickey and Sarah Gilliam are extremely competent and knowledgeable, the lack of support staff for these individuals makes the program vulnerable to regulatory noncompliance.

2) Faculty has the perception of mixed messages coming from the administration. While encouraging increase in research activity, the administration has been reducing the support for research infrastructure.

3) Faculty appears to be shifting research priorities to avoid IRB review, especially with regard to student research.

4) Faculty from the Muskie School of Public Service particularly feel ill-served by the IRB. Given the volume of funded research conducted by these faculty members and the indirect cost generated by this research, it is reasonable to expect that the IRB review process would be effective and efficient.

5) The database system seems to be insufficient for the processing and record keeping requirements for the IRB and IACUC.

6) The animal care and use program relies on the facility manager to run the program rather than a higher level administrator. This administrator should oversee the program and focus on policy and compliance issues, such as the use of controlled substances. These functions should not be the responsibility of the facility manager.

7) Some faculty members have significant complaints regarding the IRB review process. Although researchers at most institutions complain about IRBs, these complaints at USM seem to reflect a need for additional support staff, to streamline the review process and increase communication with researchers.

8) IRB/IACUC/IBC members appear to need additional training with regards to regulations. The IRB could be better trained in the requirements for IRB approval and the use flexibility in the regulations. The IBC is lacking in guidance on regulatory requirements, updated policies and procedures, and coordination with the IACUC.

9) The USM IRB reviews protocols for external organizations, including other University of Maine institutions. This increases the burden on the IRB and ORIO.

**IV. Recommendations**

As a result of this site visit, HRPA has a better understanding of the USM research compliance program. Based on this, the following are our recommendations:

1) The research compliance program must receive additional, stable funding from the University. As part of establishing stable funding for the program, a portion of the indirect costs generated by funded research should be allocated to the research compliance program. Research compliance costs are considered to be an indirect cost by federal sponsors and included in the calculation of indirect cost rates. Therefore, some of those funds should be distributed back to ORIO.

2) There must be additional well-trained staff for the IRB, IACUC and IBC committees. The use of temporary staff to support the ORIO is ill advised. ORIO
needs permanent trained individuals. We recommend the following staffing for ORIO:

a. Assistant Provost for Research Integrity and Oversight who reports directly to the Provost and oversees the research compliance program
b. Two full-time committee administrators, one for the IRB and one for the IACUC/IBC
c. An administrative assistant to provide clerical support for the office

This staffing level is based on the need for each of the committees to have well-trained staff support and the need for additional functions such as quality assurance and education, especially in human research protections. These functions (see below) can be shared by the Assistant Provost and the committee administrators.

3) In order to keep up with the current expectations in the field, USM needs to develop a research compliance Quality Assurance/Quality Improvement (QA/QI) program. The purpose of a QA/QI program is to use post-approval monitoring to measure and improve compliance with organizational policies and procedures and applicable federal, state, and local laws. In addition, the QA/QI program should evaluate and improve the effectiveness and quality of the research compliance program.

4) USM also needs a more effective research compliance education program. We recommend more training for IRB/IACUC/IBC members and chairs. This training should include: enhanced initial training for new members and chairs, on-going training by ORIO staff at committee meetings, regular training retreats for committee members and chairs, and support for attendance at educational programs and conferences, such as those presented by PRIM&R. There needs to be a more systematic and ongoing investigator education program than just CITI. This could include: ongoing provision of information via email and/or a newsletter, regular research compliance workshops (local and regional), and presentations at department meetings. There also needs to be additional education and training for students, such as classroom lectures.

5) Should USM wish to continue its animal research program, we recommend that the animal care and use program become part of ORIO. The Assistant Provost should oversee the program and the animal care staff, including the facility manager. There also should be a permanent well-trained animal care taker, in addition to the present manager, to provide back-up in times of absence of the manager.

6) We recommend the use of a commercial database system for the IRB/IACUC/IBC. Based on cost and ease of use, we recommend USM consider the use of IRBNet (www.irbnet.org) or IRBManager(www.irbmanager.com).

7) We recommend that USM continue and enhance its role as a leader in research compliance for Maine, including regional workshops, providing research review and providing animal care services. This elevates the research compliance program within USM and can provide additional resources for the program. Research review and animal care services should be structured to provide income for the program.
V. Summary

While there is a commitment to the responsible conduct of research, recent cutbacks and layoffs threaten the effectiveness of the research compliance program at USM. The system functions in large part because of the dedication of Ross Hickey and Sarah Gilliam, especially Mr. Hickey, as well as the commitment on the part of the IRB/IBC/IACUC members. Failure to adequately fund the research compliance program increases the risk to the University of investigation by regulatory agencies, litigation and negative publicity. In addition, the negative effect of the recent cut backs and layoffs on the effectiveness and efficiency of the research review process decreases the willingness of the faculty to conduct research and assign research projects to students.

The core of an effective research compliance program remains and, given adequate resources and support, Mr. Hickey is well qualified to rebuild the program and lead it forward. A suggested administrative structure for the research compliance program is attaché. If requested, the HRP Consulting Group can provide assistance in rebuilding the program.
Research Compliance Program Administrative Structure

- Provost
- Assistant Provost for Research Integrity and Oversight
- Office of Research Integrity and Oversight
  - IRB Administrator
  - IACUC/IBC Administrator
  - Administrative Assistant
  - Animal Facility Manager
    - Animal Caretaker
  - IRB
  - IACUC/IBC