DATE:  August 18, 2015
TO:  Faculty and Staff
FROM:  Dennis Manos, Vice Provost for Research
SUBJ:  Research Compliance Reminder

Attention: Export Controls managed by the Technology Transfer Office

Research is an integral part of academic life that is highly regulated by state and federal laws. We have an obligation to perform research using the best available safety practices. Please share this message with visitors, students, post docs, and others in your area, all of whom might perform research that could fall into one of the regulated areas discussed below.

Federal Regulations require formal review for certain classes of activity BEFORE employees or students begin work. Review is required whether these regulated activities are supported by external or internal funds, whether they are performed as research or as part of normal instruction in a classroom, lab, or practicum, whether they are performed on or off College grounds, and whether they are part of a formal research program or undertaken as the result of academic curiosity on the part of a professor or student.

Regulated areas of concern include:

**PHSC**-Work that involves living human subjects **including survey research or questionnaires**;

**IACUC**-Work that involves the use and care of vertebrate animals;

**RAD**-Work that uses or produces radioactive materials; and

**IBC**-Work that involves institutional bio-safety concerns such as:

- Recombinant DNA
- Work with any human fluid, tissue or infectious agent
- Research involving direct or indirect contact with wild-caught animals that may harbor infectious agents

Investigators must submit compliance proposals that include detailed step-by-step procedures to be used in the research prior to the commencement of work.

Further, compliance committee review is required for survey work that may be done year-after-year in scheduled classes or laboratories.

**Annual renewals are not automatic.** Researchers must update protocols annually in order to continue the work. Any modification in the authorized protocol during the period covered by VIMS Safety and Environmental Programs at the protocol must undergo additional review **prior** to implementation.

A detailed description of the compliance committees, along with guidance for investigators, is available on the College’s Research Compliance website:

http://www.wm.edu/offices/sponsoredprograms/researchcompliance/guidanceandprocedures/index.php

Individuals who will perform, or intend to perform, a particular activity involving regulated areas may **not** judge for themselves whether that work is exempt from formal review. If you have questions you should either submit your proposed activity through the Protocol and Compliance Management electronic submission program for review or contact a Committee Chair to discuss it. **Written committee approvals must be in place prior to beginning any project.**
An increasingly important compliance responsibility is creating and maintaining oversight and training about the role of ethical conduct in research and management of potential conflicts of interest. Some federal agencies mandate training in the Responsible Conduct of Research (RCR) prior to processing proposals or making awards. 

http://www.wm.edu/offices/sponsoredprograms/researchcompliance/research%20integrity%20and%20conflicts%20of%20interest/nsfmisconduct/index.php

William and Mary must annually renew its assurance with the Public Health Service’s Office of Research Integrity and confirm that we have a formal policy. Further, the report must include details of any misconduct allegations, inquiries and investigations handled in the previous year. We encourage you to review the Policy on Integrity in Research and Scholarly Activity found in the Faculty Handbook: 

http://www.wm.edu/about/administration/provost/forfacstaff/faculty-handbook/index.php

It is the faculty member’s responsibility to ensure that any potentially hazardous procedures will be specifically identified in protocols submitted to the College Compliance Committees (e.g., IBC, Radiation Safety, IACUC, and Human Subjects). If the research activity does not require formal compliance review, the faculty member should ensure that general laboratory and field safety protocols are documented, relevant, and enforced.

Federal law also governs the use and management of Select Agents. At W&M, oversight of Select Agents falls under the purview of the Environmental Health and Safety Office. A complete list of Select Agents and Toxins may be found at http://www.selectagents.gov/SelectAgentsandToxinsList.html

Questions about Select Agents should be directed to Sandra Prior, Director of EHS at slprio@wm.edu. VIMS faculty/staff should address questions to Tom Grose, Director at twgrose@vims.edu.

All research at the University must also comply with all United States Export Control laws and regulations that apply to certain activities involving corporations or citizens of certain foreign countries. Export Control issues are assessed on a case by case basis. The University policy and further information to assist researchers may be found on the Technology Transfer Office website:

https://www.wm.edu/offices/techtransfer/ExportControls/index.php

Faculty, staff and students should be aware of basic compliance and safety requirements. The College has available a series of training modules covering a variety of topics including responsible conduct of research, animal care, biosafety, human subject research, and export controls. The modules can be accessed at https://www.citiprogram.org.

We encourage everyone to take advantage of the training opportunities.