



DATE: April 8, 2015
TO: Faculty and Staff
FROM: Dennis Manos, Vice Provost for Research
SUBJ: Research Compliance Reminder

Please Note: New Emphasis on Laboratory Safety (page 2)

We are distributing this message to all William and Mary faculty and staff members as a reminder that research is an integral part of academic life, and we have an obligation to perform it using the best available safety practices and in close compliance with laws and regulations. We urge you to share this message with all of the students, post-doctoral associates, and others whose research you mentor, as well as with students in your lecture, lab, or practicum classes who might perform surveys or other types of 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.

Areas of concern include:

- a) Work that involves living human subjects (***including** survey research or questionnaires*);
- b) Work that involves the use and care of vertebrate animals;
- c) Work that uses or produces radioactive materials; and
- d) 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

By law, proposed work in any of the four categories above must be reviewed by duly constituted committees appointed by and reporting to senior College administrators. Investigators must submit compliance proposals that include detailed, step-by-step procedures to be used in the research. Further, 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. Further, any revision in the authorized protocol during the period covered by the protocol must undergo additional review **prior** to implementation.

Another regulatory compliance concern is 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 VIMS Safety and Environmental Programs at twgrose@vims.edu.

A detailed description of the compliance committees, along with guidance for investigators, is available on the College's 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/training/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 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.

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 this training opportunity.