Integrity Is the Cornerstone

By James Trempe, Ph.D., Vice President for Research

Integrity is the cornerstone upon which public research and scholarship is built. Without the shared trust that is inherent in peer-reviewed research and scholarly activities, the benefits of scientific breakthroughs that we enjoy today would never have materialized. Moreover, we would be incapable of achieving the goal of improving the human condition. Protecting the integrity of scholarly inquiry is the shared responsibility of faculty, students, staff and administrators. Federal law and university policies provide us with the tools of protection to help achieve this goal. The principles for responsible conduct of research and scholarship are contained in university policy Responsible Conduct of Scholarship and Research (3364-70-02). Another university policy--on Integrity in Research and Scholarship and Procedures for Investigating Allegations of Misconduct in Research and Scholarship (3364-70-21)--contains a thorough discussion of misconduct as well as extensive instructions for investigation of alleged misconduct.

One of my roles in research administration has been to serve as the university’s Research Integrity Officer (RIO). The RIO is the institutional official responsible for assessing allegations of research misconduct and overseeing inquiries and investigations. In the five years that I served as the RIO, I responded to more than a dozen such allegations. Upon receipt, the RIO is bound by policy to initiate a three-step investigation process (See policy #3364-70-21 for more specific information). Allegation assessment is the first step performed by two senior faculty members chosen by the RIO. According to policy “this assessment is intended to separate serious allegations from trivial, frivolous, unjustified, or clearly mistaken allegations or from situations that clearly do not involve serious academic misconduct and which may be pursued appropriately through other administrative channels.” If the allegation is found to be credible, the allegation moves to the inquiry phase conducted by a panel of three senior faculty members chosen by the RIO. An inquiry is an information-gathering and fact-finding process to determine whether the allegation or apparent instance of misconduct warrants a formal investigation. The key criterion in the decision to move forward with a formal investigation is the determination of whether “the allegation is sufficiently credible and specific so that potential evidence of misconduct may be identified.” If the panel decides that a formal investigation is warranted, then a new panel of five senior faculty members is chosen to conduct the investigation. An investigation is a formal examination and evaluation of all relevant facts to determine if a major offense has taken place. If research misconduct has occurred, the investigation panel prepares a report of the proceedings and recommends sanctions against the accused. The appropriate provost, in consultation with the RIO and investigation committee, decides whether to concur or reject the finding of misconduct and decides what action should be taken.

My experiences as RIO have provided some insights in dealing with academic misconduct allegations. The first being that it is very difficult to prove research or academic misconduct. Among all allegations that came across my desk in the past five years, only one resulted in a finding of serious misconduct. That finding was enabled by significant evidence provided by a funding agency. Most allegations are made in good faith and the accuser appears to be sincere. However, allegations that initially appear to be strong often unravel as additional information is acquired during the assessment, inquiry or investigation phases. During the assessment process allegations collapse when the assessors determine that serious academic misconduct is not involved and that the allegation can be handled via other administrative channels. During the inquiry or investigation phases allegations falter because solid evidence of serious misconduct is never found.
A common, but not exclusive, theme of misconduct allegations is the revelation of animosity between the principals. As the assessment and inquiry panels perform their roles, new information is sometimes uncovered revealing animus directed at the accused from the accuser. This may stem from a variety of reasons: professional jealousy, a feeling that the accused has received undue accolades or that the accused has mistreated students, postdoctoral fellows or staff. Unfortunately, mistreatment of subordinates is common but rarely does it rise to the level of serious and provable academic misconduct. It is incumbent upon all to separate emotions from the facts when considering filing an allegation of academic misconduct against a colleague.

Our procedures are designed to insure that faculty decide the fate of the accused. The time-honored process of peer review, or judgment by peers, is the foundation of our academic and legal systems. Integrity is the cornerstone of that foundation. Dealing with academic misconduct allegations has been my least favorite task as Vice President for Research, however it has been an honor for me to have worked with numerous University of Toledo faculty who have performed these assessments with the utmost professionalism and integrity.

[After more than 30 years of service to the Medical College of Ohio and University of Toledo, Dr. Trempe retires as Vice President for Research in January 2014]

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**UT to Implement Kuali Coeus, Research Administration Software**

By Rick Francis, Ph.D., Director, Research and Sponsored Programs & Research Information Services

In 2014 the University of Toledo will be implementing multiple modules of research administration software. The benefits will be felt by investigators, chairs, and department administrators. After a rigorous selection process, a committee chose Kuali Coeus, an open-source product developed by many universities as members of a consortium. The Kuali project grew out of the desire of several institutions to develop an open-source alternative to Banner, Peoplesoft, and other corporate products for enterprise management. For the research administration portion of Kuali, the consortium team built on a product originally developed at MIT as Coeus, named for the Greek Titan god of intelligence. More information is available at [http://www.kuali.org/kc](http://www.kuali.org/kc).

The modules to be implemented include protocol review and administration for both the IRB and IACUC; grant proposal development, endorsement, submission, and tracking; and grant award tracking and reporting.

While each module will first be implemented for use by the staff in each area, the functionality will -- in later phases -- provide web-based tools to replace the paper-based systems now in use. The resulting system will require less time on the part of investigators to prepare and track research-related proposals and protocols.

In the case of grant applications, investigators will have an online tool for budget development, proposal development (including collaboration), and endorsement by department chairs, deans, and RSP. Proposals in development will be accessible by investigators using ordinary browsers and UTAD authentication. For proposals to federal agencies, RSP will be able to submit proposals system-to-system to grants.gov, reducing redundant data entry and the opportunities for errors.

UT’s research administrators anticipate that implementation of Kuali Coeus will reduce the bureaucratic load of investigators, who will be able to concern themselves less with internal forms, signatures, budget rates, and institutional data for grant proposals, and more with the presentation of ideas.

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**UT Research Education Day - save the date: January 14th, 2014**

What is actually required in the drug and device regulations that impact day-to-day tasks of clinical research?

IMARC Research Inc, will be on site to direct the day’s discussion on this issue. The program will begin at 8:30AM and adjourn at 4:15PM. Registration and CME costs will be covered by the JCCTR.

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**Newly enrolling clinical trials**
Putting the Pieces Together

By Carolyn Pinkston, MPH, RN, CIP

The process leading to the initiation of a research study is much like putting a puzzle together. Each piece is critical to a successful outcome. In addition to the complexities of the overall process, the individual components also require their own internal orchestration. The following synopsis briefly describes the path to the final IRB approval of a research study.

APPLICATION - The quality and completeness of the initial IRB Application significantly impacts the timeliness of the approval. The IRB administrative staff members perform a pre-review of the submission packet for completeness and then assign the application to either the full board or to an expedited reviewer. Staff members cannot approve research studies or changes to studies. Per federal regulations, a formal determination regarding research is the responsibility of the IRB via the appropriate mechanism. Returning an application to the investigator due to a lack of information, associated documents, training certifications or inadequate consent forms can add days and weeks to the process as a review cannot be performed until the packet is complete and submitted in its entirety. The applications and supporting documents were designed to elicit pertinent information required by federal regulation and necessary for the protection of human subjects in research. On a monthly basis the IRB office retains 30-60 incomplete applications pending investigator follow-up. A timely response significantly impacts the review process.

IRB APPROVAL - The turn-around time from application submission to IRB approval is predicated on the type of review and the availability of IRB members. The IRB is comprised of nineteen members and meets once a month to review Convened studies. For complete “clean” submissions, the IRB turnaround time averages 35-45 days from submission to approval. That time frame is reflective of the IRB review component. However, when changes or modifications are warranted, sponsor input is required and/or contract negotiations are ongoing, the finalization requires additional time.

The review and approval of research studies and amendments meeting the Expedited review criteria depends on two important factors; 1) the completeness of the application, and 2) the availability of a board reviewer. As with general IRB membership, this important function is a volunteer role and a handful of members perform this additional duty on a regular basis. While attempts are made to schedule a reviewer on a weekly basis, the IRB member’s clinical, teaching and other professional responsibilities take precedence and time is allotted accordingly.

CONTRACT & SPONSOR NEGOTIATIONS - The contract process for funded studies occurs in a separate office. This component involves negotiations between a sponsor and the institution and the agreement to specific stipulations related to our status as a state university. The IRB office is not involved in the contract process and is notified of the executed contract at the same time as the investigator. Upon notification of a finalized agreement, the contract and Informed Consent Form (ICF) are reconciled to assure they reflect the same information. Once that has been accomplished, the investigator is officially notified in writing that the research may begin.

As described above, the final approval of a research study requires considerable orchestration on the part of many people; investigators, research coordinators, contract specialists, sponsors, IRB office personnel and board members. An understanding of each component’s responsibilities, cooperation and coordination among those groups and realistic expectations all work toward putting the pieces together and successfully
launching a new research study.

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