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RESEARCH QUARTERLY NEWSLETTER   January – March 2012

ENQUIRY

Inaugural Issue

Vice President's Message

The Office of Research is initiating a new way to get information to those of you who support the VCU research enterprise. Each quarter the Office of Research will send a newsletter containing the most current information, reminders and other useful information from the areas of Sponsored Programs, Research Subjects Protection, Grants and Contracts, and Compliance. We will try to include brief answers to the questions most received during the previous quarter and give you a "heads up" as to any changes or new additions to the federal rules and regulations affecting research. I sincerely hope that each of you knows how much the staff of the Office of Research appreciates the hard work that you do each day. We welcome your comments and suggestions regarding the content of this newsletter. Using "Newsletter" as the subject, send your comments and suggestions to: jslalich@vcu.edu. I hope this newsletter will give you an additional tool in your toolbox as you support the growth of the research enterprise at VCU.

Best wishes for 2012.

Francis L. Macrina, Ph.D
Vice President for Research

SPONSORED PROGRAMS

OSP Staffing Updates

Several staffing changes have occurred in OSP. We are pleased to announce that, effective January 17, 2012, Mr. Jason Withers has been appointed as Blue Team Leader. Jason previously held positions of Green Team member and ARRA Reporting Manager in OSP. He will continue in the oversight of ARRA Reporting in his new role.

We also welcome Ms. Georgiana Ball, who started as Green Team reviewer on January 17, 2012. Georgiana has grants experience at both the state level and JMU.

NIH Salary Cap

On January 20, 2012, NIH released its guidance for application of the NIH Salary Cap (see NIH Notice NOT-OD-12-035). For FY2012, the Consolidated Appropriations Act, 2012 (Public Law 112-74) signed into law on December 23, 2011, restricts the amount of direct salary charged to NIH funds to the Executive Level II of the Federal Executive Pay scale ($179,700). In prior years, the amount was restricted to Executive Level I.   This is the first time that the salary limitation has been reduced. Information on how to apply the new cap was presented at the Research Administration and Compliance Meeting on Thursday, January 26, 2012, at 1:00 p.m. at Larrick Hall. The information, with examples, is available on the OSP website (http://www.research.vcu.edu/osp/january26_2012racm.pdf)

Accelerated Spending of American Recovery and Reinvestment Act (ARRA) funding

The Office of Management and Budget announced in September that federal agencies should revise the terms and conditions of their ARRA awards to ensure expenditure prior to September 30, 2013. Funds unspent as of that date are to be reclaimed by the federal agency unless a waiver has been granted by OMB for a particular award. Both NSF and NIH have issued guidance associated with this requirement. The NSF Notice, dated December 13, 2011, is posted at: http://www.nsf.gov/recovery/acceleration.pdf. The NIH Notice, also dated December 13, 2011, is posted at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-014.html. If you have any questions related to these notices, please contact Jason Withers at ospblue@vcu.edu.

COMPLIANCE

Just a reminder that each university member, whether faculty, staff or student, has an obligation to faithfully manage the resources entrusted to the university and to protect the integrity of the research being conducted in order to maintain the public's trust.

When you have concerns, you have options:

You may report violations or concerns to your immediate supervisor or department head, if appropriate.

- You may call the individual responsible for the related compliance area, if appropriate. Please see the Compliance Partners (http://www.assurance.vcu.edu/cac.html) You may call the Compliance Helpline at 1-888-242-6022, or log a report online at www.vcuhelpline.com. Both of these options provide university members an anonymous and confidential reporting option 24 hours a day, 365 days a year.

   You may call or email the ICO directly at (804) 828-2336 or email ucompliance@vcu.edu

Examples of violations that should be reported include:

- Suspected cases of fraud, waste or abuse
- Violations of governmental regulations

- Violations of ethics
- Violations of VCU policies and procedures

All reports must be made in good faith and are protected from retaliation by the VCU policy on *Reporting Suspected University related Misconduct/Noncompliance and Protection from Retaliation*, and state and federal whistleblower protections.

Reports made to the Helpline are handled and investigated by the Integrity & Compliance Office, with assistance from other areas as needed.

RESEARCH SUBJECTS PROTECTION

Animal Care and Use Program (ACUP)

DAR Announces New Incident Reporting Process

As part of a larger initiative to improve the quality of service and to promote improved communications at all levels, DAR is introducing a new *Incident Reporting Process (DAR IRP)*. The purpose of the DAR IRP is to prompt timely investigation, resolution, and reporting of any issues or concerns under the VCU DAR. The goal is to continue to improve the quality of services and to promote clarity of communication throughout the animal research community.

The DAR Incident Reporting Process, currently to be piloted within Sanger Hall, includes the following supporting documents and functions, all of which are available at the following VCU link: https://www.vcu.edu/dar/incident_reporting.htm

1. DAR Incident Reporting Form: use to report animal area and/or personnel concerns or complaints (kudos are also welcome). During this pilot phase, reporting is limited to matters within the Sanger Hall Vivarium. This form can be completed by investigators or their personnel as well as by DAR staff and is submitted to DAR@vcu.edu.

2. DAR Incident Reporting Process SOP: The incident reporting submission and investigation process has been described within DAR Standard Operating Procedure (DAR SOP 100.104) and has been uploaded to the Animal Care and Use Program website.

3. DAR Incident Reporting Process flowchart and FAQ is available on the ACUP website to help visualize the process, as well as to detail the differences between an "incident" and a "service request". https://www.vcu.edu/dar/incident_reporting.htm

Please take a few moments to familiarize yourself with the Pilot DAR Incident Reporting Process using this link https://www.vcu.edu/dar/incident_reporting_SOP.pdf   Your participation in this pilot study is highly encouraged and greatly appreciated.

Please feel free to contact Donna Tignor, Special Assistant to the Director, DAR, at dtignor@vcu.edu if you have any questions or suggestions. She will serve as the first point of contact for this program and will be happy to meet with you as needed.

Animal Care and Use Program (ACUP) Guidance Documents Recently Reapproved

The following ACUP guidance documents have recently been re-reviewed and approved by the VCU IACUC:

- Analgesia and Sedation category:
  - Guidelines for Moribund Condition as an Endpoint

- Drug Usage category:
  - The Use of Pharmaceutical or Nonpharmaceutical-Grade Chemicals/Compounds
  - Use of Expired Medical Materials in Animal Research at VCU

Investigators are encouraged to review these documents for familiarity. All are posted on the ACUP website at https://www.vcu.edu/research/acup/vet_services.htm.

VCU Animal Care and Use Program (ACUP) Transition to the New Guide

On December 2, 2011, OLAW (Office of Laboratory Animal Welfare) announced (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-020.html) the transition to the 8th edition of the Guide for the Care and Use of Laboratory Animals effective January 1, 2012. In OLAW's judgment, the 8th Edition of the Guide empowers continued advancement in the humane care and use of vertebrate animals in research, research testing, and biological testing. The latest edition has been expanded to reflect new standards of practice and technology, along with updated references. Additions to this edition of the Guide include expanded coverage of the ethics of laboratory animal use; components of effective Animal Care and Use Programs; and new guidelines for the housing, environment, and enrichment of terrestrial and aquatic animals, and for veterinary and clinical care (read more details, visit "Key Findings" posted at http://dels.nas.edu/Report/Guide-Care/12910)

All individuals using animals in research, teaching or testing should read the entire Guide, as it forms the basis for many VCU animal care and use program (VCU ACUP) practices and policies. The purpose of this article is to provide a brief overview of the changes in the new Guide and the implications for the VCU ACUP. VCU will be implementing changes in the ACUP over the next 10 months to ensure compliance prior to our next scheduled AAALAC site visit, which will occur in the first quarter of 2013.

Chapter One

Chapter one (Key Concepts) includes some material from the Introduction to the 7th edition and covers several important terms used throughout the Guide (and also within the VCU ACUP).   These include the three R's (replacement, refinement and reduction) within a new section on ethics of animal use, humane care, the animal care and use program, engineering, performance and practice standards, policies, principles and procedures, and the use of the terms *must*, *should* and *may* in the Guide. View this document to see an analysis of the use of these terms in the Guide.

Chapter Two

Chapter two (Animal Care and Use Program) discusses the overall animal care and use program (including some material from chapter one of the previous edition), including regulations, policies and principles, program management, program oversight, and disaster planning/emergency preparedness.   Principal investigators (PI's) will find the section on protocol review particularly relevant. There are new sections dealing with experimental vs. humane endpoints, unexpected outcomes, the use of non-pharmaceutical grade chemicals and other substances, field investigations and agricultural animals. The sections on physical restraint, multiple survival surgical procedures and food/fluid regulation have also been updated. As a result of these changes in the Guide, several new questions and/or help text items will be added to the IACUC Protocol submission in Click Commerce later this year. Look for future communication to provide more information about these necessary changes.

Chapter Three

Chapter three (Environment, Housing and Management) focuses on the animals themselves. This material is of primary interest to the Division of Animal Resources (DAR) and facilities management personnel responsible for maintaining the animal facilities. However, PI's and other animal handlers should be aware of expanded sections on social housing and environmental enrichment that could require changes to current practices. All investigators using aquatic species should read the new section on management of these animals, since the monitoring requirements will impact their protocols. Finally, there are topics on sound and vibration within the animal facility, cage sizes for breeding rodents, procedural habituation/training, and unexpected outcomes that may be of interest. DAR will work with investigators to ensure any necessary changes are implemented.   Again, the specific protocol changes needed within Click Commerce will be communicated later this year.

Chapter Four

Chapter four (Veterinary Care) has additional material on the role of the Attending Veterinarian (AV) as well as expanded sections on surgery, including a new section on intraoperative monitoring. The Guide also introduces the concept of animal biosecurity, which provides useful background for many of the changes required by DAR for animal facilities (especially the MMRB barrier). Therefore, all animal users should read this chapter.

Chapter Five

Chapter five (Physical Plant) covers the operation of animal facilities and is of primary interest to facilities management and DAR staff. However, there are also topics of interest to animal users such as facility security, surgery in labs, additional material on vibration and animal biosecurity, and information on special facilities for surgery, barriers, imaging, whole-body irradiation, hazardous agent containment, behavioral studies and aquatic housing.
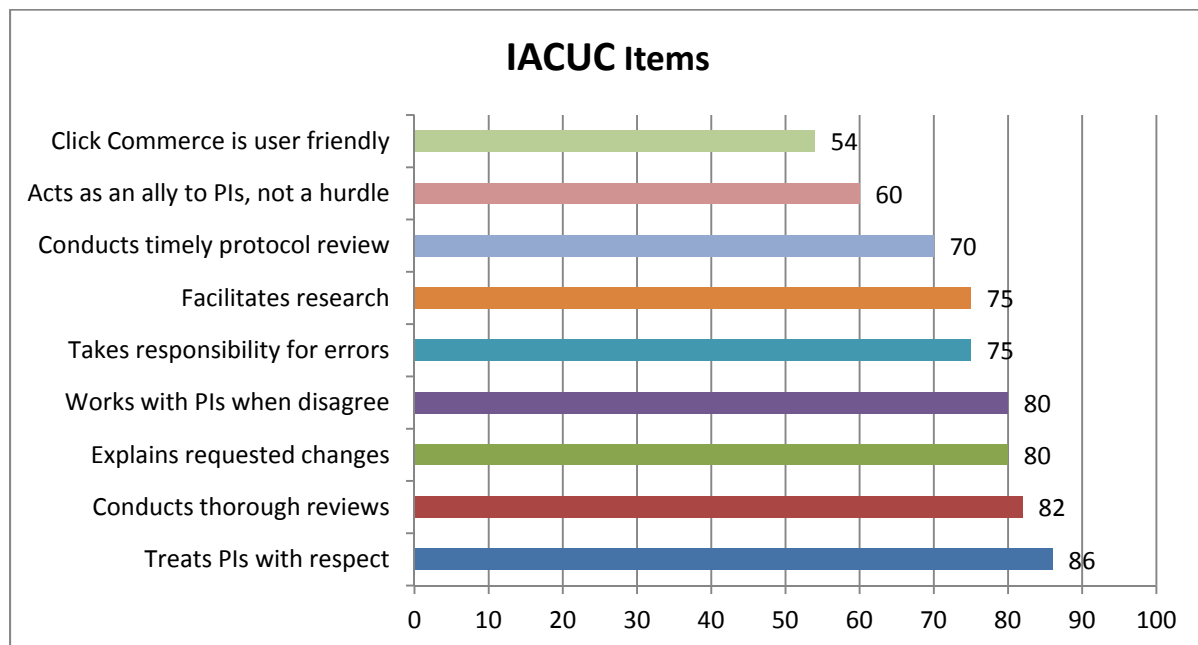
Because the Guide covers a large variety of topics, readers will find the updated bibliography in Appendix A very useful. Appendix B contains the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Teaching, Research and Training, while Appendix C contains the Statement of Task and Appendix D contains author information.

We hope you will find the new Guide useful as it forms the foundation for the VCU Animal Care and Use Program. If you have questions regarding the new Guide, do not hesitate to contact the IACUC coordinators via email (IACUC@vcu.edu), who will direct your questions or comments to the appropriate ACUP personnel for a response.

The new Guide can be downloaded in pdf format at no charge from the OLAW website (http://www.grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf) or can be read online for free and purchased in paperback format at the National Academies of Sciences Press website (http://www.nap.edu/catalog.php?record_id=12910).
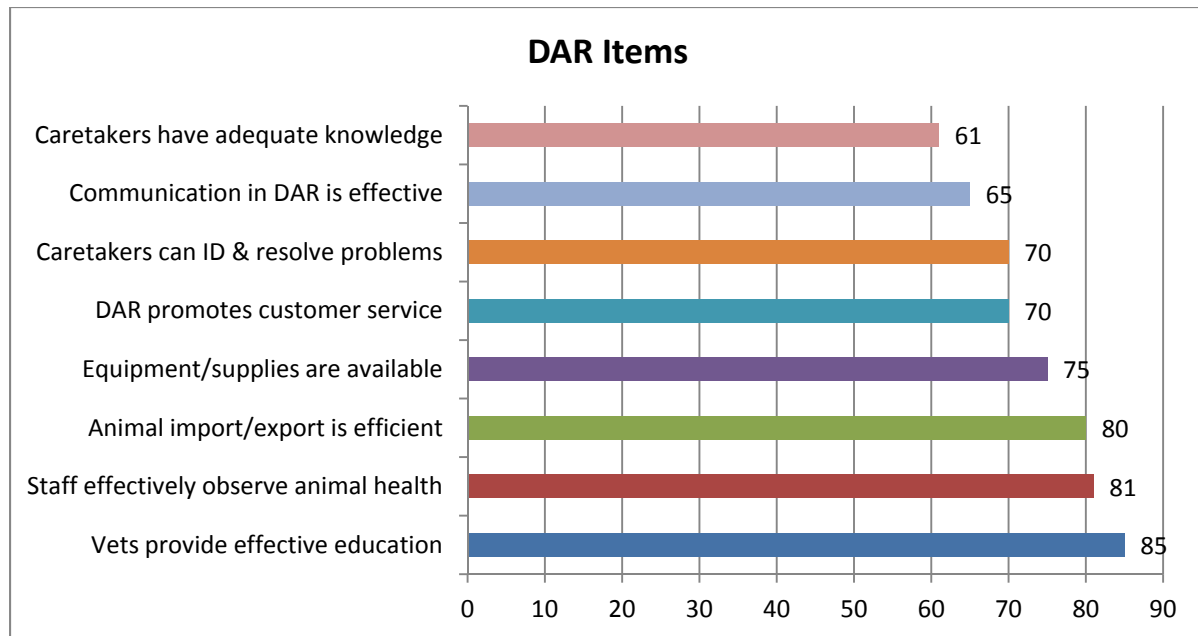
2011 Animal Care & Use Program Survey Results

During the Fall 2011 semester, the Office of Research conducted a survey of VCU animal researchers to collect feedback about the Animal Care and Use Program (ACUP). Invitations to complete the survey were sent to 829 animal users who are named on active IACUC protocols. A total of 91 responses were submitted in the REDCap survey program, resulting in an 11% response rate.   Researchers were asked to rank 24 questions on a scale of 0-100. Mean responses to the 24 questions are represented below.

IACUC Items

Item	Value
Click Commerce is user friendly	54
Acts as an ally to PIs, not a hurdle	60
Conducts timely protocol review	70
Facilitates research	75
Takes responsibility for errors	75
Works with PIs when disagree	80
Explains requested changes	80
Conducts thorough reviews	82
Treats PIs with respect	86

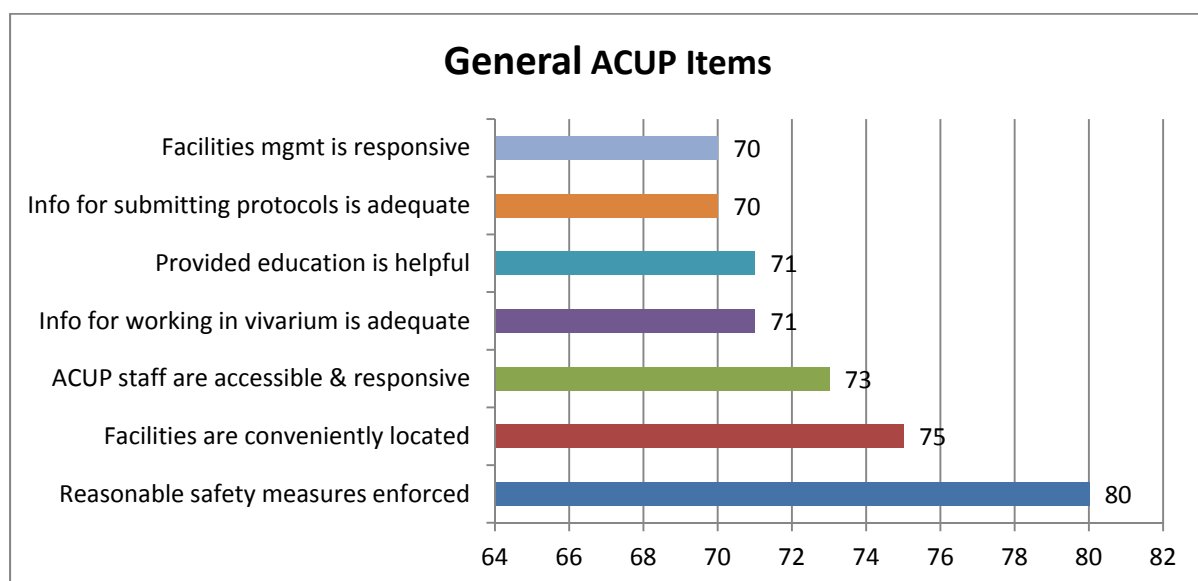Prominent themes identified in the written comments for each IACUC-related question include:

- IACUC reviews and interactions with reviewers are inconsistent.
- The IACUC focuses too intently on regulations to the point of hampering research efforts.
- Educational programs are adequately available.
- SOPs and guidance documents are difficult to find and often confusing.
- The transition to Click Commerce has been difficult.

DAR Items

Item	Value
Caretakers have adequate knowledge	61
Communication in DAR is effective	65
Caretakers can ID & resolve problems	70
DAR promotes customer service	70
Equipment/supplies are available	75
Animal import/export is efficient	80
Staff effectively observe animal health	81
Vets provide effective education	85

Prominent themes identified in the written comments for each DAR-related question include:

- There has been noticeable improvement in the animal care provided by animal caretakers.
- The veterinarians are helpful and responsive.
- Caretakers should pay closer attention to the information noted on cage cards.
- The animal importation process has improved significantly and is efficient.
- Communication within DAR is often lacking.
- Animal caretakers do a good job of observing animal health.
- DAR is generally responsive to requests for help or complaints.
- Communications within DAR and between DAR/investigators is inadequate, but improvement is being noted.

General ACUP Items

Item	Value
Facilities mgmt is responsive	70
Info for submitting protocols is adequate	70
Provided education is helpful	71
Info for working in vivarium is adequate	71
ACUP staff are accessible & responsive	73
Facilities are conveniently located	75
Reasonable safety measures enforced	80

While numerous initiatives are underway in the various ACUP components in response to the survey results, the need to collect more frequent feedback has been determined to be particularly important. As a result, the ACUP will be establishing more frequent opportunities to communicate feedback directly to the ACUP administration. One such mechanism will be to hold town-hall style meetings throughout the year, providing a venue for animal researchers to provide comments and ask questions. Look for exact dates and locations to be announced soon.

Institutional Review Board (IRB)

IRB Principal Investigator Eligibility Process Updated

IRB Written Policy and Procedure (WPP) IX-1: Principal Investigator Requirements has recently been revised to provide additional instruction regarding eligibility to serve as a PI on human research studies. This policy is particularly relevant to VCU affiliate and adjunct faculty. The WPP is available on the IRB website at: http://www.research.vcu.edu/irb/wpp/flash/IX-1.htm. To make the process of determining eligibility simpler, a PI Eligibility form is now available for submission to the IRB. The form is located on the VCU IRB forms page at: http://www.research.vcu.edu/forms/vcuirb.htm.

IRB Electronic Submission and Review System in Development

The Office of Research Information Technology (ORIT) and the Office of Research Subjects Protection (ORSP) are actively collaborating on the development of an electronic submission and review system for human participant research studies. The system under development is called Click Commerce, which is already in use by the animal research community at VCU.

The system will provide a more efficient mechanism for submitting studies to the IRB, as well as for carrying out the review and approval process. Significant benefits to the system include:

- Submission applications that, based on user responses, customize to the type of study being submitted.
- A self-contained environment for capturing communications between the IRB and investigators.
- Ability to easily view the status of submissions in real time.
- A convenient system for maintaining all official correspondence from the IRB.
- A resource for maintaining current study documents and tracking document versions.
- Elimination of paper submissions.

Development of the IRB system began in early 2010 with the creation of a question set for the initial review submission form. These questions have since been vetted by an oversight committee comprised of investigators and coordinators, as well as by additional volunteer investigators. Development, interspersed with extensive testing periods, will continue through the remainder of 2012. ORIT anticipates initial implementation with segments of the user community to begin during the 1st quarter of 2013.

IRB Seeks Volunteers for Electronic Submission System Testing

The Click Commerce electronic submission system is nearing the first and most important testing period of the development process. This testing period will focus on the initial review submission application. The primary emphasis for this testing is to ensure that the question set is as clear as possible to researchers and that the branching of questions works effectively. Additionally, the workflow of moving a submission through the review and approval process will be tested.

The IRB is looking for investigator and coordinator volunteers who would like to participate in a testing session. It will involve entering information into an initial submission application based on a real research study; although, it is important to be aware that the data entered will not impact current studies and cannot be saved. The testing period is scheduled for the week of March 12. If you are interested in participating in one of these testing sessions and want to get a first glance at the new electronic IRB submission process, please complete the survey at https://redcap.vcu.edu/rc/surveys/?s=V2cBJX . Further details regarding the testing sessions will be provided to all interested individuals at the end of February. If you have any questions, please contact Michelle Stickler (mcstickler@vcu.edu).

TRAINING OPPORTUNITIES

Required Investigator and Administrator Training

The Office of Sponsored Programs and Office of Grants and Contracts Accounting will soon be launching its required training for Investigators and Administrators for Managing a Project and Effort Certification in Blackboard. Specific details, including access information, will be sent out from the Vice Presidents soon.

Click Commerce Training/Help Session

A Click Commerce protocol submission help session is scheduled for Friday, February 13 at 2:00pm in Sanger Hall B1-020. This is a working session where users can enter protocol information in real time. The instructor will be available to answer questions and provide guidance as needed. A brief overview of the Click Commerce functionality and navigation will be provided. Register for the session here: http://training.vcu.edu/course_detail.asp?ID=9621 .

Workshop for Building Fellowship Applications

The Office of Research uses VCUeRA (VCU electronic Research Administration) for the electronic submission of proposals to NIH utilizing Grants.Gov. This class will focus on building fellowship applications (NIH F Mechanism) and is geared towards helping pre- and post-doctoral students who may be working towards creating and completing their applications in the system.
To register:
March 5 class http://training.vcu.edu/course_detail.asp?ID=9704
March 12 class http://training.vcu.edu/course_detail.asp?ID=9705