



## The Federal Academic Research Partnership

In the aftermath of WWII, national leaders recognized an opportunity for basic and applied research to aid in war efforts. With motivation to establish a flow of federal funds to research, the federal government decided to partner with academic research institutions, like UGA. This unique, decentralized and merit-based partnership allows for federal investment in and oversight of research activities. Research institutions do accept primary responsibility to enable, administer, and oversee faculty conduct of research. Each partner, however, is expected to fulfill its roles and obligations with honesty, integrity and with the public good always in mind. The success of this partnership has led to a system of education, mentorship, and discovery in America that is renowned internationally.

As the US continues to lead the world in science, technology, and social & behavioral sciences, tremendous value is derived from partnering with the federal government. In fact, US universities where research is pursued with federal funding have been the home institutions of more Nobel Prize winners than any other country. A prime example of the partnership's success is that of the federally supported research in fiber optics and lasers which helped to create the telecommunications and information technology networks that now account for one-seventh of the US economy. Similarly, life-saving diagnostic medical technologies such as CT, MRI, and ultrasonography have evolved through federally supported animal use.

While the continued benefits are pervasive and remarkable, the federal-academic research partnership is under stress. Continuous expansion of the federal regulatory system and its ever growing requirements has led to a highly complex and burdensome regulatory environment surrounding research. For context, from the 1990s to the 2000s the number of new or substantially changed regulations promulgated by the federal government per year that directly affected the conduct of research under federal grants or contracts more than tripled.



## A Partnership Under Stress

It is important to recognize that federal regulations, policies, and guidance are created with the good intention of devoting attention to objectivity, accountability and performance in research. When effective and well-coordinated, these regulations serve an important role in protecting the government, universities, investigators and the public, as well as helping to prevent fraud, waste and abuse. However, the proliferation of these regulations and guidance often has unintended consequences which encumber the nation's investment in research.

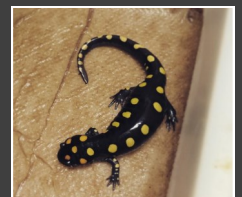


The cost associated with compliance is referred to as regulatory burden. As the regulatory system expands, regulatory burden increases. This results in a diversion of investigator time and expertise to compliance efforts rather than research and training. Similarly, with an influx of new or revised regulation, stress is put on institutions to create effective policies and guidelines which facilitate federal compliance. Regulatory burden can also be associated with a potential decline in interest of future researchers, who may be wary of the complex regulatory environment and choose to pursue other careers. This opportunity cost, the cost of diverting investigator time and expertise as well as the cost of administrative personnel all undercut research productivity. With lost productivity and reduced interest in research, the effectiveness of federal funding is diminished.

## Announcements

The following Policies/Guidelines are new or have been updated:

- [Housing Locations Policy](#)
- [Transport Policy](#)
- [Guillotine Guidelines](#)



A brief survey is now being sent with inspection reports. We hope you'll consider providing feedback about the inspection process.

## On the Horizon: Regulatory Reform

The complexity of the current regulatory environment around research is the cumulative effect of overlapping and incongruent federal regulations, contradictions in processes, and redundancy in reporting. This ubiquitous issue was addressed by the federal government in December 2016 with the passing of the 21<sup>st</sup> Century Cures Act.



The Cures Act was intended to expedite the processes for medical product development such that advances and innovations could be brought to patients and the market more quickly and efficiently. Recognizing the impact of regulatory burden on productivity, the reduction of administrative burden for researchers was also mandated in the Cures Act. Federal oversight entities, namely the NIH, the USDA, and the FDA were directed to conduct, over a 2 year period, a comprehensive review of applicable regulations and policies to identify inconsistencies, overlap, and unnecessary duplication. It was recommended that the federal entities tasked with this review seek input of experts as appropriate.

Experts such as the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the Council on Governmental Relations (COGR), with the assistance of the National Association of for Biomedical Research (NABR) convened a workshop in April 2017 to identify animal care and use requirements which demand significant administrative burden but do not enhance welfare. From this meeting a report to the federal government was generated which provided specific and actionable recommendations for regulatory reform. The full report can be found [here](#).

Some notable recommendations in this report include:

- Amend the Animal Welfare Act to require only one IACUC inspection annually
- Amend the Animal Welfare Act to remove requirement for annual USDA inspection, instead base frequency of inspections on compliance history
- Executive Office of the President and the Office of Management and Budget should consider 60 day comment period on merit and impact of new policies, documents, and FAQs before they are issued. Final documents should include material changes germane to comments.
- NIH should streamline the assurance process, and allow accreditation in place of Program Description for Category 1 institutions.
- Revise USDA Animal Care Policy #14 such that multiple survival surgeries on USDA covered species can be approved by the IACUC with justification
- NIH should eliminate the requirement of protocol and grant congruency from NIH Grants Policy 4.1.1.

## UGA's Commitment to Research

In an effort to reduce administrative burden on investigators, UGA:

- Requires USDA literature search only for USDA covered species
- Enables the VVC and Administrative Amendment processes for certain protocol changes, See [Policy for Changes to an Approved Protocol](#)
- Reduces inspection frequency of inactive sites
- Allows an acclimation period of 3 days for rodents involved in certain studies, See [Acclimation Guidelines](#)

If you would like to get in touch with Animal Care & Use about institutional policies or guidelines that you think could be revised to better facilitate research at UGA, please email us at [iacuc@uga.edu](mailto:iacuc@uga.edu).

If you have ideas about federal regulations, guidance documents or any other policy documents which you think are in need of reform, please consider submitting comments electronically to the USDA's notice in the Federal Register [here](#).

## Inspections Update

- 6/13 Central GA Experiment Station
- 6/15 ADS Equine
- 7/10 Meat Science Technology Center
- 7/10 Veterinary Teaching Hospital
- 7/11 PI Wildlife Lab
- 7/26 Teaching Dairy
- Upcoming in August: Poultry Genetics Farm, Herpetology Labs, South Georgia Circuit



**Current inspection trends** have identified Recordkeeping and Labeling deficiencies as the most commonly cited so far in 2018. Incomplete medical or surgical records are often cited as Recordkeeping deficiencies. Please see the [Anesthesia](#), [Survival Surgery Policy](#) and the [Health Records Policy](#) for guidance as to what is required in a complete medical record. Secondary container labeling is the most often cited Labeling deficiency. Please see the [Labeling Guidelines](#) for information about secondary container labeling.