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To: Emory University Animal Users

Re: IACUC protocol reviews, CITI training, and post-approval compliance monitoring

Dear Emory Animal Users:

I am writing to bring to your attention several issues that appear to be causing a number of you varying levels of frustration with your IACUC protocols – particularly with respect to obtaining timely renewals of your active protocols. If you are like me, you frequently leave submitting your 3 year IACUC renewal or new application to the last minute. This unfortunately is increasingly problematic for several reasons - which are outlined below.

(1) Protocol extensions. It is critical to emphasize that federal guidelines do NOT allow the IACUC office to grant any extensions – once a protocol has expired, all work must cease until the renewal is approved. Please do not call the IACUC office seeking such extensions or asking that the review of your protocol be expedited – it simply isn't possible to honor these requests.

(2) Time from submission to approval. It should be noted that very few IACUC protocols are approved as is – the vast majority of protocols are sent back to the PI to address various issues (often very minor). This means that if you do not want your protocol to lapse, you must allow sufficient time for review of a revised application (not very different from what most of us are experiencing with our NIH grants).

(3) CITI training. As animal care and research methods change over time, updated training is necessary to stay abreast of current methods. Thus, starting in January, 2008 Emory has changed from the LATA training to the more current and comprehensive CITI training. Please note that all animal users must complete the relevant CITI modules before their IACUC protocol can be approved (new or renewal). Please also note that the CITI modules are more detailed and take more time to complete than the LATA modules. You will find that not all aspects of the modules are directly relevant to the type of animal research that you are doing (for example, the Working with the IACUC module) – however, this doesn't exempt you (and your lab members working with animals) from having to complete these modules. It is impossible for the IACUC to tailor the training to each lab's research program. In addition, because many individuals during their time at Emory move between different labs at Emory, the general animal training required ensures that all individuals have been broadly trained. Please note that general training in animal usage/care is mandated by federal guidelines and is closely monitored by AAALAC (the international group that accredits our animal use program) during their review of our animal program. I encourage all of you (and your lab members) to update your training as soon as possible to avoid having to do this at the last minute. I would also ask you to please refrain from making phone calls to the IACUC office complaining about the CITI training – the office staff did not institute these policies and has no authority to give you a reprieve. As always, constructive criticism is welcome – please do this in the form of a

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letter or email addressed to either me and/or David Knight, Director of the IACUC office. Instructions regarding CITI training are available on the Emory IACUC web site (<http://www.emory.edu/IACUC/>).

(4) Biosafety, chemical & radiation safety approvals. If your animal research involves the use of potentially hazardous compounds, radioactivity, drugs, infectious agents, or cell lines, you must get approval from the Environmental Health and Safety Office. IACUC protocols cannot be approved before we receive notification of appropriate EHS approval. Again, I encourage you to factor in sufficient time to get your biosafety/chemical/radiation safety protocols submitted and approved.

(5) Occupational Health & Safety. We are required by Public Health Service Policy (implemented through the National Institutes of Health Office of Laboratory Animal Welfare), to institute a health risk assessment (Occupational Health & Safety) for all animal users. We have instituted improvements to our current processes that were necessary to ensure continued compliance, and all animal users must comply with these processes. Please see the Emory IACUC web page for details (<http://www.emory.edu/IACUC/>).

**POST-APPROVAL MONITORING OF IACUC PROTOCOLS.** PHS Policy and Animal Welfare Act regulations charge the IACUC with continuing review of animal research to ensure that it is being conducted in accordance with all applicable regulations and with the requirements of IACUC-approved protocols. In order to carry out these obligations, the IACUC has instituted a process for monitoring approved protocols to ensure that animal users are adhering to approved procedures. Ms. Casey Brinsfield in the IACUC office has been hired to oversee protocol compliance. I want to emphasize that it is imperative that all animal users cooperate with Ms. Brinsfield – indeed, this is a condition of your IACUC protocol approval. One important way in which we can all ensure that this system works well is to make sure that all individuals working with animals in your lab have read your IACUC protocols and are familiar with the approved procedures. As such, I would encourage all investigators to print out their IACUC protocols and put them in a notebook that you make available to all your lab members. The most common problems that Casey encounters are: (i) individuals who have not read the protocol and thus are not familiar with the procedures that have been approved (e.g., giving post-operative analgesics); and (ii) changes in the procedures being used that have not been submitted to IACUC for approval (via a modification). Both are unacceptable and represent protocol violations.

In closing, I want to acknowledge the outstanding effort put forth by David Knight and the IACUC office, Mike Huerkamp and the Emory DAR, and Jim Else and the Yerkes DAR, to keep Emory University in good standing with federal regulatory agencies. The bar continues to be raised with respect to what is expected from us by these agencies (AAALAC, OLAW and USDA) – as evidenced by the issues discussed above. The upside is that we have exceptionally well run animal facilities - which, in the end, I would argue benefits all our animal research.

Sincerely,



Samuel H. Speck,  
Chair, Emory IACUC