Dr. Collins, Mr. Levinson,

I am contacting you today regarding an incident of serious non-compliance with the NIHGPS at Harvard Medical School, a substantial recipient of NIH grants.

As you know, the National Institutes of Health Grants Policy Statement says:

“Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.

2. The conduct of animal activities in the absence of a valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

. . . In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges.”

In a USDA inspection report for Harvard Medical School dated 7/19/11 (attached), the facility is cited for a violation of section:

“2.31 Institutional Animal Care and Use Committee (IACUC) (c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities:
“At the end of June 2011, it was discovered during the research facility’s post-approval monitoring program (PAM) that there has been more than one instance when procedures were performed on study animals that were not described in the IACUC approved proposal for animal use.”

It is clear that the staff of Harvard Medical School were in violation not only of the Animal Welfare Act for performing unapproved and therefore illegal surgical procedures on animals, but that this has happened repeatedly at the Harvard Medical School.

Therefore, since multiple unapproved surgical procedures have been performed by Harvard Medical School staff, this facility (Harvard Medical School) was/is in violation of the above quoted section of the NIHGPS as listed above, and the NIHGPS also states that:

“In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges.”

Therefore, I must insist that the National Institutes of Health, in conjunction with the Office of the Inspector General, immediately launch an investigation of all primate projects that involve surgical procedures at the New England Primate Research Center to discern an overall quantity of unapproved surgical procedures, and that following this determination, a refunding of relevant grant amounts be required of Harvard Medical School.

I am sure that the National Institutes of Health and the Office of the Inspector General are both very concerned with insuring that grantees follow all parts of the NIHGPS and that insuring that serious offenders be required to return illegally used NIH funding.

I hereby request a copy of all documents regarding this investigation under the federal Freedom of Information Act, 5 U.S.C. sec. 552. at the completion of this process.

Sincerely,

Michael A. Budkie, A.H.T.,
Executive Director, SAEN