March 16, 2009

Mabel Echols
Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budge
Room 10102, New Executive Office Building
725 17th Street, NW
Washington DC 20503

BY ELECTRONIC MAIL TO**:** oira submission@omb.eop.gov

Re: Executive Order on Federal Regulatory Review

Dear Ms. Echols:

I am pleased to have the opportunity to comment on ways to improve the process and principles governing Federal regulation. My name is Joseph R. Haywood, and I am a faculty scientist at Michigan State University. I am also an Assistant Vice President for Regulatory Affairs at the University; however, this letter represents my personal views. Like many in the scientific community, I strongly believe in the value of the oversight of research to ensure the public trust. I also share with my fellow scientists the highest standards for the safe and responsible conduct of research. In this letter, I would like to reiterate comments made by FASEB and expand on their suggestions.

With this in mind, I am also cognizant of the amount of time and energy that is devoted to the administrative process. In a 2007 survey conducted by the Federal Demonstration Partnership (FDP), scientists estimated that 42% of the time they spend on federally funded research was devoted to administrative and regulatory activities. Based on these data, the FDP estimated that federal agencies and institutions spend $85 million on administrative tasks directly linked to those projects. While there is no doubt about the importance of regulatory oversight, we must find a balance between protecting research subjects and the public investment against scientific productivity.

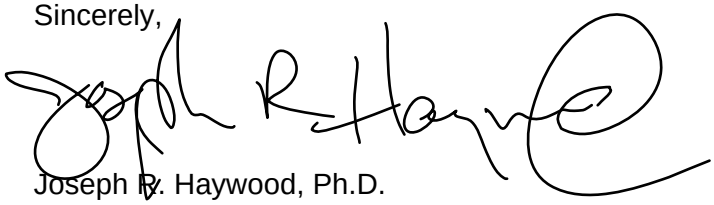
In developing its recommendations for a new Executive Order on Federal regulatory review, OMB should make every effort to ensure accountability and transparency in research while minimizing the administrative burden that regulations place on the scientific community. I would suggest the follow principles to consider:

1. OMB should review any proposed regulations to determine whether additional burdens and costs are balanced by meaningful improvements to the current oversight system.
2. Where new regulations are necessary, they should, when possible, be based on sound science. They should also be harmonized with existing regulations across agencies in order to avoid unnecessary duplication, confusing inconsistencies, and conflicting requirements which may have a negative impact on the research process.
3. OMB should solicit input from the scientific community when making regulatory decisions related to science. By including researchers, research institutions, and funding agencies in regulatory decision making, OMB can foster an environment of mutual cooperation that will serve both the progress of science and the public good.

4. Paperwork should be reduced as much as possible by using common forms for common outcomes. This will enhance compliance and save institutions within and outside government time and money.
5. A “sunset” review of regulations should be conducted on a periodic basis to ensure that the regulation is meeting its purpose and unintended consequences of the regulation do not impede science without benefiting research subjects or the public good.

Again, I would like to thank you for considering these comments. I would sincerely welcome the opportunity to engage in further discussion with OMB on this important topic.

Sincerely,



Joseph R. Haywood, Ph.D.