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Brian Harrison
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U.S. Department of Health and Human Services
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Washington DC, 202021

Submitted electronically via e-mail: DuplicativeRegulations@hhs.gov

RE: Comments in Response to FR Doc. 2020-26022, "Request for Information on Redundant, Overlapping, or Inconsistent Regulations"

Dear Mr. Harrison,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Immediate Office of the Secretary's (IOS) Request for Information (RFI) seeking input on duplicative or inconsistent regulations from the U.S. Department of Health and Human Services (HHS). As a coalition of 29 scientific societies representing over 130,000 individual scientists, FASEB is committed to streamlining policies to reduce administrative burden while maintaining accountability, integrity, and safety in the research enterprise. FASEB's response draws upon prior statements and comprehensive reports and emphasizes ways to improve inconsistent and redundant HHS policies pertaining to animal research and data sharing.

Animal Research Regulations

In 2013, FASEB developed a survey to gain insight from its society members regarding regulatory issues affecting research productivity. Among the many themes of administrative burden to emerge from the survey responses was the lack of coordination among federal agencies in the development and implementation of regulations, policies, and guidance documents. Survey respondents indicated Laboratory Animal Care and Use/ Institutional Animal Care and Use Committees (IACUC) as one of the top areas of administrative burden. Accordingly, in 2017, FASEB published a collaborative report, *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*, to provide federal agencies actionable recommendations to reduce inefficiencies in animal research while enhancing animal welfare.

Since the report's publication, the agency's efforts to reduce redundancy and inconsistencies in regulations related to animal research have been commendable. For example, the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) encouraged greater use of designated member review for "low risk" protocols in the collaborative agency draft report, *Reducing Administrative Burden for Researchers: Animal Care and Use.* More recently, FASEB provided input on Public Health Service (PHS) Policy requirements that pose significant burden on researchers, including flexibilities for conducting animal facility semiannual inspections and grant to IACUC protocol congruency review.

While laudable, these efforts are only initial steps towards fulfillment of the 21st Century Cures Act. Similar to this RFI, the law mandated resolution of inconsistent or duplicative policies, elimination of overlapping regulations, or implementation of other actions to improve coordination of policies pertaining to laboratory animals. Thus, FASEB strongly encourages HHS to address the remaining inconsistencies related to animal research to both enhance research productivity and support the next generation of researchers pursuing careers in biomedical sciences. For instance, because IACUC protocols require renewal every three years, a frequent challenge investigators face when completing congruency review, as outlined in NIH Grants Policy 4.1.1.2, is accounting for research conducted after this period, including years four and five of a five-year R01 grant. While we recognize these policies are intended to ensure maintenance of animal welfare standards, existing mechanisms such as post-approval monitoring and semiannual inspections are already in place for this purpose, rendering congruency review duplicative and time consuming for investigators. This could be resolved by aligning IACUC approval with the grant length. Should investigators secure multiple grants of variable length, we suggest aligning IACUC protocol approvals with that of the lengthier grant.

Several policies for animal research are inconsistent with HHS regulations for human subjects research. Apart from its redundancy with existing animal welfare policies, grant-to-protocol congruency review emphasizes the comparison of two documents written at separate times, potentially up to nine months apart. This format prohibits researchers from integrating scientific developments that occur in the interim. More importantly, congruency review for animal studies is contradictory to the revised Common Rule, which states, *"…experience suggests review and approval of the grant application is not a productive use of IRB time."* Therefore, FASEB recommends a comparable modification for congruency review to provide investigators the flexibility to integrate advancements in research objectives.

Finally, per NIH Grants Policy section 8.1.2.5, prior approval is required for investigators seeking a change in research scope involving live vertebrate animals. However, this is inconsistent with corresponding policies for human subjects research, which specify the need for prior approval only when a change in scope results in an increased risk for participants. To decrease the level of administrative burden for both investigators and institutional IACUCs and ensure parity between these areas of research, FASEB recommends NIH similarly amend its policy to require prior approval for change in research scope only when increased risk to animals would result.

Data Management and Sharing

Research efficiency is also decreased by inconsistent policies pertaining to data management. FASEB's 2016 Statement on Data Management and Access affirmed the importance of data management and access to scientific progress and noted that good data practices are necessary to achieve the maximal benefit of research for all stakeholders. However, the diversity of data types, research areas, and available resources make it challenging to identify data management and accessibility strategies that are practical

and relevant for all life science fields.

Earlier this year FASEB organized a Science Policy Symposium focused on data management and sharing to identify remaining barriers and policy gaps that hinder data sharing as well as opportunities for which FASEB is uniquely positioned to lead development of possible resolutions. A key theme that emerged from this discussion was the lack of consistency in data management policies across different government institutions and agencies. Even among the individual NIH Institutes and Centers, inconsistent data submission requirements and supplementary information exist, greatly increasing the administrative burden for grant applicants and recipients, especially for researchers with multiple grants.

Recognizing that policy harmonization across the various government agencies is beyond the scope of this RFI, FASEB encourages HHS to continue engaging diverse stakeholders throughout the development and implementation of new data management policies to ensure these policies are consistent both within HHS agencies and across the federal government. We also encourage HHS to address the resources and measures needed to promote productive data sharing, such as development of a single unified portal system to enhance data discoverability and provision of long-term data storage options.

By implementing policies that would provide researchers with sufficient support to ensure compliance with all applicable data management and access requirements *as part of a project's funding*, HHS has the opportunity to serve as a leader in these conversations. Support consists of skilled human labor and training necessary to prepare and maintain data and metadata, technological infrastructure, and continued development of effective search platforms. Similarly, datasets frequently have little value for reuse (e.g., a short "shelf-life") after designated funding periods. To mitigate inefficiencies in resource distribution, FASEB recommends HHS ensure data access policies prioritize preservation of data with the potential for reuse and consistent with FAIR (Findable, Accessible, Interoperable, and Re-usable) data principles.

Redundancies and inconsistencies in policies and regulations lead to unnecessary increases in administrative burdens for the research community. Many respondents to FASEB's 2013 survey expressed a general concern regarding the amount of paperwork and regulatory oversight required to conduct laboratory research, with one PI commenting that they no longer felt confident recommending medical research as a rewarding career path for incoming scientists due to the increasing level of bureaucracy. Thus, FASEB appreciates the opportunity to provide feedback on this important topic and looks forward to additional streamlining and refinement of HHS policies and regulations.

Sincerely,

Louis B. Justement
FASEB President

Attachment: Links to FASEB Statements and Resources on Administrative Burden

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Administrative Burden

FASEB 2013 Survey on Administrative Burden: Link

FASEB RFI Response on Reducing Investigator's Administrative Workload for Federally Funded Research: Link

Animal Research

Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden: Link

FASEB RFI Response on Flexibilities for Conducting Semiannual Animal Facility Inspections: Link

FASEB RFI Response on Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency: Link

Data Management

FASEB Statement on Data Management and Access: Link