COGR
Advancing Effective Research Policy

July 14, 2025

Submitted Electronically: https://www.regulations.gov
Department of Health and Human Services
Attention: Jennifer Burnszynski, Office of the Assist. Sec. for Planning & Evaluation

RE: Request for Information: "Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again" (Docket No. AHRQ-2025-0001)

Dear Ms. Burnszynski:

We write to offer comments in response to Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Health Again published in the Federal Register on May 14, 2025. [90 F.R. 20478].

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 230 research universities and affiliated academic medical centers and research institutes. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

Addressing excessive, duplicative, and outdated federal research regulations and requirements is essential to improving the ability of researchers and their institutions to productively perform research on behalf of the federal government. Accordingly, we support the Department of Health and Human Services' (DHHS) efforts to gather public input on regulatory obligations ripe for streamlining and/or repeal via publication in the Federal Register. In implementing the recommendations received, DHHS should similarly follow the notice and comment rulemaking process established by the Administrative Procedures Act[1] to ensure robust stakeholder input on final regulatory action and timelines.

Finally, we also urge DHHS to ensure regulatory consistency and harmonization both within DHHS and across other federal agencies that issue regulations covering similar areas/activities. In this respect, we note our response to the Office of Management and Budget's (OMB) April 2025 *Request for Information: Deregulation* [90 F.R. 15481], which contains recommendations for changes DHHS could implement to achieve better inter-agency regulatory consistency and promote common administrative processes and forms to reduce regulatory and administrative burden.[2]

[1] 5 U.S.C. §551, *et. seq.*
[2] COGR, Response to Request for Information: Deregulation (May 7, 2025) at

The remainder of this letter sets forth our comments on specific regulations/policies. For each item, we list the DHHS agency(ies) involved, the regulations/policies at issue, the category of concern as listed RFI preamble,[3] a discussion of the reasons modification and/or repeal is necessary, and recommendations.

Item 1:

Agencies: Federal Drug Administration (FDA) and DHHS, Office of Human Research Protections (OHRP)

Regulations/Policies: 21 C.F.R. Parts 50 and 56; 45 C.F.R. Part 46 ("Common Rule") -- regulations governing protections for human subjects and institutional review boards (IRBs).

Categories of Concern: Regulations that impose significant costs upon private parties that are not outweighed by public benefits because they are applied in a duplicative manner.

Discussion: Currently, clinical research that receives DHHS funding and an FDA-regulated product is subject to both the FDA and DHHS regulations for the protection of human subjects in research and IRBs. Over the past several years, FDA has been working to harmonize its regulations with the Common Rule, and thus the FDA and DHHS regulations are largely aligned. Accordingly, dual regulation by both agencies imposes unnecessary regulatory burdens on researchers and research institutions and wastes institutional resources on duplicative processes without conferring any additional benefit to the public.

Recommendations: COGR urges DHHS to: (a) facilitate complete harmonization between DHHS and FDA human subjects research regulations; (b) establish FDA as the sole federal agency regulating human subject research concerns for clinical research subject to FDA jurisdiction; and (c) designate the Office for Human Research Protections (OHRP) as the sole federal agency regulating human subjects research that does not involve FDA-regulated products.

Item 2:

Agency: National Institutes of Health (NIH)

Regulations/Policies: ClinicalTrials.gov – NIH Grants Policy Statement (GPS) §4.1.3, and 42 C.F.R. Part 11, Clinical Trials Registration and Results Information Submission -- regulations/policies regarding registration of clinical trials in ClinicalTrials.gov.

Categories of Concern: Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition.

https://www.cogr.edu/sites/default/files/COGR%20Response_Deregulation%20RFI-_0.pdf.

[3] 90 F.R. at 20479.

Discussion: ClinicalTrials.gov is a databank of clinical trials that was established pursuant to the Congressional directives set forth in Section 801 of the Food and Drug Administration Amendments Act of 2007[4] as codified at 42 U.S.C. §282(i)-(j) ("Sec. 801"). Sec. 801 sets forth specific definitions for the types of clinical trials that must be registered in ClinicalTrials.gov. Despite this clear legislative direction, Section 4.1.3.1 of the NIH Grants Policy Statement (GPS) vastly expands the type of clinical trials that must be entered into ClinicalTrials.gov far beyond the statutory mandate. Specifically, Sec. 801 requires registration only for "applicable clinical trials" as they are narrowly defined at 42 U.S.C. §282(j)(1)(A). However, the NIH GPS requires registration of all "NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation" [i.e., the regulation at 42 CFR Part 11 implementing Sec. 801], thus exceeding the statutory authority underlying the ClinicalTrials.gov website.

Recommendations: NIH should conform the registration requirements under GPS §4.1.3 to the language of Sec. 801 so as not to expand the ClinicalTrials.gov registration requirement beyond what was contemplated under the authorizing statute.

Item 3:

Agency: Office of Laboratory Animal Welfare (OLAW)

Regulations/Policies: Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (rev. 2015) ("PHS Policy") and U.S. Dept. of Agriculture (USDA) Animal Welfare Act (AWA) Regulations at 9 C.F.R. Chapt. 1 – regulations governing animal research.

Categories of Concern: Regulations that impose significant costs upon private parties that are not outweighed by public benefits because the regulations are duplicative and inconsistent.

Discussion: DHHS funded research on animal species that fall within the scope of the AWA ("Act Species") are subject to regulation under both PHS Policy and the AWA. The PHS Policy and AWA regulations are overlapping, duplicative, and in some cases inconsistent, and require institutions to establish multiple administrative and reporting processes.

Recommendations: Both the PHS Policy and the AWA and its implementing regulations contain very similar robust protections for the health, safety, and welfare of animals used in research. Subjecting research to regulation under both the AWA and PHS Policy adds unnecessary regulatory burden and forces spending on duplicative compliance processes without affording additional protections for lab animals. Accordingly, we urge DHHS to defer to USDA as the sole regulator for research using Act Species and limit the scope of the PHS Policy to animal research on non-Act Species.

[4] Pub. L. 110-85, 121 Stat. 823 (Sept. 27, 2007).

Item 4:

Agency: Office of Laboratory Welfare (OLAW)

Regulations/Policies: PHS Policy and OLAW's Frequently Asked Questions (FAQs) on the PHS Policy ("OLAW FAQs") – policies governing animal research.

Categories of Concern: Regulations/policies that are based on anything other than the best reading of the underlying statutory authority or prohibition.

Discussion: Section IV.A.1 of the PHS Policy "requires institutions to use the Guide for the Care and Use of Laboratory Animals (Guide)[5] as a basis for developing and implementing an institutional program for activities involving animals." However, the language of the Guide makes clear that it was never meant to serve as a regulation but rather is "***intended to provide information to assist*** researchers, institutional animal care and use committees (IACUCS), veterinarians, and other stakeholders in ensuring the proper implementation of effective and appropriate animal care and use programs that are based on humane care.[6] [***Emphasis added***]. Accordingly, incorporating the Guide into the PHS Policy by reference exceeds the Guide's stated purpose.

Recommendations: DHHS should revise the PHS Policy to make clear that the Guide is not a set of regulatory requirements that are incorporated by reference into the PHS Policy, but rather an informational resource meant to assist persons and entities involved in implementing and overseeing research animal care and use programs.

Item 5:

Agency: OLAW

Regulations/Policies: Guide; PHS Policy Sections IV.B.3.c; OLAW FAQ C.7; and NOT-OD-05-034, Guidant or Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals – policies regarding reporting departures from the Guide.

Categories of Concern: Regulations/policies that are based on anything other than the best reading of the underlying statutory authority or prohibition.

Discussion: The Guide's recommendations statements fall into one of the following three categories:

- **Must Statements** – "Imperative and mandatory duty or requirement for providing humane animal care and use."

[5] National Research Council, 8th ed. (2011) at https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf.
[6] *Id.* at . p. 2-3.

- **Should Statements** – "Strong recommendation for achieving a goal," however, "individual circumstances might justify an alternative strategy."
- **May Statements** – "Suggestion to be considered."[7]

OLAW FAQ C.7. considers IACUC -approved departures from "should statements" in the Guide to be a departure from the Guide that must be reported in the semiannual report to the institutional official. This reading goes beyond the Guide's requirements, which define "should statements" as recommendations. The Guide clearly recognizes that there is no "one-size fits all" approach to animal care and use programs. Thus, considering an IAUCUC-approved alternative to a "should statement" to be a "departure" from the Guide is an overly broad and incorrect interpretation of the Guide's requirements.

Recommendations: OLAW should provide a clear definition of the term "departure from the Guide" that excludes IACUC-approved departures from "should statements" in the Guide.

Item 6:

Agency: OLAW

Regulations/Policies: PHS Policy Section IV.A. – requirement for filing an Animal Welfare Assurance ("Assurance") with OLAW.

Categories of Concern: Regulations that impose significant costs upon private parties that are not outweighed by public benefits.

Discussion: The process for filing an Animal Welfare Assurance with OLAW is inefficient and overly burdensome. The process often takes months and is carried out via email between OLAW and the institution. Institutions agree to abide by the PHS Policy and the AWA when they accept DHHS funding for animal research activities. Accordingly, endless back and forth wordsmithing of detailed program descriptions is an inefficient use of both agency and institutional resources. In comparison, the Office for Human Research Protections' (OHRP) Federalwide Assurance Form (FWA) consists of a single page that is completed via a portal.[8] Although they are somewhat more detailed, the USDA required forms for registering a research facility are more condensed, available for filing via a portal, and per USDA, the process takes approximately 30 days to complete.[9]

Recommendations: OLAW should streamline its current Animal Welfare Assurance forms and filing process using the OHRP FWA form and process as a model.

Support for Other Comments: In addition to the items set forth above, we also support the suggestions included in the letter filed by the National Association for Biomedical Research (NABR) in response to this RFI.

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[7] *Id.* at p. 8.
[8] OHRP, Register IRBs and Obtain FWAs at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html (last reviewed Dec. 9, 2021).
[9] U.S.D.A, Animal and Plant Health Inspection Service, Apply for an Animal Welfare License or Registration at https://www.aphis.usda.gov/awa/apply (last modified Mar. 13, 2025).

Conclusion: We appreciate the opportunity to provide these comments. Please contact me or Kristin West, COGR's Director for Research Ethics & Compliance at kwest@cogr.edu.

Sincerely,

Matt Owens
President