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University Groups' Analysis of Public Comments Finds Deep Concerns with Administration's Proposed Changes to Common Rule

Primary Proposal Would Compromise the Development of Tests, Treatments and Cures for Disease

Washington, DC – The Council on Governmental Relations (COGR), with support from the Association of Public and Land-grant Universities (APLU), today released a [comprehensive review and analysis](#) of 2,186 public comments on the Obama administration's 2015 Notice of Proposed Rulemaking (NPRM) for revising the "Federal Policy for the Protection of Human Subjects," better known as the "Common Rule."

In addition to comments that came from the general public, submissions came from patients and members of the research community -- researchers, physicians, universities, medical centers, and industry – as well as associations, advocacy and advisory groups and others. Most focused on the proposals to: change the definition of "human subject" to include biospecimens, such as tissue, blood and urine, from which any personally identifiable information has been removed; require broad, non-specific consent for storage and possible secondary research use of all biospecimens; and restrict institutions' discretion to waive consent for biospecimens that have been stripped of identifying information and where data security plans have been proposed and approved by institutional review boards (IRBs).

The analysis found that over 95 percent of patients and members of the research community were opposed to one or more of the major proposed changes.

"There is broad consensus that the proposed regulations regarding biospecimens, as written, would be damaging to science, medicine and human health and would not improve participant safety and autonomy," COGR, APLU, and the Association of American Universities (AAU) said in a joint statement.

"There is no question that protocols must be in place to safeguard biospecimens and any resulting data. But the administration's primary proposal to make currently unidentified biospecimens, the majority of which will never be used in research, subject to consent is a dramatic shift in policy that would unnecessarily impede much-needed research aimed at unlocking cures and treatments to the most devastating diseases and illnesses.

"The proposal would reduce the number and diversity of biospecimens available for disease research; potentially place significant limitations on research using existing identified biospecimens for which consent

has been obtained; and dramatically increase the cost of conducting research, effectively reducing research funding without providing additional protections for research participants.”

Key findings of the analysis included:

- **Biospecimens:** The majority of responses, approximately 1,520, addressed one or more of the proposed changes involving non-identified biospecimens. Of these responses, 95 percent of patients and members of the research community opposed the changes. Opposition to the proposed changes related to biospecimens ranged from 67% to 79% among health departments, disease registries, professional associations, biorepositories and independent IRBs. Fifty-five percent of the comments from the general public opposed changes to the biospecimen policy despite a popular op-ed in The New York Times that encouraged comments in support of the proposed changes. And, advisory groups, including the Department of Health and Human Services Secretary’s Advisory Committee for Human Research Protections and the Presidential Commission for the Study of Bioethical Issues, opposed the primary proposals.
- **Single IRB:** Only 14 percent of those submitting comments addressed the proposal to mandate use of a single IRB review for research carried out at multiple sites, with a very slight majority (51 percent) opposed to the idea. Universities, which would be required to implement the proposed change, were overwhelmingly opposed, while researchers, their professional societies, industry, and advocacy groups supported it, arguing the change would streamline operations by having only one, rather than multiple, reviews, and reduce delays in research. Those opposed suggested that a single IRB would in many instances increase delays, cost, and administrative work due to the continuing need for biosafety, conflict of interest and other reviews, compliance with state and local laws and the need to modify electronic systems and agreements for each study. Concern was also expressed that a one-size-fits-all prescription was not appropriate for all studies.
- **General Concerns with Rulemaking Process:** Just over 5 percent of all comments suggested that the overall NPRM did not meet necessary standards or requirements, and called for part or all of the NPRM to be withdrawn, rewritten and republished for comment. Some comments argued that the NPRM reflected inadequate consideration of important ethical, practical, and logistical implications. Others argued more flexible alternatives were not considered.

The analysis, including data tables, data summaries by respondent category, and an overview and summary of all findings are available on the [COGR website](#).

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COGR is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

[APLU](#) is a research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities in the U.S., Canada, and Mexico. With a membership of 235 public research universities,

land-grant institutions, state university systems, and affiliated organizations, APLU's agenda is built on the three pillars of increasing degree completion and academic success, advancing scientific research, and expanding engagement. Annually, APLU member campuses enroll 4.7 million undergraduates and 1.2 million graduate students, award 1.2 million degrees, employ 1.4 million faculty and staff, and conduct \$42.7 billion in university-based research.

The [Association of American Universities \(AAU\)](#) is an association of [60 U.S. and two Canadian public and private research universities](#). It focuses on issues such as funding for research, research policy issues, and graduate and undergraduate education. AAU member universities are on the leading edge of innovation, scholarship, and solutions that contribute to the nation's economy, security, and wellbeing. AAU's 60 U.S. universities award nearly one-half of all U.S. doctoral degrees and 55 percent of those in STEM fields.