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Contact: <u>Barry Toiv</u> (AAU): 202-408-7500 <u>Lisa Nichols</u> (COGR): 202-289-6655 <u>Jeff Lieberson</u> (APLU): 202-478-6073

University Groups' Statement on National Academies Report to Optimize Federal Investments in Academic Research

Washington, DC – The Association of American Universities (AAU), the Association of Public and Landgrant Universities (APLU), and the Council on Governmental Relations (COGR) today released the following statement regarding a National Academies of Sciences, Engineering, and Medicine committee report on reforming federal regulation of U.S. research.

"AAU, APLU and COGR welcome the release of Part II of the National Academy of Sciences Committee on Federal Research Regulations and Reporting Requirements report, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.*

"We are pleased that the committee has addressed regulations relating to export controls, select agents/dual use research, and intellectual property and technology transfer reporting. We also share the committee's concerns regarding the recent Common Rule Notice of Proposed Rulemaking (NPRM) for the treatment of human subjects in research.

"<u>AAU, APLU</u> and <u>COGR</u> submitted comments on the NPRM in January. We expressed concern that the NPRM did not fully consider the potential negative impact on research and medicine and the very significant cost of implementing the proposed changes. We also noted that key elements such as the informed consent templates and privacy safeguards were appreciably undeveloped. These concerns were echoed by many others in the scientific community, including HHS and NIH scientific advisory panels.

"The overall concerns and sentiments of the research community were demonstrated by the comprehensive <u>COGR-APLU analysis</u> of public comments on the NPRM as well as an analysis by HHS. Our associations are concerned about the rush to issue a final rule and believe there is no urgency to do so. We agree with the committee's assessment that 'the NPRM does not adequately or effectively address the breadth, depth, and import of unanswered questions' and that the current complexity of issues requires thorough and thoughtful consideration from a broad range of disciplines and stakeholders."

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