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***For Immediate Release***

# News Release

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## **Investing in Clinical Trial Compliance Top Academic Health Center Priority** ***AAHC Says Costs Emerging National Issue***

WASHINGTON, May 15 - To respond to a concurrent increase in the number of clinical trials, an expanded regulatory environment, and the ever-present need to ensure safe and effective clinical trials for patients nationwide, academic health centers are allocating increasing amounts of funds to infrastructure, personnel, and IT systems to administer and manage clinical trials and the associated compliance functions, according to a statement by the Association of Academic Health Centers (AAHC). Released today, *Investing in Clinical Trial Compliance* says that the costs of compliance is a national issue confronting the academic health center enterprise.

Academic health centers must place clinical trials compliance among their highest priorities despite the regulatory burden, the rapid utilization of resources needed, and the complexity of managing this process, says the AAHC. Ultimately, patient safety and the public's trust in the institution must be the guiding forces in all aspects of clinical trials compliance and the issue against which all expenditures of effort and finances should be judged.

Academic health centers are faced with a growing number of requirements that must be met with limited and strained resources. The costs of compliance are skyrocketing; for a one year period, some institutions reported increases as high as 70%, according to a recent AAHC report. Expenditures are required to create and staff the systems needed to increase efficiency and effectiveness and to recruit personnel—now in short supply—to manage the complex and technical aspects of clinical trial processes.

Compliance functions related to clinical trials, including budgeting, billing, training, auditing, and monitoring, within academic health centers are being transformed to ensure that clinical trials, the backbone of the nation's efforts to bring new drugs and technologies to market, remain an essential element of the research mission of academic health centers nationwide. Researchers in academic health centers generate the ideas that eventually need to be tested in clinical trials. The competencies and skills, as well as the necessary research infrastructure to conduct such trials, are found largely within the nation's academic health centers.

Clinical trials advance scientific knowledge and promote discoveries to treat and cure illness and disease and increase the quality of life and longevity of countless people around the world. "The AAHC is actively pursuing solutions to the complex cost issues through its Forum on Regulation," said AAHC President/CEO Dr. Steven Wartman.

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*The Association of Academic Health Centers (AAHC) is a national, non-profit organization that seeks to improve health and well-being through vigorous leadership of the nation's academic health centers.*