



# COMPLIANCE ALERT

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## Audit and Investigations

### Basic Anti-Fraud Measures for Universities

"Most universities often are fraud victims because of their unique control environments. An atmosphere of openness and collegiality, and faculty members who don't want to be controlled, can lead to a lack of segregation of duties and independent oversight. Learn how universities, and other nonprofit organizations, can overcome entrenched ideologies to prevent and deter fraud and reputational damage."

## Health Science Compliance

### HHS and NIH Take Steps to Enhance Transparency of Clinical Trial Results

"The U.S. Department of Health and Human Services today issued a Notice of Proposed Rulemaking (NPRM), which proposes regulations to implement reporting requirements for clinical trials that are subject to Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). The proposed rule clarifies requirements to clinical researchers for registering clinical trials and submitting summary trial results information to ClinicalTrials.gov, a publicly accessible database operated by the National Library of Medicine, part of the National Institutes of Health. A major proposed change from current requirements is the expansion of the scope of clinical trials required to submit summary results to include trials of unapproved, unlicensed, and uncleared products."

## Upcoming Educational Opportunities

- 2/4 to 2/6 – 2015 UC Compliance Symposium (Irvine)
- 2/11 to 2/12 – Title IX Investigators Training (Irvine)
- 2/26 – Non-stranger Sexual Assault Cases: Trauma-Informed Training for Investigators (Oakland)
- 2/27 – Non-stranger Sexual Assault Cases: Trauma-Informed Training for Investigators (Irvine)
- 3/9 to 3/10 – Title IX Investigators Training (Oakland)

### IG 2015 Work Plan Increases EHR scrutiny

"The U.S. Department of Health and Human Services Office of Inspector General continues to ramp up its scrutiny of electronic health records, adding a new focus area specific to EHRs in its 2015 work plan and continuing most of its EHR-related reviews from last year."

## Human Resources Compliance

### New Guidance on Pregnancy and Related Issues

"The Equal Employment Opportunity Commission (EEOC) recently issued comprehensive ["Enforcement Guidance on Pregnancy Discrimination and Related Issues"](#) (the Guidance). Along with the Guidance, the EEOC issued a [Q&A document](#) as well as a [Fact Sheet for Small Businesses](#). This is the first update of the EEOC's guidance on pregnant workers since the 1983 publication of its Compliance Manual."

## Research Compliance

### New Institutional DURC Policy Recently Announced

"On September 24, 2014, the USG released the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#). The policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Insti-



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tutional oversight of DURC is the critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC.

## [Associations Raise Concern Regarding USPTO Proposed Guidance](#)

"The university community looks forward to the final guidance that the U.S. Patent and Trademark Office (USPTO) will issue to address the subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, and natural products... The four associations on behalf of the university community expressed concern about the March Guidance being overly broad, extending well beyond Supreme Court rulings in recent patent-eligibility cases."

## [You Can't Ask That!](#)

George Mason University's Zachary Schrag offers the opinion that: "Enacted a generation ago in response to real abuses by some notorious medical researchers, so-called institutional review boards have morphed into entities that are stifling and distorting important research throughout academia."

## [Policy](#)

### [The Case for Student Shields](#)

"Should colleges and universities indemnify students who bring charges of sexual assault for lawsuits launched by their alleged attackers? New developments in an ongoing case at Northwestern University have brought that question to the fore, with proponents saying that indemnification promotes environments in which victims feel comfortable coming forward, without the threat of financial devastation if they're sued. Opponents, meanwhile, say that such policies could encourage false claims."

### [Universities' Updates Sexual Misconduct Policies Leads to Critiques and Legal Challenges](#)

There is growing social and political pressure to strengthen sexual misconduct policies and universities are rushing to respond. Most of these policies are meant to offer victims greater protections and recourse. Some critics argue that these new protections are coming at the expense of the rights of the accused. In November a group of [Harvard law professors published an op-ed](#) critiquing Harvard's new sexual harassment policy. They argue that new policy is "overwhelmingly stacked against the accused" in part because the accused is offered inadequate representation. On other campuses, the issue of representation of the accused has led to [lawsuits based on Title IX challenges](#). A [group of private defense attorneys](#), who are leading the effort, argue the new policies are biased against men on the basis of sex.

## [Quarterly Newsletter from Association of College and University Policy Administrators](#)

## [Privacy](#)

### [Hackers are Getting Personal Information Easier than Before: Symantec](#)

"In the mobile app world, when hackers want access to personal information, they need simply ask."

### [Sony Emails Show a Studio Ripe for Hacking](#)

"In the weeks before hackers broke into Sony Pictures Entertainment, the studio suffered significant technology outages it blamed on software flaws and incompetent technical staffers who weren't paying attention, even as hackers targeted executives to trick them into revealing their online credentials."

### [Cyber Attack Could Cost Sony Studio as much as \\$100 Million](#)

"Sony Corp's movie studio could face tens of millions of dollars in costs from the massive computer hack that hobbled its operations and exposed sensitive data, according to cybersecurity experts who have studied past breaches. The tab will be less than the



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\$171 million Sony estimated for the breach of its Playstation Network in 2011 because it does not appear to involve customer data, the experts said."

## Getting Privacy Policies Right...the First Time

"Privacy policies for websites are usually written by lawyers who sacrifice readability in search of strict legal accuracy. Maximum rights are reserved for the company, with caveats that allow changes in the future. For companies serving students, this model is simply not a feasible option."

## Protecting Whom?

"The U.S. Department of Education is seeking to help block the release of records about how the University of Montana punished a student accused of sexual assault, citing student privacy laws at a time when the Obama administration is pressuring colleges to become more transparent about the issue."

## In a Surprising Move, Congress Passes Four Cybersecurity Bills

"In a flurry of activity on cybersecurity in the waning days of the 113th Congress, Congress unexpectedly approved, largely without debate and by voice vote, four cybersecurity bills that: (1) clarify the role of the Department of Homeland Security ("DHS") in private-sector information sharing, (2) codify the National Institute of Standards and Technology's ("NIST") cybersecurity framework, (3) reform oversight of federal information systems, and (4) enhance the cybersecurity workforce."

## Sony Hackers Offer to Withhold Stolen Data From Promised Leak

"A group claiming responsibility for the devastating hacking attack against Sony Pictures Entertainment on Sunday offered to selectively hold back on releas-

ing email correspondence of its employees, provided that they write in and ask."

### UC Compliance Leadership

Sheryl Vacca

Senior Vice President and Chief Compliance and Audit Officer

David Lane

Systemwide Deputy Compliance Officer

### Campus Compliance Officers

UC Berkeley: Linda Williams

Associate Chancellor

UC Davis: Wendi Delmendo

Chief Compliance Officer

UC Irvine: Meredith Michaels

Vice Chancellor of Planning and Budget

UCLA: Ed Pierce

Director of Audit & Advisory Services

UC Merced: Luanna Putney

Associate Chancellor & Senior Advisor to the Chancellor

UC Riverside: Maria Anguiano

Vice Chancellor of Planning and Budget

UC San Diego: Judy Bruner

Chief Ethics & Compliance Officer

UC San Francisco: Theresa O'Lonergan

Associate Vice Chancellor, Chief Ethics & Compliance Officer

UC Santa Barbara: Pamela Lombardo

Acting Associate Vice Chancellor

UC Santa Cruz : Sarah Latham

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