



# COMPLIANCE ALERT

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## UC Policies and Guidance

### Establishing and Maintaining Presidential Policies

This new policy:

- describes the University of California approval process for Presidential Policies and sets out the general rules and responsibilities for the development, review, and ownership of Presidential Policies;
- describes the steps required for policy development, review, and approval for adoption of new policies, revision of current policies, and rescission of existing policies;
- outlines required consultation with the Academic Senate, Academic Personnel and Programs staff, Human Resources, and students.

### Updated Information for Researchers on Conducting Marijuana Research at UC

This guidance document, prepared by Research Policy Analysis & Coordination (RPAC) in consultation with the Office of General Counsel (OGC) and Environment Health & Safety (EHS), updates and expands upon guidance originally issued to address the effect of Proposition 64. The updated guidance summarizes relevant laws, regulations, and UC policies related to marijuana and industrial hemp research conducted at UC. The guidance states before a researcher considers applying for and accepting non-governmental research funding, from individuals or entities whose income derives from cannabis activities that fall outside of what is permitted by federal law, to contact their campus sponsored projects office (for grants/contracts) or the external relations/development office (for gifts), who in turn contact the RPAC office.

### Guidelines on Contracting for Services

These systemwide guidelines are intended to guide management contract decisions in circumstances in which University staff are displaced. Effective August 16, 2018, the guidelines include added language that locations will periodically analyze and evaluate the decision to contract for services from non-University staff for cost-saving purposes.

### Supplement to Military Pay

This policy describes the salary supplement provided to those University academic and staff personnel serving on active military duty in support of an ongoing overseas military mobilization campaign. This policy is effective July 1, 2018 through June 30, 2022. Policy updates include:

- Replaced reference to former campaign name with more general term.
- Additions/update of existing Policy language including definitions, compensation, duration and procedures.
- Clarification of existing benefits language.

### Sustainable Practices

This policy establishes goals in nine areas of sustainable practices: green building, clean energy, transportation, climate protection, sustainable operations, waste reduction and recycling, environmentally preferable purchasing, sustainable foodservice, and sustainable water systems. As of August 10, 2018, policy expanded to include UC Health and updated the following sections with new goals and clarifying language: definitions, green building design, clean energy, zero waste, and sustainable procurement.

## New Legislation and Guidance

### California Passes Landmark Privacy Bill

On June 28<sup>th</sup>, the California Legislature passed the California Consumer Privacy Act of 2018 ([AB 375](#)). Touted as similar to the GDPR, the privacy bill implements privacy protections for consumers. Organizations who collect and manage data from Californian residents must disclose the consumer data they sell to third parties and establishes consumer rights to request what information is gathered and object to its sale. Currently, the bill applies only to businesses rather than educational organizations such as UC.

### HHS OCR Interim Guidance on HIPAA and Individual Authorization of Uses and Disclosures of PHI for Research

Section 2063(b) of the 21st Century Cures Act requires that HHS issue guidance clarifying:

1. The circumstances under which an individual's authorization for use or disclosure of PHI for future research purposes sufficiently describes the purpose of the use or disclosure;
2. When it is appropriate to provide an individual with an annual notice or reminder of the right to revoke such authorization; and
3. The appropriate mechanisms by which an authorization for future research purposes may be revoked.

HHS OCR issued interim Guidance on HIPAA and Individual Authorization of Uses and Disclosures of Protected Health Information for Research on June 14, 2018. The interim guidance clarifies the requirements for describing future research in HIPAA authorization forms, stating that though each future study does not need to be specified, the authorization must adequately describe such purposes such that the data subject could expect that protected health information (PHI) could be used or disclosed for future research.

### National Defense Authorization Act for Fiscal Year 2019

President Trump signed the John S. McCain National Defense Authorization Act (NDAA) on August 13<sup>th</sup>, which introduces changes to military spending in addition to:

- Establishing an inter-agency process for

advising the government on how to export and control access to emerging technologies (Sections 1741-1793).

- Authorizing the Department of Defense to set up a forum with the university community to support intellectual property protection and support domestic talent in science and engineering fields (Section 1286).

## Regulatory News

### [Revised Compliance Date for the Common Rule](#)

The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies are issuing a Final Rule to delay for an additional 6 months the general compliance date for changes recently made to the revised Federal Policy for the Protection of Human Subjects (also known as the Common Rule). The revised date is now January 21, 2019. During the delay period, federal agencies expect Institutions to comply with pre-2018 requirements or use three burden-reducing provisions.

### [State Appeals Court Reinstates Physician-Assisted Death Law](#)

On June 15<sup>th</sup>, a California appeals court reinstated the End of Life Option Act after it had been briefly declared unconstitutional. Terminally ill patients and healthcare providers can once again participate in the physician-assisted death process.

## Conflicts between Regulations

### [Aspirin and Terrorism in Sudan](#)

The Office of Foreign Assets Control (OFAC) repealed sanctions on Sudan in their entirety, allowing the export of agricultural commodities, medical equipment and medicine, including aspirin, without a license. However, due to remnants of anti-terrorism legislation, the Trade Sanctions Reform and Export Enhancement Act of 2000, agricultural commodities, medicine and medical devices require a 1-year license for export to a state sponsor of terrorism. The lifting of the sanctions are in apparent conflict with the licensing remnants – in that while Sudan is no longer embargoed, humanitarian efforts require licensing, resulting in an incongruity between the remaining obstacles and the lofty goals in lifting sanctions.

### [GDPR Impact on Human Subjects Research](#)

The Secretary's Advisory Committee on Human Research Protections (SACHRP), under the U.S. Secretary of Health and Human Services, outlined concerns on how the European Union General Data Protection Regulation (GDPR) affects researchers conducting trans-national human subjects research. Some problematic areas include:

- GDPR's scope and application on U.S. based studies.
- Gathering consent from subjects for future use of data.

- Possible contradictions with European Medicines Agency policy.
- Legal obligations by the U.S. Food and Drug Administration following subject withdrawal.

A [July 2018](#) update on GDPR's impact presented to SACHRP is available for online streaming on the [NIH VideoCasting and Podcasting](#) website (update starts on 2h:53m).

## Foreign Agents at Universities?

### [How One Graduate Student Allegedly Stole Duke Research to Create a Billion-Dollar Foreign Company](#)

A former graduate student from China showed signs of an ulterior motive throughout their involvement in a Duke University lab and helped replicate research data in China. In this account, the intellectual property helped the student and others create a Chinese government supported conglomerate worth billions. At very least, the graduate student took advantage of academic collegiality and the exposure to research performed collaboratively in an open academic environment.

### [Targeting U.S. Technologies](#)

The U.S. Defense Security Service (DSS) recently published its annual analysis of efforts by "foreign actors" to obtain technology and information that might be used to acquire emerging technologies to support foreign militaries. The report summarizes trends by region of the world and outlines specific technology targets. Of interest to the UC community is the finding that academic personnel are targeted when they travel, especially to high risk countries. Any person invited to a conference in these countries or offered honorarium to offset the costs of a presentation should be on-guard. The report also clearly outlines best practices when traveling abroad or when approached by persons who might have interests that extend beyond fundamental research queries. The annual Targeting U.S. Technologies report is due for release in September 2018 available on the [DSS website](#).

## Compliance Tips and Resources

### [Back-to-School Cybersecurity](#)

Over 200,000 UC students will be starting classes over the next couple of months. The new school year is an exciting time for students, faculty, and staff.

It's also an exciting time for hackers, identity thieves, and other unscrupulous types who take advantage of people during this busy time of year.

#### Watch out for typical beginning-of-the-year scams:

- Emails supposedly containing "important information about your UC account," or a "problem with your registration."
- Scams specifically designed to cheat students out of money, such as scholarship scams, fake "tuition payment processors," textbook rental

or book-buying scams, housing scams, tutoring scams, and work-from-home scams.

- “Tech support” scams where you get a call supposedly from “ResNet” or “the Service Desk” or even “Microsoft” or “Apple” telling you there’s a problem with your computer.
- IRS impersonators demanding that students or their parents wire money immediately to pay a fake “federal student tax.”
- Messages asking for your login information, no matter how legitimate they may look. No one other than you needs to know your passwords.
- Fake friend requests on social media.
- Fake Box or Google Doc notices.

#### **How to stay safe:**

The best way to avoid scams is to approach all unexpected messages, offers, and phone calls with a healthy skepticism. Helpful habits include:

1. Always think twice before clicking on links or opening attachments, even if they look like they’re from someone you know. If you’re not sure, contact the sender by a method you know is legitimate to confirm they sent it.
2. Verify requests for private information. Remember, con artists know how to fake their identity.
3. Protect your passwords. Make them long and strong, never reveal them to anyone, and use different passwords for different accounts. Also, use multi-factor authentication (MFA) where possible.

For more about these and other effective cybersecurity habits, check out UC’s [“Make It a Habit” webpage](#) and the [back-to-school cybersecurity awareness toolkit](#).

## **Compliance Pitfalls**

### **UC Lawsuit Alleges UCSF Employee Steered Building Deals to Contractor**

In a civil suit, the University of California (UC) asserts a UC San Francisco deputy building inspector received payments from a contractor in exchange for rewarding campus building projects. Since 2011, the UCSF employee served on panels, which reviewed and ranked bidders for university contracts and would allegedly provide advice to the contractor on how to outrank other companies. The university also cites the employee violated university policy by not disclosing their relationship with the contractor.

### **New Research Misconduct Debarment Case Based on the “Reckless” Standard is Rare and Worth Noting**

The July 13, 2018, Administrative Law Judge Decision, U.S. Department of Health vs. Dr. Christian Kreipke,

imposed a five-year debarment after finding that Kreipke recklessly caused or permitted twenty-three (23) instances of research misconduct in his three (3) grant applications, two (2) articles on which he was the first listed author, and two (2) posters on which he was the first listed author. The judge precisely defined “reckless” within the context of research misconduct in his ruling that Kreipke “used materials without exercising proper care or caution and disregarded or was indifferent to the risk that the material were false, fabricated, or plagiarized.” The significance of this case is that a PI cannot simply trust or rely on a colleagues work, the PI must always verify the data, or risk a fate similar to Kreipke’s.

### **Texas Cancer Center to Pay \$4.3 Million in Penalties for HIPAA Violations**

The University of Texas MD Anderson Cancer Center must pay \$4,343,000 to the Office for Civil Rights (OCR) for HIPAA violations stemming from a stolen laptop and loss of thumb drives, all of which were unencrypted. The cancer treatment and research center failed to follow its own internal security policies and address gaps identified in a risk assessment.

### **Health Quest and Putnam Hospital Center to Pay \$14.7 Million to Resolve False Claims Act Allegations**

Whistleblowers in operationally important roles at Health Quest submitted complaints alleging the provider submitted false claims to federally funded healthcare programs. After investigation, Health Quest and PHC accepted responsibility for certain facts involving the submission of false claims:

- Insufficient home health documentation including documentation of a face-to-face encounter with a physician;
- Insufficient documentation to support the Evaluation and Management (E/M) level of service billed;
- Compensation in excess of fair market value for administrative services of two orthopedic surgeons where it appears one purpose was to improperly induce patient referrals.

## **Ethics in Healthcare**

### **Refusal to Permit Medical Treatment and the Power of Person-Centered Care**

A patient may refuse medical services deemed critical to their life and well-being. It is at these moments that healthcare professionals should turn to the key ethical principles of:

- Autonomy: Respect a patient’s right to make decisions.
- Beneficence: Provide the best medical care.
- Non-maleficence: Prevent harm.
- Justice: Follow ethically recognized laws and provide equitable treatment.

Sometimes at odds, all principles work together when approaching patient care as person-centered with a focus on improving the provider-patient relationship and understanding of a patient's point of view.

potential pre- and post-symposium sessions. Further details, including dates and venue, will be announced once finalized.

## **Significant New Developments**

### **[U.S. Government Lifts Ban on Cody Wilson's 3D Printed Guns](#)**

Defense Distributed, an open source-sharing site, won a legal battle to allow the online publishing of 3D-printed firearm files under a certain caliber threshold. This settlement is a significant development for one of the main challenges to the freedom of 3D printing, especially for universities where there is access to some of the most advanced equipment. It is also potentially a significant First Amendment development. The effects of this ruling are now being considered in addition to the proposed movement of certain small arms from the U.S. Munitions List (ITAR CAT I, II, III) to the Commerce Control List (EAR listed dual use commodities).

### **[California Soon may be First State to Require Public Universities to Offer Abortion Pills](#)**

A bill advancing in the California Legislature would make California the first state in the nation to require that abortion pills be available at on-campus health centers. The legislation, which has passed the Senate and is advancing in the Assembly, would mandate that all California State University and University of California campuses make the prescription abortion drug RU 486 available at their on-campus student health centers by Jan. 1, 2022.

## **What's Happening at ECAS**

### **New ECAS Principal Investigator**

ECAS welcomes Kevin Sherburne to the ECAS team as our newest Principal Investigator. Mr. Sherburne comes to ECAS after a twenty-year career with the Federal Bureau of Investigation. He has extensive experience conducting complex and sensitive national security and white-collar investigations. Part of his job duties with the FBI was coordinating outreach efforts with colleges and universities and later served as the program manager for liaison with college and university police departments. Mr. Sherburne led the FBI's Civil Rights Program in the San Francisco Bay Area, which included working with minority and underrepresented individuals and groups to combat hate crimes. He is a long time resident of the Bay Area, a graduate of Bellarmine College Preparatory in San Jose, and holds a B.A. in History from Santa Clara University. Mr. Sherburne received his J.D. from The American University's Washington College of Law. You will be able to meet Kevin at the LDO Conference in October.

### **Audit and Compliance Symposium**

The Office of Ethics, Compliance and Audit Services (ECAS) will sponsor an Audit and Compliance Symposium in 2019. The two and half day event will include both general and breakout sessions, with