COMPLIANCE ALERT

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Featured Article: GDPR and How is UC Responding

Now That It's Here, What Exactly is the European Union's General Data Protection Regulation (GDPR)? And How is UC Responding to It?

As some of you may be aware from the numerous email notices flooding your inboxes from your favorite websites and vendors announcing, "Changes to our privacy policy," the European Union's General Data Protection Regulation or GDPR went into effect on Friday, May 25, 2018. But what is the GDPR and what does it mean for UC?

What it is:

GDPR is a European Union (EU) regulation designed to protect the privacy rights of individuals in the European Economic Area (EEA), which includes the EU, Iceland, Norway, and Lichtenstein. It is intended to be an overarching privacy regulation for all EU Member States and replaces prior EU privacy regulations.

What it does:

GDPR expands privacy rights for individuals located in the EEA. Specifically, it guarantees certain rights, depending on how the data is used:

- The right to be informed about data collection, the specific intended use of the data, and the right to be informed if the intended use changes;

- The right to make informed decisions regarding the use and disclosure of the data;

- The right to access the data; and

- The right to have the data returned or deleted.

It also impacts data pertaining to these individuals even when the data is located in other countries, regardless of the citizenship of the individuals. Specifically, GDPR establishes a framework for safeguarding how personal data is used, such as:

- Ensuring that the data is transferred, processed, stored and eventually disposed of using appropriate technical safeguards;

- Limiting the use/processing of the data to purposes that comply with GDPR requirements (e.g., managing the academic records of UC students studying in the EEA as part of Education Abroad);

- Requiring third parties who receive the data to adopt UC's GDPR protections and safeguards through changes to contract terms.

Who it applies to:

GDPR applies to organizations established in the EEA (for example, a study center in Europe). It also applies to organizations not physically in the EEA when goods or services are offered to individuals in the EEA (e.g.,

applications for admissions), or monitor the behavior of individuals in the EEA (e.g., research that includes EU citizens).

Are there penalties for non-compliance?

Yes, GDPR imposes significant monetary penalties for organizations that do not comply with the regulation.

What is UC doing to prepare for GDPR?

UC's compliance, privacy and informational technology functions are working together to develop an effective GDPR compliance program. This program is specifically designed to enhance the existing robust privacy infrastructure at UC to ensure compliance with this new regulation. Program activities include:

- Assessing how GDPR will affect UC programs.

- Developing tools and templates to assist UC programs with GDPR compliance.

- Developing communication tools to provide greater transparency to UC students, employees and other UC program participants regarding the collection and use of personal data.

- Ensuring that appropriate physical and technical safeguards are in place to protect the personal data of individuals.

- Working with our partners and vendors to ensure that data protections are maintained when personal data is transferred outside UC.

To find out more, contact your campus privacy officer. Campus privacy official contact information is available on the UCOP ECAS website.

UC Policies and Guidance

Export Control

This new UC policy, issued June 21, 2018, addresses the University of California's compliance with U.S. export control laws and regulations by all members of the University community. Frequently Ask Questions about Export Control Compliance are available for viewing. If you have any questions, need to refer researchers to an Export Controls expert, or wish to run through any scenarios, please contact your local Export Control Officer.

Employee Non-Cash Awards and Other Gifts

Update to the policy includes all gift cards and gift certificates given as Length of Services Awards are subject to wage withholding because they are not considered tangible personal property for such awards under I.R.C. Section 274(j)(3)(A)(ii). The University will be subject to unrelated business income taxes (UBIT) on the cost (or value) of pretax transportation benefits awards under I.R.C. Section 512(a)(7). The changes are due to Public Law No. 115-97. Footnote added to define "State Funds" and made minor technical revisions. Revised to reflect the increase in the one-month parking permit and transit pass per Rev. Proc. 2017-58.

BFB G-13 Policy and Regulations Governing Moving and Relocation

Updated that all moving expense payments to employees or third parties on behalf of employees from January 1, 2018, through December 31, 2025, are includible in an employee's gross income, subject to withholding of applicable federal income, social security, and Medicare taxes. Such amounts must be tax coded for reporting on the employee's IRS Form W-2. These changes are in response to Public Law No. 115-97.

Smoke and Tobacco Free Environment

Policy language revised to explicitly incorporate marijuana, to broaden the scope of products included (electronic smoking devices), and removal/clarification of allowed exemptions.

PPSM-30 - Compensation

Language added to the Procedures section affirming that, as locations, transfer to UCPath, General and Merit Increases based on a percentage increase will be rounded up.

As a result of the issuance of this policy, the following document is rescinded as of the effective date of this policy and is no longer applicable:

- Personnel Policies for Staff Members 30 dated December 15, 2015.

UC Guidelines on Contracting for Services

These systemwide guidelines describe how to contract out for services where University staff would be displaced. Effective May 31, 2018, added to FAQs clarification on applying guidelines for contracting out for services under $100,000 and that the guidelines are only services, not goods.

Clery Act Policy – Campus Safety and Security Reporting

Footnotes added to reference Federal Regulations and DOE Handbook for Campus Safety and Security Reporting, and California State Laws.

University of California Employee Housing Assistance Program

These implementation guidelines contain the specific procedures associated with the operation of the UC Employee Housing Assistance Program.

UC Guidance: Compendium of Conflict of Interest and Integrity Policies

Formerly Business and Finance Bulletin G-39, this guidance collects existing University policies related to conflict of interest and conflict of commitment. It does not include all possible state or federal laws and local policies issued by campuses.

UC Out in the Field

UC Project: Discovery of World War II Plane

A missing World War II bomber was recovered in Papua New Guinea by Project Recover, comprised of researchers from Scripps Institution of Oceanography at UC San Diego, University of Delaware, and non-profit BentProp members. This project involved the use of specialized equipment requiring ITAR (International Traffic in Arms) licensing for non-military purposes.

New Legislation and Guidance

Right-to-Try Act Signed into Law

Senate Bill 204, commonly known as the federal Right-to-Try Act, seeks to give persons with life-threatening conditions who have exhausted treatment options access to experimental drugs, bypassing the FDA's existing requirements for the expanded access program as well as other clinical trial regulations. Under the law, FDA oversight of the approval process is significantly weakened, and IRB review is not required, as the legislation specifically exempts compliance with 21 C.F.R. Part 56.

FDA Guidance

The FDA has issued two final guidance documents on next-generation sequencing (NGS) diagnostic tests, "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics" and "Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing-Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases." The provisions of the Genetic Variant Databases guidance are substantively identical to the draft guidance issued in July 2016; conversely, the NGS guidance has undergone significant changes since the draft guidance released in July 2016.

Regulatory News

California's Right-to-Die Law on Hold

Nearly two years after it went into effect, California's End of Life Option Act is, for the moment, suspended. A Riverside County Superior Court judge ruled it unconstitutional, restricting doctors from prescribing life-ending medication to qualified patients.

CURES 2.0 Mandatory Use

On April 2, 2018, the Department of Justice (DOJ) certified the Controlled Substance Utilization Review and Evaluation System (CURES) for statewide use. CURES is a database that contains records of prescriptions for Schedule II, III and IV controlled substances dispensed in the state. Beginning October 2, health practitioners will be required to consult a patient's history in CURES before prescribing him or her a Schedule II, III or IV controlled substance for the first time and then at least once every four months as long as the prescription is renewed.

Controlled Substances: Change to DEA Registrations

A recent campus inspection by the Drug Enforcement Agency (DEA) changed the method by which campuses can register for controlled substances licenses. The DEA will allow UC campuses to adopt the departmental model for controlled substances registrations, rather than enforcing Principal Investigator registrations on an

individual-by-individual basis.

EH&S and OGC, through consultation with the UC Controlled Substances Program Administrators (CSPAs), will continue to work with the DEA on the definition of "department" to ensure the DEA understands the non-contiguous nature of UC campus departments.

Please contact your CSPA for information related to your campus.

Cannabis Research

Despite California state legalization, most cannabis use remains illegal under the Federal Controlled Substances Act. Marijuana is still classified as a Schedule I Controlled Substance - the most restrictive control. While Federal restrictions are significant, research is allowed under a Schedule I Drug Enforcement Agency License. On June 8th, the UC San Diego Center for Medicinal Cannabis Research hosted a one-day symposium on Cannabis and Health where Dr. Daniele Piomelli presented the National Academies of Sciences Engineering Medicine's study: *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, Jan. 2017. The study results illuminate the need for more research on the health effects of cannabis/cannabinoids. The public perception of cannabis as a cure-all is not always borne out by research. However, there are areas of research with significant promise. On June 25th, the FDA approved the first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy. UCOP guidance on marijuana/cannabis research is forthcoming.

Travel

Export Control Officers and Foreign Travel

ECAS and Risk Services are teaming up to provide Local Export Control Officers (ECO's) with tools to aid UC personnel preparing for foreign travel. A small number of sanctioned countries pose risks which are best mitigated by consulting with your local ECO's. Countries of greatest concern include Cuba, Iran, North Korea, and Syria. The pre-travel planning stage is the ideal time for mitigating steps which may require altering travel plans, export control licensing, identifying license exceptions or preparing other security precautions.

Previously, the travelers planning these trips were unaware of local resources available through the ECO's and the ECO's were unaware of the planned travel. Travelers who plan travel to these destinations of concern via UC Travel/Connexxus can now automatically benefit from a pre-travel review triggered by travel to these destinations. There is no requirement to work directly with the ECO's, however, travelers to these destinations would benefit by the advice and guidance of their export control compliance teams and could avoid travel interruptions, delays, or regulatory surprises.

Cyber-Smart Traveling

For many of us, having a cell phone or other electronic device is an integral part of daily life, whether at home or on the road. Traveling today is so much easier with technology. You can stay productive, entertained, and in touch.

Unfortunately, traveling with devices can mean increased cyber risks for keeping your personal and University information private, as well as increased potential for device theft.

Stay cyber safe while traveling:

A good rule of thumb when traveling is to assume your devices will be lost, stolen, compromised, or even confiscated at an international border at some point during your trip, and plan accordingly. It is also important to remember that anything you do over unsecured Wi-Fi may be seen by others, including your passwords and the contents of your messages. With this in mind…

- Make sure you can connect to the Internet securely while you're away.

- Encrypt your devices or at least any sensitive information on your devices.

- Only bring what you're willing to lose – both stored information and the devices themselves, even if they're encrypted.

- If you're traveling for UC business, research, or as an international student or scholar, work with your IT department to make sure you're taking a clean machine or an appropriate loaner device, and that you have the tools you need to connect to the Internet securely.

- Immediately report lost or stolen devices used for work – follow your location's reporting requirements.

General cybersecurity tips and information about inspection of electronic devices at the US border is available on the UC Systemwide Information Security Awareness website. Additional information when traveling internationally for UC business, research, or for international students or scholars is on the UC Global Operations (UC GO) website.

Compliance Tips and Resources

Digital Spring Cleaning

Many of us are familiar with the concept of spring cleaning. This year, consider taking some time to spring clean your digital life too. Just like your home, your digital life can become cluttered; things pile up, get out of date, get lost, are no longer needed or need some care.

A good digital spring cleaning can help keep your devices and information safe and secure year round. It can also help improve the speed and performance of the devices and services that you use and reduces the risk that a hacker could access your old and forgotten information.

Here are a few tips for refreshing, renewing, and reinvigorating your cyber life. For more info on any of these, please see the full article.

1. Review your online accounts.
2. Update your devices.
3. Tune up web browsers.
4. Purge old digital files. (Keep UC retention requirements in mind when purging work files!)
5. Lock down your login.
6. Refresh your online presence.
7. Back up your files.
8. Dispose of electronic devices securely.

Cybersecurity is an active and ongoing process. For additional news and updates on how best to maintain cybersecurity, go to the UC Systemwide Information Security Awareness webpage.
For assistance with UC record retention requirements, contact records@ucop.edu or 510-987-0399.

HHS Guidance on Substance Use Disorder Confidentiality Regulation

The Department of Health and Human Services released two fact sheets, "Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?" and "Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?," to help healthcare providers apply the 42 CFR Part 2 regulations on confidentiality of substance use disorder patient records.

Compliance Got You's!

The $3-Million Research Breakdown

The University of Illinois – Chicago repaid $3.1 million for grant money received from the National Institute of Mental Health after findings of research misconduct by a clinical trials psychiatrist. The research conducted was noncompliant with protections for human subjects and is undergoing two investigations by the U.S. Department of Health and Human Services' Office of Inspector General and Office of Research Integrity.

Health System in Georgia to Pay $4.1 Million Settlement for Poor Drug Handling

Effingham Health System agreed to pay $4.1 million to resolve allegations that the health system failed to provide adequate controls against the theft or loss of controlled substances and failing to report the suspected drug diversion timely.

Department of Public Health Fines Hospitals and Clinics Millions for Patient Privacy Violations

The California Department of Public Health posts its investigative findings concerning reported This is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital, breaches of patient privacy by healthcare providers and medical centers. The list makes penalties issued and plans for corrective action and monitoring publicly accessible,

included are incidents at UCSF and UCLA dating back several years.

University Scientist Spilled No Secrets But Went to Prison

A former University of Tennessee at Knoxville professor sent to prison for violating the Arms Export Controls Act gives his first interview since being released. The violations stemmed from sharing restricted research with foreign Ph.D. candidates without a federal license and traveling internationally with a laptop containing data on an Air Force project.

California Health System Settles Case Involving Excluded Individual

Alameda Health System agrees to pay $257,874 to settle allegations that it employed an excluded individual not permitted to participate in any Federal health care program. According to the OIG investigation, the excluded eligibility clerk provided items or services to Alameda Health Systems patients that were paid for by the Federal health care programs.

Here's What's Happening at ECAS

Cybersecurity Audit Specialist Position

ECAS is recruiting a Cybersecurity Audit Specialist to join the Cybersecurity Audit Team responsible for conducting audits and advisory service projects to provide independent assurance of adequately implemented cybersecurity controls designed to effectively reduce cyber risks. Information for this position is available through the following link: UCOP Job Post – 20180273.

Principal Auditor Position

Under direction of the Systemwide Deputy Audit Officer, responsible for planning and performing audits, advisory services, and investigations at all levels of complexity, and communicating the results to University leadership and management through verbal presentations and written reports. Further information available through the following link: UCOP Job Post – 20180239.