

RESEARCH COMPLIANCE REVIEW GETS A MAKEOVER

The Research Compliance Program evaluated audit practices during 2023, seeking to improve efficiency and effectiveness. A primary area identified for improvement was turn-around time for issuing reports to study teams, particularly for study-level findings and observations. New practices resulting from implementation of the OnCore Clinical Trial Management System (CTMS) also warranted greater focus on performance of study-level reviews.



Additionally, the Research Compliance team recognized the need for validation of billing and privacy practices performed for a study after receipt of a Patient Zero Compliance Review report to evaluate corrective actions implemented by the study team and the effectiveness of education provided during the Patient Zero Compliance Review.

A pilot was initiated in 2023 to split the existing Patient Zero Compliance Review methodology into two stand-alone reviews. Additionally, an investigator whose study underwent a Patient Zero Compliance Review invited the Research Compliance team to audit their study again - perfect timing to pilot the validation review methodology. Following these pilot reviews, the new methodology was documented and put into practice in 2024. The new three-pronged audit program is diagrammed below. Questions and discussion are welcome at any time during the review, close-out meeting, and follow-up period.

Patient Zero Compliance Review was split into two stand-alone reviews

Review Type	Study Initiation Review	Patient Zero Review
Focus	<ul style="list-style-type: none"> Privacy Practices & Activities Study Minimum Footprint in OnCore Research Billing Plan OnCore-Epic Subject Association Workflows 	<ul style="list-style-type: none"> Subject status management in OnCore Order and Encounter Association in Epic Research Billing in Epic
Eligibility	<ul style="list-style-type: none"> Conduct of the protocol will result in billable charges in Epic A subject (Study Initiation Subject) has enrolled beyond screening 	<ul style="list-style-type: none"> Study Initiation Review was conducted. Billing sample review period has passed for Study Initiation Subject
Selection	<ul style="list-style-type: none"> Randomized amongst all studies meeting criteria each month 	<ul style="list-style-type: none"> Only a subset of studies that had Study Initiation review
Elements	Review Study's: <ul style="list-style-type: none"> Bridge or OnCore Study Entry Billing Grid Elements Billing Grid Payor Designation Medicare Coverage Privacy Practices ICF and HIPAA Authorization OnCore – Epic Association Workflow 	Review Study Initiation Subject's: <ul style="list-style-type: none"> EMR Research Functionality Charge Review and Disposition Billing sample defined as 90 days from first charge or 10 DOS.

Validation review added

Patient n Review NEW
<ul style="list-style-type: none"> Privacy Activities OnCore-Epic Subject Association Workflows Subject status management in OnCore Order and Encounter Association in Epic Research Billing in Epic
<ul style="list-style-type: none"> Study Initiation Review was conducted
<ul style="list-style-type: none"> Compliance Rate below institutional average for more than one component from either the Study Initiation or Patient Zero Reviews Only a subset of studies that had Study Initiation or Patient Zero reviews
Review up to 5 subjects: <ul style="list-style-type: none"> ICF and HIPAA Authorization OnCore – Epic Association Workflow EMR Research Functionality Charge Review and Disposition 90-day billing sample defined for each subject



SEARCHING FOR RECORDS WITHIN EPIC

For this newsletter, we conducted a poll of our Compliance Investigators. We asked: “What is the number one thing you wish employees would stop doing?” They answered immediately: “Using Epic as a personal phone book.” Let’s unpack this. Epic is the electronic medical record system utilized at UC Davis Health. A common way to access a patient’s medical record is to search for their name, medical record number, date of birth, or any combination thereof, by typing this information in the Search fields shown below.

The information that results from these searches is patient information. Unless an employee has a work-related reason for needing to access a patient’s information, they should not search for records in Epic. The Compliance and Privacy Services Department conducts routine surveillance of access to our patients’ information. Prior investigations of questionable activity within Epic have exposed employees using the system for the following reasons:

- To obtain the birthdays of multiple co-workers while compiling a “birthday list” for their department/clinic;
- To find a co-worker’s cell phone number to quickly reach them with a work-related question;
- To see how old their peers are by checking their dates of birth;
- To know whether their friends and personal acquaintances have medical records at UC Davis Health;
- To obtain their co-workers’ addresses in order to send holiday cards;
- To see who their co-workers’ primary care providers (PCP) are when choosing a new PCP for themselves; or
- Just because... “but I didn’t know I couldn’t.”

In these examples, the employees conducted searches to obtain personal information about individuals who are co-workers, friends, and acquaintances from a system containing patient data. None of these scenarios involve providing services or treatment to these individuals as patients or performing any operational tasks related to these individuals as patients. Given this, none of the employees had valid reasons for searching for these individuals’ records within Epic and accessing their patient information. Even though these employees did not enter the individuals’ electronic medical records, their searches resulted in access to patient information using a work tool (Epic). Policy 2454, Employee Access to Protected Health Information and Personal Information, states: “Access or viewing [Protected Health Information] and [Personal Information], including, but not limited to, demographic information, account data, and health information, is confidential and shall not be accessed or viewed other than the sole purpose of performing employment duties and responsibilities.” Thus, the actions of the employees above constituted policy violations.

SAFEGUARDING PATIENT CONFIDENTIALITY: UPHOLDING EXCELLENCE IN A BUSY ENVIRONMENT

Throughout the flow of daily patient interactions at UC Davis Health, maintaining confidentiality can feel like an ongoing challenge. During the bustling of activity, it is crucial to stay vigilant to prevent the potential of causing a patient privacy violation.

Many of our workforce, with their remarkable ability to juggle multiple tasks, often find themselves at the forefront of patient care. However, among these notable multitasking efforts, there exists a vulnerability—the potential for inadvertent unauthorized disclosures. Beyond multitasking, it is crucial to remain vigilant and avoid slipping into the trap of operating on autopilot.

Enter the simple practice of double-checking documents. This seemingly mundane yet invaluable step serves as the cornerstone of our workforce's commitment to ensuring patient confidentiality while handling patient documents. Whether handling after-visit summaries, lab/test orders, medication lists, face sheets, patient labels, or pharmacy receipts, every disclosed document that contains patient information has the power to either uphold or compromise patient privacy. Our workforce can prevent privacy breaches by simply reviewing documents before dissemination to patients or the patients or patient representatives. UC Davis Health's commitment to safeguarding protected health information can only be carried out by ongoing organization-wide vigilance at every moment. In doing so, we not only fulfill our duty as UC Davis Health professionals but also honor the fundamental right to privacy that every patient deserves.

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TO RECEIVE A GIFT OR NOT TO RECEIVE A GIFT

Generally speaking, most people either like to give or receive gifts; however, in the healthcare setting, giving, and receiving gifts is not always black and white. In fact, UC Davis Health is subject to the Political Reform Act (PRA) and internal policies regarding conflict-of-interests. UC Davis Health precludes their workforce from engaging in acts that create either an actual or perceived conflict of interest. Gifting from vendors is just one specific area where a gift is not simply a gift, especially if that gift is from a "Vendor."



UC Davis Health's Policy 2601, Gifts and Interactions with Vendors defines a vendor as "Any organization or person that provides, attempts to provide, or is willing to provide goods, equipment, or services of any type to UC Davis Health, regardless of the organization's or person's expectation of compensation for such good, equipment, or services." The policy defines a gift as, "The payment or provision of free or discounted items, medical samples, food, or travel when the recipient is not providing a service of similar or greater value to the Vendor policy."

TO RECEIVE A GIFT OR NOT TO RECEIVE A GIFT (con't.)

The University Office of the President has provided guidance on some frequently encountered scenarios that might exist in the health care setting: **HealthVendorRelations (ucop.edu)**.

- **When attending conventions or other professional meetings either on campus (such as vendor days) or away from campus, can I accept Health Care Vendor gifts or samples for evaluation or personal use?**
 - No. You may not accept samples. Other items directly provided by Health Care Vendors (e.g., at their booths) also could not be accepted. However, if you paid a registration fee that included refreshments or give-aways (e.g., a tote bag), you would not be receiving a “gift” under the Policy and could attend the event and accept food and other items provided to all attendees.
- **If a faculty member attending a conference engages in interactive exchange, may a Health Care Vendor pay their travel expenses?**
 - No. Mere interactive exchange would not constitute genuine consulting services.
- **Our department often receives invitations to dinner lectures sponsored by Health Care Vendors, held at restaurants downtown. Could an individual covered by the Policy attend the event and accept free dinner? Faculty attend dinner on their own time.**
 - If the invitee is not providing a service to the Health Care Vendor of similar or greater value than the dinner (e.g., giving a lecture, or participating in a panel or seminar), they could not accept the free dinner. However, the individual could attend the event and pay for their own dinner.

The UC Davis Health Compliance department oversees the vendor gift policy and addresses issues concerning conflict-of-interest questions. We encourage anyone who has a conflict-of-interest question and/or vendor and/or gift related question to reach out for guidance on what is acceptable pursuant to policy.

Policy Highlight

1506 Clinical Research Regulatory Agency Review: addresses visits by regulatory agencies such as an FDA inspection. The most critical take-away for researchers is to contact Compliance and the IRB immediately upon receipt of notice that a regulator plans to visit. Once notified, Compliance staff will aid the researchers in arranging comfortable space for the visit to occur and other logistics.

Need to Reach out to Your Compliance Team?



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