

Research Compliance

News and Announcements

Updates at a Glance

- The updated HIPAA authorization form "Version 2017" will be required for all newly activated research studies approved by an IRB on or after **June 1, 2018**.
- Upload the signed ICF and HIPAA form to the EMR for all subjects enrolled to studies that must be entered in Epic. The policy previously applied only to studies utilizing an investigational drug or device.
- The Bridge entry must be completed in full and the study uploaded to Epic prior to enrollment of study subjects.
- Study status for research subjects must be updated in the EMR for each status change.

Updated HIPAA Form: Version 2017

Access to and use of patient information from the EMR and other UC Davis Health sources for purposes of research requires written authorization from the study subject unless a waiver or exception has been issued by an IRB or Compliance.

Research teams will be required to use the updated form ("Version 2017") for research studies that will access or use PHI when new studies are activated for subject enrollment unless a waiver or exception was provided by the IRB or Compliance Department.

It is important to note that an updated form will not be required for research subjects who have already signed a valid UC Davis HIPAA authorization form for the same study.

The HIPAA Authorization for Research form was developed by UC Office of the President to ensure compliance with state and federal privacy regulations. Therefore it is of critical importance to always use the current, approved version of the form with each newly activated study.

The current, approved HIPAA authorization form is available on the [IRB Forms](#) webpage.

Updated Form:
HIPAA Authorization
for Research

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P&P 2306: Upload the signed ICF and HIPAA forms to the EMR

[P&P 2306](#) has been updated to require the signed HIPAA Authorization for Research form and research ICF to be uploaded to the EMR for subjects enrolled in all studies which require documentation of research patient status in the EMR per [P&P 2317](#). The policy previously applied only to studies utilizing an investigational drug or device. It is advised that the upload of the signed forms be added to the new subject enrollment workflow as soon as possible to ensure compliance moving forward. The compliance date for this policy update is June 1, 2018. The original, signed forms should be maintained in the research record.

P&P 2317: Complete the Bridge prior to enrollment

Updates were made to [P&P 2317](#) with the goal of ensuring the study's Bridge and Epic entries are completed prior to enrollment of study participants. Ideally, the study's Bridge entry should be completed and ready for upload to Epic at least two days in advance of subject enrollment to ensure the Epic study entry will be available when needed.

P&P 2317: Update Epic study status

Another important change specific to [P&P 2317](#) involves the study status for subjects enrolled in studies. The Epic study status generally describes the stage of the subject's participation in the research study. This information is not only critical to providers but also to the institution for identification of patients actively participating in research studies. Study status definitions can be found on page 10 of the Clinical Research Coordinator Research Study Management [Epic Quick Start Guide](#).

Frequently Asked Questions (FAQ): see page 3

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P&P 2306: Medical Record Legal Content

The signed HIPAA Authorization for Research form and research informed consent form (ICF) must be uploaded to the EMR for all subjects enrolled to studies subject to P&P 2317.

P&P 2317: Documentation of Research Patient Status in the EMR

The Bridge must be completed in full and the study uploaded to Epic prior to enrollment of study subjects.

Additionally, subject status for research subjects must be updated in the EMR for each status change.

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Frequently Asked Questions (FAQ)

Does the requirement to use the updated HIPAA form apply to existing studies?

No. HIPAA form Version "Updated 5/14" may continue to be used for studies currently enrolling new subjects. If a version other than "Updated 5/14" is currently in use, use form "Version 2017" as new subjects are enrolled.

How can I tell what form version we are using?

The form version can be found in the lower left corner of the page. The previously approved version was identified as "Updated 5/14." The currently approved, updated version is identified as "HIPAA Research Authorization Version 2017."

Do currently enrolled study subjects who already signed a HIPAA form for the study have to sign a new form?

No. It is not necessary to obtain signature on the updated form for any subject who already signed a valid version of the UC Davis HIPAA Authorization form for the same study.

I don't know if the changes specific to P&P 2306 apply to my study. How can I tell?

If a study must be completed in the Bridge and uploaded to Epic, then the study is subject to P&P 2317, and the ICF and HIPAA authorization must be uploaded to the EMR. This includes all studies that meet one or more of the following criteria:

- a) All studies that utilize a drug or device;
- b) All studies which require items or services that result in **any** charge or billing component (including billing to a third-party insurance, study sponsor, or patient) in the Epic billing system;
or
- c) All studies that include, as part of their protocol, any clinical intervention, including the invasion of any research participant (control or subject) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Medical Center (UCDMC) licensed facility.

We conduct specimen collection studies, and we have not uploaded the ICF and HIPAA authorization documents before. Do we need to upload the signed HIPAA authorization and ICF for subjects already enrolled to our studies?

No. However, the documents must be uploaded for all subjects who sign consent on or after June 1, 2018, the compliance date for changes to P&P 2306. Prior to the policy change, the requirement to upload the signed ICF applied only to studies involving an investigational drug or device.

Will updating a research subject's status to "Off Study" interfere with research billing?

No. A research subject's active or inactive study status does not influence how charges move through the billing system. Charges qualify for Epic research billing review when charges are generated from an order or encounter associated to the study. The study status can be updated to "Off Study" as soon as a study subject completes participation in a study, and billing will not be impacted.

If you have additional questions, please send your questions by email to:
HS-ResearchCompliance (hs-researchcompliance@ou.ad3.ucdavis.edu)