This email was sent to.

Please be sure to include the protocol number, if available. This will help the OIA

Also, be sure to continue triage and troubleshoot.

If you are a researcher, you should install and enable the

This module discusses the basic privacy protections for health information provided

that creates, obtains, uses, or discloses health data, principally the protections that

data, completion of the following modules in CITI's Research Privacy curriculum is

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A study is not human subjects research

NEW: Negotiating Sponsor Consents

NEW: Updated IRB Forms for UCSD investigators

NEW: New IRB Forms for UCSD investigators

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NEW: Assessing the UCSD IRB "Enrollment" Definition

NEW: UCSD/RCHSD is not engaged in the human subjects research

A study is not human subjects research

KBA on this topic

KBA on this topic

In This Issue

The OIA generally has 5 types of administrative determinations it can make:

If you are a researcher, you should:

4. Follow your departmental policies on renewing (or not) accounts in a timely fashion so

5. Be on the lookout for unexpected changes to protocol IRB requirements, especially in light of single IRB

For questions about the Office of Compliance and Privacy's HIPAA training

What if my study doesn't require documented informed consent?

What if my study doesn't have a consent process?

What if my study is unfunded?

If the audio/video recording will be used for research purposes, information about the

If the audio/video recording will be used for research purposes (and thus fall out of our purview) or they are locked by the

Historically, the OIA accepted and reviewed many standardized institutional

In the wake of the NIH's single IRB mandate and the Revised Common Rule's single

The number one issue that OIA catches in our review of studies going to external

HIPAA Language

For UCSD Health,

institution's PR department to obtain the standardized form for use in non-research

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insitution/legal and cannot be altered. This means that HIPAA authorizations,

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UCSD IRB will not review these documents is because either they are used for non-

documents including audio/video recording consents and HIPAA authorization

This comes at an additional cost which is not otherwise covered by OIA's current

policies at the external sites, and evaluate investigators we aren't familiar with. All of

site. This fee should be incorporated into the budgets for studies with a proposal due

for external sites, these studies will be subject to the new one-time fee of $800 per

For studies with any kind of funding where the UCSD IRB will be the IRB of Record

30% F&A for a total of $800

Additionally, as a reminder, the Common Rule (both the Revised and Old versions)

language. OIA's

be compensated for research related injuries and replace it with the approved

changes to this language outside of the options listed on our

document, researchers can provide them the

HIPAA Language

For phrases like "I authorize release of my medical information" or "I allow the study

HIPAA Language

GRANT OR LOAN

with the approved

FCRA

Language

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