Research Compliance: The Research/Privacy Nexus

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The Privacy Nexus in Research

- You are a member of the UCDHS Workforce
- UCDHS is a Covered Entity (CE) under Federal HIPAA Law
- All CEs (and its workforce) are responsible for complying with HIPAA
- The CE is required to ensure that access to its patient information is in accordance with the law
- PRIMARY ISSUE FOR RESEARCHERS: When can you access patient records?
WHEN ARE WE ABLE TO ACCESS PATIENT RECORDS?

When the patient consents:
- Signed Release of Information (ROI)
- Signed Research Consent/HIPAA Authorization

When the patient does not consent:
- For Payment
- For Treatment
- For Operations
- If the law provides an EXCEPTION
Access with Authorization

Research Question → IRB Submission → IRB Approval → Patient Consent and HIPAA Authorization → ACCESS TO PHI

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):

Sponsor/Funding Agency (if funded):

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical record and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

- Entire Medical Record
- Radiology Reports
- Pathology Reports
- Laboratory Reports
- Dental Records
- Operative Reports

Other:

- Emergency Medicine
- Outpatient Clinic
- Records
- EKG
- Radiology images
- Psychological Tests
- Health Care Billing Statements

(Updated 5/14)
**Authorization Issues**

**Sponsor wants HIPAA Authorization changed**
- OP/UC-wide form
- Generally, don’t permit changes
- However, compliance can review and approve
- Approval dependent on request

**Missing Authorizations**
- Immediately notify IRB and Compliance
- Need to secure signature
- Compliance will need to review for privacy implications

**Completing the Authorization**
- Check the boxes
- Sign and date
- Special Signatures

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**B. What Personal Health Information will be released?**

If you give your permission and sign this form, you are allowing your healthcare provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

- Entire Medical Record
- Radiology Reports
- Pathology Reports
- Laboratory Reports
- Dental Records
- Operative Reports
- Emergency Medicine Center Reports
- Outpatient Clinic Records
- EKG
- Radiology images
- Exams
- History & Physical
- Discharge Summary
- Psychological Tests
- Consultations
- Health Care Billing Statements

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**C. Do I have to give my permission for certain specific uses?**

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

- I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
- I agree to the release of HIV/AIDS testing information.
- I agree to the release of genetic testing information.
- I agree to the release of information pertaining to mental health diagnosis or treatment as follows:

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**I. Signature**

If you agree to the use and release of your Personal Health Information, please sign below. You will be given a signed copy of this form.

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Subject's Name (print)

Subject's Signature __________ Date __________

Note: if the subject is a minor, an individual signing with an “X”, an adult incapable of giving consent, or is unable to read the authorization, fill out and attach the “special signatures” page (sections “J” and “K”).

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**SPECIAL SIGNATURES PAGE**

J. If the subject is a minor, or an individual signing with an “X”, or an adult incapable of giving consent (where IRB approved), the legally authorized representative or witness signs here:

Legally Authorized Representative’s Name or Witness to the “X” (print) __________

Relationship to the Subject __________

Representative or Witness Signature __________ Date __________
Access Without Consent: What are the Research-Related Exceptions?

When the patient does not consent:

- Waiver of HIPAA Authorization (IRB)
- For Preparatory Research
- For Decedent Research
- Limited Data Sets with a Data Use Agreement
Access Without Consent: Waiver of HIPAA Authorization

- Granted by IRB during submission process
- Access must match the brief description of the PHI for which use or access has been determined to be necessary by the IRB
- Must comply with Accounting of Disclosures (HIPAA Rule and UCDMC P&P)
Access Without Consent: Preparatory to Research

- Access available prior to IRB approval
- For preparatory purposes only
- Submit request to: https://ctscassist.ucdmc.ucdavis.edu/redcap/surveys/?s=VRGYXq8PVW
Preparatory Research Requests

- What do you need the data for?
- What information do you need to review?
- Whose PHI do you want to see?
- What is the desired data source
- Have you considered cohort discovery?

If my application is approved, by checking the box, I affirm that the following statements are true:

1. The request to access PHI is solely to review as necessary to prepare a research protocol or for similar purposes preparatory to research
2. No PHI will be removed from the electronic medical record
3. The PHI for which use or access is sought is necessary for the research purpose
4. No potential research subject will be contacted as part of the preparatory to research

* must provide value

I Agree  I Do Not Agree

Submit
Access Without Consent: Decedent Research

- Access available through compliance (must also get approval from IRB if access involves death certificate)
- Representation from the researcher that the use or disclosure being sought is solely for research on the protected health information of decedents, that the protected health information being sought is necessary for the research.
- Submit request to: https://ctscassist.ucdmc.ucdavis.edu/redcap/surveys/?s=VqdaAG8o6M
For All Access Without Authorization: Must Account for Disclosures

- HIPAA requires covered entities (UCDHS) to maintain records of certain disclosures without authorization, including disclosures to researchers (not part of the covered entity) including disclosures pursuant to a waiver of authorization, preparatory to research reviews, and decedent research (45 CFR 164.528)

- UCDMC P&P 2446: Investigators who receive (view/disclose) protected health information (PHI) of the CE without a patient’s written authorization are responsible for accounting for this access
HIPAA Tracking of Disclosure

Please log in using your UCDHS System / Citrix / Active Directory credentials.

**UCDHS LOGIN CREDENTIALS**

- **User Name:**
  - 

- **Password:**
  - 

**Log In**
Quick Disclosure Activity

With the Quick Disclosure activity, Research Coordinators can quickly and conveniently record what information they view and print, all from their clinical workspace. For example, after viewing patient information from Chart Review, coordinators can use the Quick Disclosure activity to record necessary information about what they viewed so that it can be included in disclosure reports. Tracking these patient disclosures helps UC Davis comply with State / Federal statutes.

Access the Quick Disclosure
1. Go to Hospital Chart or Chart
2. Click "More Activities and choose Quick Disclosure"
3. Quick Disclosure opens. Fill out the appropriate fields
   - Purpose Field - type "Research" and choose the appropriate purpose
   - Info Requested - click the magnifying glass to see all categories
   - Authorization Received - click "Third Party" and type "UCD" in requester field then press enter.
   - Authorization Received? - choose "Yes" or "No"
EMR Surveillance Program

- Process by which we review EMR users’ access to patient records to determine if access in the EMR is for a legitimate purpose
- Do this to:
  - Comply with HIPAA requirements that we have appropriate safeguards in place to ensure privacy
  - Comply with HITECH Security rules to ensure we have appropriate monitoring activities
  - Do this to mimic federal privacy audits & ensure compliance with P&Ps
Hypothetical #1:

Surveillance identifies access by CRC Homer to Patient Marge’s PCN encounter on 7/20/15. Homer BTG and entered protocol #123 as the reason.

- We know the following:
  - Protocol #123 was approved on 10/30/14
  - IRB also approved a Waiver for Recruitment purposes on 10/30/14
  - Homer was added to the RPL on 4/25/15
  - There is no signed consent, HIPAA Authorization, or disclosure tracking in Marge’s record

*Is this access appropriate?*
**Answer: YES, but...**

Surveillance identifies access by CRC Homer to Patient Marge’s gynecology encounter on 7/20/15. Homer BTG and entered protocol #123 as the reason.

- Access to record (on 7/20/15) was after IRB approval and waiver (on 10/30/14)
- Homer was on RPL before access (4/25/15)
- However, there is no signed Authorization, so Homer needed to do an Accounting of Disclosure
- **We would also consider whether study still open to recruitment & eligible population**
Hypothetical #2:

Surveillance identifies access by CRC Jill to Patient Jack’s radiology results on 5/1/15. Jill BTG and entered protocol #789 as the reason.

We know the following:
- Protocol #789, a medication trial, was approved on 6/1/15
- IRB approved Waiver for Recruitment on 6/1/15
- Jill was listed on the RPL on 7/1/15
- No signed consent or HIPAA authorization

*Is this access appropriate?*
**Answer: Probably Not.**

Surveillance identifies access by CRC Jill to Patient Jack’s radiology results on 5/1/15. Jill BTG and entered protocol #789 as the reason.

- There is no consent or Authorization in the record
- Jill’s access (5/1/15) was before IRB approval and waiver (6/1/15)
- The only way access would be appropriate was if a Waiver for Preparatory was granted by compliance (and this would require accounting of disclosure)
- Even if waiver was granted, the fact that Jill isn’t on the RPL until 7/1/15 would also raise some additional questions...
Hypothetical #3:

Surveillance identifies access by CRC Homer to Patient Bart’s PCN encounter on 11/1/15. Homer BTG and entered protocol #234 as the reason.

- We know the following:
- Protocol #234, a study of postnatal outcomes, was approved on 10/1/15 with Homer listed on RPL
- IRB also approved a Waiver for Recruitment purposes on 10/1/15
- No signed consent or HIPAA authorization
- Homer entered an Accounting of Disclosures log

*Is this access appropriate?*
Answer: Probably Not.

Surveillance identifies access by CRC Homer to Patient Bart’s PCN encounter on 11/1/15. Homer BTG and entered protocol #234 as the reason.

- Homer accessed the record (11/1/15) after approval with a Waiver of Authorization (10/1/15) with Homer listed on RPL
- Homer is on the RPL
- No signed consent or authorization, but Accounting of Disclosures
- However, Protocol #234 is a study of postnatal outcomes
Thank you!

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