UC San Diego Health

HIPAA Authorization in Research

HIPAA Authorization form for Research

A signed HIPAA Authorization form is required for all subjects enrolled in studies for whom data is accessed, obtained, and/or added to the Electronic Medical Record, or the project must have a Waiver of Authorization approved by the IRB**.** Although federal regulations allow the HIPAA language to be included in the consent form, California state law requires a separate "stand-alone" HIPAA authorization form. The HIPAA authorization form is available in the following languages: English, Cambodian, Farsi, Mandarin, Russian, Spanish, and Vietnamese.

Per MCP 340.1, all research subjects that will be seen or receiving services at any UC San Diego Health facility must have a copy of the signed Informed Consent Form and HIPAA stand-alone form forwarded to Health Information Services (HIS) for filing in the subject's legal medical record.

How to complete a HIPAA Authorization form

HIPAA Authorization form with the following sections completed by the research unit - header, sections A, B, and D - must be provided to the UC San Diego IRB for documentation purposes. Sections C, G, and J must be completed by the research subject. **Do not** alter the HIPAA Authorization's language, ***except*** for the fields in the following sections:

Header
IRB number, name of your specific UC system/unit, study title, Principal Investigator's name, sponsor/funding agency.

Section A - *What is the purpose of this form?*
Insert the name of your health system covered component (i.e. UC San Diego Health).

Section B - *What Personal Health Information will be released?*
Insert PI's name and indicate the minimum necessary information the research team will be accessing by selecting appropriate boxes.

- Ensure it is clear which boxes are selected
- If "Entire Medical Record" is marked, no other checkboxes should be checked.
- Do not delete items from this section
- If the information to be accessed is not listed, select the 'other' box and list the information to be accessed on the line provided

Section C - *Do I have to give my permission for certain specific uses?*
The research subject must initial the appropriate line(s) if specific information is needed to be used for research purposes. If the subject does not initial the line(s), this information cannot be used (accessed / viewed / obtained) for purposes of the research study. If the information in Section C is not being collected in the protocol, having the subject address this section is going beyond the minimum necessary requirement of the HIPAA Privacy Rule 45 CFR 164.502(b), 164.514. If the items in Section C are not applicable, the subject can either write N/A in this section or leave it blank as it does not apply.

Section D - *Who will disclose and/or receive my Personal Health Information?*
Insert the name of the study sponsor and Contract Research Organization (CRO) (if applicable).

Section G - *Optional research activity*
If the research study offers additional optional research activity, and the subject allows his/her information to be disclosed for this activity, s/he must mark the checkbox in this section or initial.

- By leaving this section blank, the subject will automatically opt-out of the optional research activity.

Section J – *Signature*
The subject, parent or Legally Authorized Representative (LAR), and/or witness must sign and date the HIPAA authorization form.

- Witness: is an individual who is independent of the trial and who cannot be unfairly influenced by people involved in the trial. The witness is attesting to the accuracy of the written information that was explained to, and apparently understood by the subject when the subject cannot read the form.

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HIPAA Authorization Form example

IRB#_____

University of California (insert the name of your health system)[1]
Permission to Use Personal Health Information for Research

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

Principal Investigator Name:

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 for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the _____[2] can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by _____[3] 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 _____ to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☐ Entire Medical Record	☐ Lab & Pathology Reports	☐ Emergency Department Records
☐ Ambulatory Clinic Records	☐ Dental Records	☐ Financial records
☐ Progress Notes	☐ Operative Reports	☐ Imaging Reports
☐ Other Test Reports	☐ Discharge Summary	☐ History & Physical Exams
☐ Other (describe)	☐ Consultations	☐ Psychological Tests

[1] Each UC Health System or business unit may elect to leave this as UC or add the name of their specific
[2] The name here should match how the organization is identified in the Notice of Privacy Practices.
[3] The name here should match how the organization is identified in the Notice of Privacy Practices.

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.

D. Who will disclose and/or receive my Personal Health Information??

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor (insert the name of the sponsor) or the sponsor's representatives including but not limited to (insert the name of the CRO), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

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H. **Does my permission expire?**

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. **Can I cancel my permission?**

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. **Signature**

Subject

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

_____

Subject's Name (print)–*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____

Parent or Legally Authorized Representative's Name (print) Relationship to the Subject

_____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date

UC HIPAA Research Authorization 2014

Please send your questions, comments, and feedback to the Research Compliance Program at rcp@ucsd.edu or (858) 657-7487.

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