

Research and Privacy Protection at the University of California

Introduction

The following Frequently Asked Questions have come up in discussions with clinical trial sponsors who are viewing the UC Research Authorization form for the first time.

Frequently Asked Questions about the UC Research Authorization Form

1. Why is UC's Research Authorization form constructed as it is?

The UC Research Authorization form is constructed to comply with both HIPAA and the California Confidentiality of Medical Information Act, California Civil Code Sec 56 – 56.16 (CMIA). HIPAA and the CMIA define protected health information differently and contain different rules concerning subject Authorization to release health information for research.

Research is not a covered function under HIPAA and research is not a HIPAA-covered function at UC. When PHI is disclosed to a researcher at UC, it is released from the Covered Entity, e.g., UC medical centers, medical clinics, health care providers, health plans, and student health centers, to a non-covered entity, i.e., the researcher. The UC Research Authorization covers the disclosure from the Covered Entity to the researcher. In those cases where the sponsor receives Protected Health Information from the researcher and does not receive information directly from the Covered Entity, no HIPAA Authorization is required. However, if the information released contains CMIA-defined medical information, a CMIA Authorization is required.

CMIA defines medical information as individually identifiable medical information regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes an element that identifies the individual, such as the patient's name, address, email address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity. Cal.Civil Code 56.05(g). The CMIA provides exceptions to the authorization requirement for release of personal health information, including disclosure for bona fide research or as "otherwise required by law."

The Research Authorization form meets both HIPAA and CMIA requirements by explaining to the subject the circumstances under which identifiable information may be released to researchers and sponsors. The Authorization form also explains the difference between identifiable information that may be released as required by law, and unidentifiable information that may be released as defined by the CMIA.

2. Why is the term Personal Health Information used instead of Protected Health Information?

The term “Personal Health Information”: 1) captures the meaning of both protected health information (HIPAA term) and medical information (CMIA term); 2) communicates to the research subject that the information is “personal;” and 3) is understandable at an 8th grade reading level. It is a coincidence that the acronym for Personal Health Information and Protected Health Information is identical. In practice, UC does not intend to use an acronym for Personal Health Information and has not done so in the Research Authorization.

3. Some sponsors want the Authorization form to notify subjects that they will not be allowed access to their research information during the course of the study. Why has UC not included this language in the Authorization?

Information that is maintained in a medical record is covered by HIPAA, and HIPAA allows patient access to medical records in most circumstances. Thus, if the subject is to be restricted from accessing the research information in the medical record they have to be advised of the restriction. But research is not a HIPAA covered function at UC and therefore information created or maintained by researchers is not available for the subject to review. Therefore, the subject need not be advised that they do not have access to the research data because they do not have that right anyway. Sponsors may be confused about this issue because some academic medical centers have included research as a covered function under HIPAA. At those institutions, the subject would have access to research data, and would have to be advised of the restriction on access to research data.

4. Why is the expiration date stated this way? Why isn't there an option for “no expiration”?

The UC Research Authorization form does not provide for “no expiration” because the CMIA requires a subject’s authorization to state “the length of time during which the information will be kept before being destroyed or disposed of.” 56.104(a)(2). In addition, subjects should not have to authorize open-ended access to their medical records for purposes unrelated to the specific research project for which they gave their consent. Accordingly, the subject gives permission for release of specific personally identified medical information used in the research only until the study and all required monitoring is complete. The Research Authorization form also makes clear that there is no expiration date for the use of Research Reports, which contain study data that is stripped of the subject’s name, address, telephone, and social security number.

5. Can a sponsor audit the source documents contained in the official medical record to verify the accuracy of research reports?

Yes, under limited circumstances. Access to subjects’ medical records containing individually identifiable patient information may be granted to sponsors for the limited

purpose of auditing data quality and monitoring the study as required under FDA regulations. Such disclosure is allowed under the CMIA without authorization by the subject because the disclosure is authorized by law (Cal. Civil Code sec. 56.10(c)(14)). The disclosure is also allowed under HIPAA (45 CFR 164.512(b)).

Section D of the UC Research Authorization form notifies the subject of the possibility that the sponsor, the FDA, and other regulatory agencies may access their medical records containing identifiable information to monitor the quality and safety of the study when required by law. If a company supporting the research is not the regulatory “sponsor” with the legal authority for such access, the company may not access medical records unless a revised authorization specific to the study and which complies with all CMIA requirements is obtained from the subject. Such an authorization would require the review and approval of UCOP and the IRB. However, in most investigator-initiated studies, the company need not have access to records containing direct identifiers such as the subjects’ names, addresses, or social security numbers. The company may (with the Principal Investigator’s concurrence) be provided with copies of case report forms, or “research reports” as described in the UC Research Authorization, and/or technical reports summarizing the results of the study.

6. Can a sponsor of an FDA-regulated trial continue to monitor or audit source documents generated during the trial after the expiration date?

Yes, if the monitoring is required by or allowed under other laws. A company sponsor and its authorized representatives may continue to monitor or audit source documents so long as the time period is anticipated under the laws, even if the study has concluded. If the sponsor has a duty to monitor the source documents supporting the data submitted to the FDA under FDA regulations, HIPAA does not require an authorization (Section 164.512 (b) (iii)). However, UC decided to include authorization for these required audits so that the UC covered entity does not have to track such disclosures in order to provide an accounting of disclosures to the subject if requested, as would be required under HIPAA in cases where a legally required disclosure is made without authorization from the subject.

7. Can adverse events and other developments required to be reported to the FDA, the sponsor, or other agencies be reported without the subject’s authorization or after the Authorization form has expired?

Yes. Reporting of adverse events can occur without the subject’s authorization, pursuant to HIPAA Section 164.512(a) and CMIA Section 56.10(c)(14). The UC Research Authorization form secures approval for certain monitoring and auditing of source documents (e.g., medical records held by a UC HIPAA covered entity) during the conduct of FDA-regulated clinical trials. Voluntary reporting of adverse events may continue as required under applicable regulations if adverse events occur after FDA approval of the study drug application, during a study that is not FDA-regulated, or during post-marketing approval.

8. Why can't the UC Research Authorization form be modified or a sponsor's Authorization form used?

The UC Research Authorization form may not be modified because: 1) of the complexities of both HIPAA and the CMIA; 2) of the significant amount of analysis required to ensure compliance with all applicable laws; 3) of the continuing obligations and duties under CMIA once the identifying information is released; and finally 4) UC is the entity responsible for maintaining the confidentiality of health information of research subjects and is responsible for compliance with HIPAA and the CMIA. UC cannot use sponsor forms, nor can modifications be made on a project-by-project basis. Nonetheless, the UC Office of the President regularly reviews its HIPAA implementation. Suggestions for improvement in the clarity and workability of the UC-wide form should be sent to Rebecca.Landes@ucop.edu, with a copy to Barbara.Yoder@ucop.edu.

9. Can information about HIPAA be included in the research study's informed consent form?

It is unadvisable to include information about HIPAA in the informed consent form. Other than referencing the UC Research Authorization, the consent form should not cover the same topics covered in the Authorization. This eliminates the possibility of contradiction and helps to limit the complexity of the consent form. However, new information about how the UC research records will be stored and protected, and what study data will be shared with the subject, are certainly appropriate information to be included in a consent.

10. How can "Research Reports" (Section E of the Research Authorization) be used? Are there any restrictions on access or use?

In general, research reports include information that would be included on a "case report form"—health information created, received or maintained by the research team in the course of the study and dates of service, birth/death, randomly created identification numbers and initials. This information is considered identifiable health information under HIPAA, and use of this data must meet all HIPAA requirements when the covered entity discloses it to a researcher. However, this information is not "medical information" under the CMIA because it does not contain information that directly identifies the subject, such as their name, street address, telephone or social security number, and also does not contain data that in combination with other publicly available information could be used to specifically identify the subject.

In most cases, UC researchers and team members can use the records containing the personally identifiable health information to conduct the study, and then generate a data set of the study results that eliminates all the direct identifiers, including the subject's name, address, telephone and social security number, instead reporting the results under a study identification number. The data set using the study identification number can then be shared with the sponsor and other researchers, or used for other purposes,

and no authorization would be necessary since the data set does NOT meet the definition of “medical information” under the CMIA, and is no longer covered by HIPAA.

11. What should be done if the sponsor desires access to records containing a subject’s identity and the project does not qualify as an FDA-regulated clinical trial or there is no “otherwise required by law” provision that would allow the sponsor’s access to individually identifiable information without authorization?

If the sponsor seeks access to research records containing identifiable information but such access does not qualify for a CMIA exception to authorization, such as “otherwise required by law,” the subject’s authorization must be obtained. Alternatively, identifiable information may be redacted from the records prior to the sponsor viewing them. Redaction is an administrative burden and expense, but if the sponsor is willing to pay the cost and the project staff is willing to assume the additional work, this is the best solution for a sponsor that insists upon inspecting source documents that contain a subject’s identity.

12. What will the sponsor and the University have to do if release of CMIA-covered medical information is to be made to others besides the UC researcher and the release does not qualify for a CMIA exception to authorization?

CMIA permits disclosure to researchers for bona fide research purposes without authorization. Therefore, in limited circumstances, other non-profit research institutions and universities may receive individually identifiable information for bona fide research and still qualify under the CMIA exception from obtaining an authorization. For all other disclosures, the subject’s authorization for disclosure of identifiable information must be obtained. If the sponsor has a compelling reason for receiving the subject’s name, address, telephone, social security, or medical record number along with other research data, then a unique Research Authorization form that meets CMIA requirements must be crafted for the project. The requesting entity must make a separate request, describing with specificity:

- What CMIA covered records are being requested?
- How will the sponsor use the subject’s identity information?
- How will the sponsor protect the identity information, including a description of how and when the records containing names and social security numbers will be destroyed?
- Names of the individuals or entities to whom the records will be re-disclosed, if any, and a description of the uses and protections provided by that entity.
- Acknowledgement of the duty to secure another authorization from the subject for any use or disclosure not previously authorized or allowed under CMIA, and acknowledgement of the duty to inform any recipients to whom the sponsor releases the records of the limitations and restrictions on the use of the records and the continuing duty to secure subsequent authorizations from the subject for any other use or disclosure.

Using this information, the campus in consultation with General Counsel, the Office of the President HIPAA Privacy Officer, and the Office of Research would craft a unique Research Authorization for use in the specific project.

Questions concerning the UC Research Authorization should be sent to Rebecca.Landes@ucop.edu, with a copy to Barbara.Yoder@ucop.edu.