Institutional Review Board Administration

OFFICE OF RESEARCH, University of California, Davis
CTSC Building, 2921 Stockton Blvd., Ste. 1429, Sacramento, CA 95817
http://www.research.ucdavis.edu/IRBAdmin

Guidance: Examination of Medical Records for Research

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BACKGROUND
Research studies requiring examination of medical records must be submitted to the IRB or HIPAA Privacy Board for review and approval prior to accessing these records. In addition, research studies that use or access medical records as a source of personally identifiable research data are using Protected Health Information (PHI) and the investigator must comply with HIPAA and state regulations.

PRIVACY RULE
The Privacy Rule's intention is to protect the confidentiality, integrity, and availability of protected health information, which the University creates, accesses, transmits, or receives in both research and patient care settings. It sets forth specific requirements for the adoption of administrative, physical, and technical safeguards for the protection of health information. All research that will enroll subjects (including existing studies) AND obtain subjects' PHI will need to comply with the Privacy Rule regulations.

According to the Privacy Rule, if a researcher wants to obtain an individual's PHI from the institution, the investigator must obtain IRB approval and must either:

- obtain permission from the individual(s) whose PHI is being accessed through a Research Authorization form(s), **OR**
- obtain a Waiver of Research Authorization from the IRB/Privacy Board by completing the HIPAA worksheet provided in the IRB application forms.

EXEMPTION REVIEW
Due to the sensitive nature of accessing protected health information, the UC Davis IRB no longer accepts exemption applications for medical records review studies or studies that access PHI. Investigators may seek expedited or full committee review.

EXPEDITED REVIEW
Medical records review may qualify for the expedited level of review only if the research presents no more than minimal risk to subjects. In addition, expedited research requires informed consent of all participants unless the IRB grants a waiver of informed consent and HIPAA authorization. It is common practice for IRBs to grant waivers of informed consent and HIPAA authorization for medical record review studies, but investigators must provide justification for such waivers. In order to be granted a waiver of informed consent, investigators must complete the "Waiver of Informed Consent" section of the IRB application form.

The expedited category typically used for medical records review is category 5, "Research involving materials (data, documents, records, or specimens) that have been collected; or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)." For a complete list of the expedited categories go to: http://www.research.ucdavis.edu/documentDisplay.cfm?ID=178,PDF.

Please note: if the expedited reviewer determines that the risk level is greater than minimal risk, the study application must be submitted for full committee review.

FULL COMMITTEE REVIEW
All research involving the review of medical records and do not qualify for expedited review must be submitted for full IRB committee review. Also, investigators must obtain informed consent of participants or provide justification for a waiver of informed consent and HIPAA authorization in the IRB full committee application form.

Should you have any questions regarding this guidance information, please contact IRB Administration at 916-703-9151 or visit www.research.ucdavis.edu/IRBAdmin.