

Accessing Patient Data for Research

In order to properly assess an individual's eligibility and ongoing participation in a research study it may be required that a researcher or research staff review a participant's hospital medical charts (paper and electronic records). In most cases, if researchers are participating in industry-sponsored clinical trials, the sponsor will send a monitor to the research sites regularly to monitor a clinical trial, and therefore will need access to these same records for verification of a site's source documents for auditing purposes.

Accessing Patient Records for Researcher and Research Staff

Patient record access by researchers and research staff is obtained through the Medical Records Department (KIDD 1) in the Kingston General Hospital, by completing the *KGH/HDH Data Request Form for Pulling Medical Records*. A copy of the latest Research Ethics Board (REB) Approval/Renewal Letter for the research study must be appended to the request form. Once completed, the documents are returned and kept on file under the researcher's name within the Medical Records Department. Researchers and research staff must read the *Kingston General Hospital's Basic Rules of Confidentiality*.

Each time the researcher or research staff requires paper medical charts to be pulled, a letter detailing the title of the study, the name of the researcher, the REB approval number, and a list of subjects (CR number included) is to be provided to Medical Records. Medical charts are usually stored at Hotel Dieu Hospital; therefore 48-72 hours notice may be required to access the medical charts. The review of the paper medical records by a researcher or research staff is to occur in the reading room located in the back of Medical Records.

Researchers and research staff can obtain access to the electronic records through chart review in the PCS system. Training courses on how to use the PCS system and to gain access to the PCS system can be obtained through the KGH Leadership and Learning Services by contacting Kris Ellis, Organizational Development Advisor, at 613-549-6666, extension 4533 or ellisk@kgh.kari.net.

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Accessing Patient Records for a Monitor

Once a researcher has completed the *KGH/HDH Data Request Form for Pulling Medical Records* and a copy of the latest REB Approval/Renewal Letter is on file within the Medical Records Department, patient medical records can be retrieved for a monitor of industry-sponsored clinical trials. Researchers or research staff must have the monitor read the *Kingston General Hospital's Basic Rules of Confidentiality* and complete the *Confidentiality Agreement for Accessing Information by Non-Hospital Staff*, preferably at the site initiation visit, before the research study starts enrolling participants into the study. Once completed, the documents are returned and kept on file under the researcher's name within the Medical Records Department. The Medical Records Department will then submit a computer access form to KGH Help Desk to have an account set up and activated for the monitor.

When a monitor is required to be on site for study-related visits, the researcher or research staff must notify the Vice President, Health Sciences Research (ext 3344) in advance of the monitoring visits. Upon notification of the monitoring date(s) and name(s) of the individual(s) attending the visit, the Office of Health Sciences Research will send an email to Security authorizing the monitoring visit so that the monitor(s) can obtain a visitor pass in order to access the hospital. On the day of the monitoring visit, the individual must report to the Security Desk in the front lobby to obtain their visitor's pass prior to entry into the hospital.

The Medical Records Department will also need to be notified in advance when a monitor is arriving on site, if they wish access to the electronic records. On the day of the monitoring visit, they are to report to Deb Sapp (ext 4655) in Medical Records (KIDD 1) with a list of subjects (CR numbers included), and she will get them set up at a computer and show them chart review in the PCS system.

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Retention of Records for Clinical Trials

Health Canada requires that all source documents, including medical records of subjects participating in clinical trials must be retained for 25 years. Medical Records follows the Public Hospitals Act, which delineates that all medical records be maintained for a period of 10 years after the date of discharge or death, except in the case of patients who are under eighteen years of age. In this case, the record must be kept for 10 years following the patient's eighteenth birthday, after which time it may be destroyed. The value of the record as a teaching and research tool and administrative requirement will impact the record retention and destruction policies of the hospital. For the exact length of record retention, please refer to KGH policy 9-180 (*Patient Records: Retention/Destruction*).

Researchers and research staff can notify their industry, granting or other funding agency that portions of individual medical records will be maintained electronically with no plans on deletion at any point; they may be archived on a parallel server if that becomes necessary.

In order to ensure that all portions of electronic and paper medical charts are kept for 25 years for clinical trials, researchers or research staff need to notify Medical Records in order to have the medical charts flagged. At the completion of each clinical trial, researchers or research staff needs to provide Medical Records with a letter detailing the title of the study, the name of the researcher, the REB approval number, and a list of subjects (CR number included).