

In This Issue

- Researcher, Research Staff, Student, & Trainee Access to Medical Records for Research
- Medical Record Access Requests for Research
- Visitor's Pass for a Research Monitor/Auditor or Sponsor/CRO Representative
- Medical Record Access for a Research Monitor/Auditor
- Retention of Research Records



Accessing Medical Records for Research

In order to assess an individual's eligibility and ongoing participation in a research study or to extract patient data for a research project, it may be required that a researcher, research staff, student and/or trainee 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 these individuals will need access to these same medical records for verification of a site's source documents for monitoring and/or auditing purposes.

RESEARCHER, RESEARCH STAFF, STUDENT & TRAINEE ACCESS TO MEDICAL RECORDS FOR RESEARCH

Principal Investigators are responsible to ensure that requirements for medical record usage in research are specified as indicated when applying for HSREB clearance. *KHSC-Medical Records* should be selected in the TRAQ DSS form on the Approvals Tab.

Access to medical records (Patient Care System (PCS) Clinical Desktop) for researchers, research staff, students, and trainees is obtained by completing a KHSC Computer Access Request Form (CARF) and identifying "Patient Care System" as one of the systems to which you need access. For more information about this form, please see "[Research Roadmap: Computer Access at KHSC](#)".

<http://www.kingstonhsc.ca/research>

Contact:

kgfri@kingstonhsc.ca

(613) 549-6666, ext. 8171

There are online training courses available on the KHSC Intranet through KHSC's KnowledgeNow. When logged into a KHSC computer you can search for various "PCS" courses. The online course [PCS General User Orientation](#) is a beginner course. You will be able to take the course to familiarize yourself with navigating within medical records. You must have a KHSC username and password to access this course through KnowledgeNow. A KHSC username and password is issued once your KHSC CARF application is approved. For more information about PCS Clinical Desktop training, please contact the Coordinator, Leadership & Talent Development at 613-549-6666, ext. 4533 or knowledgenow@kingstonhsc.ca.

It is important to note that medical records must be verified to ensure that consent for research has not been withdrawn by a patient if extracting patient data for research purposes. To verify whether consent for research purposes has been withdrawn within PCS Clinical Desktop, researchers, research staff, students and trainees can use one of the following options, depending on your computer workstation:

Option 1:

- 1) Log onto the PCS Clinical Desktop using your personalized KHSC username and password.
- 2) Search the name of the patient that you wish to contact (CR number) and open up their medical record.
- 3) Located either within the top bar or sidebar of your screen, find the "*Other Review*" category, and click/double-click on "*View Demographics*".
- 4) Under "*CPR Registration-Chart View*" choose Option #4 by clicking/double-clicking on "*Patient Flags*".
- 5) Look under the category "*Withdrawal of Consent*": as long as there is a "*NO*" next to the category of "*Research*", then you may use the patient data or contact the patient to inquire about their interest to participate in your research project.

Option 2:

- 1) Log onto the PCS Clinical Desktop using your personalized username and password.
- 2) Search the name of the patient that you wish to contact (CR number) and open up their medical record.
- 3) Located either within the top bar or sidebar of your screen, find the "*Patient Records*" category, and click/double-click on "*Chart Review*".
- 4) Under "*Chart Review Options*" choose Option #4 by clicking/double-clicking on "*Face Sheet*".
- 5) Under "*Patient Care*" choose Option #3 by clicking/double-clicking on "*Reg/Visit Information*".
- 6) Look at the space where choice #10 should be located– if you find two asterisks (**) in this location where #10 should be then the patient has not withdrawn consent to be contacted for research: you may use the patient data or contact the patient to inquire about their interest to participate in your research project. If the #10 is written there, click on it and view the date consent was withdrawn.

If you contact a patient about their interest in participating in your study as a research participant and the patient indicates that they would like to withdraw their consent to be contacted for research and/or for surveys, fundraising, etc., please indicate that this request must be made in writing by completing a form at a KHSC Registration Desk. On this form patients can indicate in which category they wish to withdraw their consent to be contacted or they can request that they wish to withdraw their consent to be contacted for all purposes. If research participants have any questions or concerns regarding their personal health information and/or privacy, please direct them to contact KHSC's Privacy Office and/or Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB):

Andrew Rogers
Privacy Officer (KHSC)
(613) 549-6666 ext. 6640
privacy@kingstonhsc.ca

Dr. Dean Tripp
Chair of Queen's HSREB
(1-844) 535-2988
dean.tripp@queensu.ca

In accordance with KHSC Health Research policy 11-150, off-site (remote) access to medical records (PCS Clinical Desktop) will only be granted under exceptional circumstances to research staff, medical, undergraduate and graduate students, post-doctoral fellows, volunteers and trainees. Access to PCS is available from within the hospital firewall. Appropriate data encryptions/storage requirements must be followed when transporting data to or from KHSC.

MEDICAL RECORD ACCESS REQUESTS FOR RESEARCH

If researchers, research staff, students and/or trainees wish to access paper medical records which are not available electronically in PCS, they should contact the KHSC Medical Records Department at least two weeks in advance. A copy of the HSREB clearance or most current renewal letter for the research study, valid KHSC ID badge, and list of CR numbers will be required. Reimbursement for accessing the paper records will also be required. The time needed to obtain these records cannot be guaranteed. The review of the paper medical records by students, and/or trainees will occur in the KHSC Medical Records Department. The medical records may not be taken back to research space.

VISITOR'S PASS FOR A RESEARCH MONITOR/AUDITOR OR SPONSOR/CRO REPRESENTATIVE

A KHSC "Visitor's Pass" is required for any individual(s) on hospital premises who will be monitoring/auditing a research project or will be onsite for a feasibility/selection visit for an upcoming research project. A Visitor's Pass is not required if the individual is a KHSC employee, has a KHSC Research Hospital Appointment or already has a KHSC ID Badge (i.e. student/trainee).

For more information about obtaining a Visitor's Pass, please see "[Research Roadmap: Visitor Pass](#)".

MEDICAL RECORD ACCESS FOR A RESEARCH

MONITOR/AUDITOR

KHSC must authorize access to personal health information (PHI) for external visitors before they may review any paper-based or electronic medical records on-site and/or remotely. In order for a research monitor/auditor to access medical records, they must complete the *KHSC Confidentiality Agreement for Accessing Information by Non-Hospital Staff* (available from KGHRI) and review applicable hospital policies. When a monitor/auditor is required to be on site for study-related visits, the researcher or research staff, must notify the Medical Records Department at least two weeks in advance of the monitoring/auditing visit if there is a need for the monitor/auditor to access paper medical records. On the day of the monitoring/auditing visit, the researcher or research staff should report to the Medical Records Department with a list of participants (CR numbers included). Principal Investigators (Faculty) and research staff (Research Coordinators/Research Assistants) may transport paper medical records to a space reserved for an external Monitor visit provided those records are signed out and returned on the same day. If paper records are required for more than one day they must be returned at the end of each day and signed out again the next day.

NOTE: External visitor access to the KHSC EMR systems does not restrict access to only those patients participating in the research study. Their access is subject to KHSC privacy checks, as per hospital policy. If a privacy breach occurs, they must immediately notify the research staff who will initiate the required steps for notification to the KHSC Privacy Office. Site research staff and KHSC Privacy Office will appreciate the external visitor's assistance in this notification and review process, if applicable. External visitors must also remember to follow their own sponsor's privacy breach processes.

RETENTION OF RESEARCH RECORDS

Researchers are responsible for keeping their research data intact for the mandated amount of time and destroying the data by confidential means once the retention period has been attained. The timeframe is dependent on the research study type, funding agency conditions, and local/central research ethics board/governing oversight authority requirements. Funding agencies such as CIHR require grant recipients to retain original data sets for a minimum of five years (or longer if other policies apply) after the end of the grant. Industry sponsored studies (drug, device or natural health product clinical trials) generally require original data to be maintained for a minimum of 15-25 years, as per Health Canada regulations, please see [KHSC Policy 11-153 Long Term Storage of Clinical Trial Records](#). The HSREB requires that research records be retained

for a minimum of 5 years from the date of study closure or longer if mandated by a legal requirement or an applicable funding or oversight agency. Each funding agency/oversight authority will have their own guidelines, so researchers are encouraged to check with them and keep their research data in the original format for the maximum time period.

KHSC's Medical Records Department follows the Public Hospitals Act, which delineates that all medical records be maintained for a period of 15 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 KHSC's 09-180 Policy (Patient Records: Medical Records Retention/ Destruction). It is the Researcher's responsibility to contact KHSC's Medical Records Department if medical records are required to be retained longer than what is dictated by the Public Hospitals Act for research purposes so that a process can be determined. Researchers will be responsible for all costs associated with this process.

When Researchers are in a position to destroy any research records, they can call KHSC's Housekeeping at extension 7250 at either site for service. Researchers will be provided with a large grey or blue confidential locked bin on wheels in which to discard the documents. Additional grey/blue confidential locked bins can be provided as required. Researchers are to contact Housekeeping at extension 7250 when the bins are full and ready for pick-up. KHSC's Housekeeping will take care of shredding the confidential materials via safeguarding measures put in place with their preferred vendor.

Please note:

All hospital and non-hospital researchers who are given access to patient data are bound by the KHSC Statement of Confidentiality as per KHSC Health Research policy 11-150, and are responsible for de-identification of any data for their project. All non-hospital researchers are required to be credentialed through KHSC's Research Hospital Appointment process. For more information about the Research Hospital Appointment process and computer access at KHSC, please see "[Research Roadmap: Research Hospital Appointments](#)" and "[Research Roadmap: Computer Access at KHSC](#)".

KHSC's Decision Support Department offers services for researchers, research staff, students, and trainees who are seeking potential participants or data for their research project. For information about Decision Support services, please see "[Research Roadmap: Decision Support Services](#)".

Any actual or perceived breach of privacy if associated with research must be reported immediately to the Queen's HSREB (or central REB (CTO/OCREB)), KHSC's Privacy Office (contact details above) and KGHRI, please see [KHSC 01-226 Privacy Breach in Research](#) policy.