

# Research Road Map

April 2017

Accessing Patient Data for Research Issue

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## Accessing Patient Data for Research

In order to properly 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 PATIENT RECORDS FOR RESEARCH

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 Form and identifying "Patient Care System" as one of the systems that you need access to. For more information about this form, please check out "[Research Roadmap: Computer Access at KHSC](#)".

<http://www.kgh.on.ca/research>

Contact:

[kghri@kgh.kari.net](mailto:kghri@kgh.kari.net)

(613) 549-6666, ext. 3344

There are online training courses available to anyone on the KHSC Intranet through KHSC's Learning Management System (LMS). When logged into a KHSC computer you can search for various "PCS" courses. "Online Course PCS008: PCS General User Orientation" is a good course to start with. 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 LMS. A KHSC username and password is issued once your KHSC Computer Access application is approved.

As a reminder, you need to verify within each medical record that consent for research has not been withdrawn by a patient if extracting patient data for research purposes. To verify if consent for research purposes has not been withdrawn within PCS Clinical Desktop, researchers, research staff, students and trainees can use one of the following steps, depending on your computer workstation: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 than 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 and the patient indicates that they would like to withdraw their approval for consent for research and/or for being approached about surveys, fundraising, etc., please indicate that this request must be made in writing by completing a form from the KHSC Registration Desk. On this form patients can indicate 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 patients have any questions or concerns regarding their personal health information and/or privacy, please direct them to contact the KHSC Privacy Office and/or Queen's University Health Sciences and Affiliated Teaching Hospitals (HSREB):

Karen Hanewich  
Privacy Officer (KHSC)  
(613) 544-2631, ext. 2567  
[privacy@kgh.kari.net](mailto:privacy@kgh.kari.net)

Dr. Albert Clark  
Chair of HSREB  
(844) 535-2988  
[clarkaf@queensu.ca](mailto:clarkaf@queensu.ca)

It is a policy at KHSC that off-site (remote) access to medical records (PCS Clinical Desktop) will not be granted to research staff, medical and graduate students, post-doctoral fellows, and volunteers and trainees, all of whom are currently able to gain access to this database from within the hospital firewall. This decision was made after consideration of privacy issues and the risk of a breach of confidentiality, as well as a survey of other academic/research hospitals in Ontario and across Canada. KHSC decided that it would follow what is clearly the prevalent policy in the province. PCS Clinical Desktop access will need to be within KHSC's firewall to obtain any research data that research staff, students and/or trainees need to work with off-site and they must ensure proper data encryptions/storage requirements are followed when transporting data to/from KHSC.

### **MEDICAL RECORDS REQUESTED TO BE PULLED FOR RESEARCH**

If researchers, research staff, students and/or trainees wish to have medical records pulled to be viewed for research by KHSC's Medical Records Department (Kidd 1), they must complete the "*KGH/HDH Data Request Form for Pulling Medical Records*". A copy of the HSREB approval letter or renewal letter for the research study must be appended to the request form prior to submission. Once submitted the documents are kept on file under the researcher's name within KHSC's Medical Records Department for future requests to pull medical records for your project. Researchers, research staff, students and trainees must read the *Kingston Health Science Centre's Basic Rules of Confidentiality*.

Each time you require access to paper medical records to be pulled, a letter detailing the title of the study, the name of the researcher, the HSREB approval number, and a list of subjects (CR numbers included) is to be provided to KHSC's Medical Records Department. Medical records are usually stored at KHSC-Hotel Dieu Hospital Site; therefore 48-72 hour notice may be required to access the medical records. The review of the paper medical records by researchers, research staff, students, and/or trainees is to occur in the reading

room located in the back of KHSC's Medical Records Department. The medical records should not be taken back to your research space. Access to electronic medical records for a patient is through PCS Clinical Desktop which you can access from any KHSC computer. For more information about PCS Clinical Desktop training, please contact Karen Allan (eLearning & Technical Administrator) 613-549-6666, ext. 4533 or [allank@kgh.kari.net](mailto:allank@kgh.kari.net).

### **VISITOR'S PASS FOR A RESEARCH MONITOR**

A "KHSC Visitor's Pass" is required for any individual(s) on hospital premises who are monitoring or auditing a research project. A "Visitor's Pass" is not required if the individual is a KHSC employee or has a Research Hospital Appointment or already has a KHSC ID Badge (i.e. student/trainee). KHSC's Vice President of Health Sciences Research must be notified in advance of the monitoring/auditing visit(s). Upon notification of the monitoring/auditing date(s), name(s) of the individual(s) attending the visit, and institution/company/regulatory agency name(s) where the individual(s) works, KHSC's Office of Health Sciences Research will send an email to KHSC's Protection Services Office authorizing the monitoring/ auditing visit so that the monitor(s)/auditor(s) can obtain a "Visitor's Pass" in order to access the hospital premises. On the day of the monitoring/auditing visit, the individual must report to KHSC's Protection Services Kiosk in the front main lobby to obtain their "Visitor's Pass" immediately upon entry into the hospital. Researchers, research staff, students and/or trainees should meet this individual in the main front lobby and escort them to KHSC's Protection Services Kiosk to pick up their "Visitor's Pass". The "Visitor's Pass" must be returned at the end of each visit day. If the monitor/auditor is on site multiple days in a row, they must report in/out at KHSC's Protection Services Kiosk daily. To request a "Visitor's Pass", please send your information to Lisa McAvoy at [mcavoyl@kgh.kari.net](mailto:mcavoyl@kgh.kari.net).

### **ACCESSING MEDICAL RECORDS FOR A RESEARCH MONITOR**

In order for a research monitor/auditor to access medical records, a "*KHSC Data Request Form for Pulling Medical Records*" must be on file in KHSC's Medical Records Department. In addition, the monitor/auditor must have read "*KHSC's Basic Rules of Confidentiality*" and have completed the "*Confidentiality Agreement for Accessing Information by Non-Hospital Staff*". Once completed, the documents are returned and kept on file under the researcher's name within KHSC's Medical Records Department. The KHSC Medical Records Department will then submit a computer access form to KHSC's Help Desk to have an account set up and activated for the monitor/auditor.

When a monitor/auditor is required to be on site for study-related visits, the researcher, research staff, student and/or trainee must notify KHSC's Medical Records Department in advance of the monitoring/auditing visit if there is a need for the monitor/auditor to access paper and/or electronic medical records. On the day of the monitoring/auditing visit, the monitor/auditor (accompanied by the researcher, research staff, student or trainee) are to report to Maureen Lansbergen (KGH Site ext. 4655 or [lansberm@kgh.kari.net](mailto:lansberm@kgh.kari.net)) in KHSC's

Medical Records Department (Kidd 1) with a list of participants (CR numbers included) and she will get the monitor/auditor set up at a workstation/computer and show them chart review in the PCS Clinical Desktop system. If the monitor/auditor requires reviewing paper medical charts, a list of subjects (CR number included) is to be provided to KHSC's Medical Records Department 48-72 hours in advance of the monitoring/auditing visit as the records are stored at KHSC-Hotel Dieu Hospital Site. The review of the paper medical records by a monitor/auditor is to occur in the reading room located in the back of KHSC's Medical Records Department.

## **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 time frame is dependent on the research study type, funding agency conditions, and local 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 studies (drug trials) generally require original data to be maintained for a minimum of 25 years, according to Health Canada. The HSREB requires that research records are retained for a minimum of 5 years from the date of publication or other form of presentation or longer if mandated by a legal requirement or an applicable funding or oversight agency. Remember: 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 greatest time period.

KHSC's Medical Records Department 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 KHSC's 09-180 Policy (Patient Records: Medical Records Retention/Destruction).

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

If researchers are now in a position to destroy any research records, they can contact KHSC's Environmental Services Department and provide them with the

number of banker boxes of documents to destroy. KHSC's Environmental Services Department will determine whether to drop off a big bin to your research area or have you shred the documents and then they will take away the boxes. At KHSC-KGH Site, please contact Environmental Services Administration at KGH Site ext. 2309 or [conroyd@kgh.kari.net](mailto:conroyd@kgh.kari.net). At KHSC-HDH Site, please contact Housekeeping at HDH Site ext. 3031 or [hdhfacilities@hdh.kari.net](mailto:hdhfacilities@hdh.kari.net).

## SERVICES OF DECISION SUPPORT

KHSC's Decision Support Department offers services for researchers, research staff, students, and trainees who are seeking potential patients (participants) for their research project. Data sources that this department use include, but are not limited to, the KHSC Patient Care System (PCS), the Local and Provincial Canadian Institute for Health Information (CIHI) Inpatient Data (Discharge Abstract Database (DAD)), the Local and Provincial CIHI Ambulatory Data (National Ambulatory Care Reporting System (NACRS)), and the Operating Room Data (Operating Room Scheduling Office System (ORSOS)). There are two types of scenarios that this Department can assist you with:

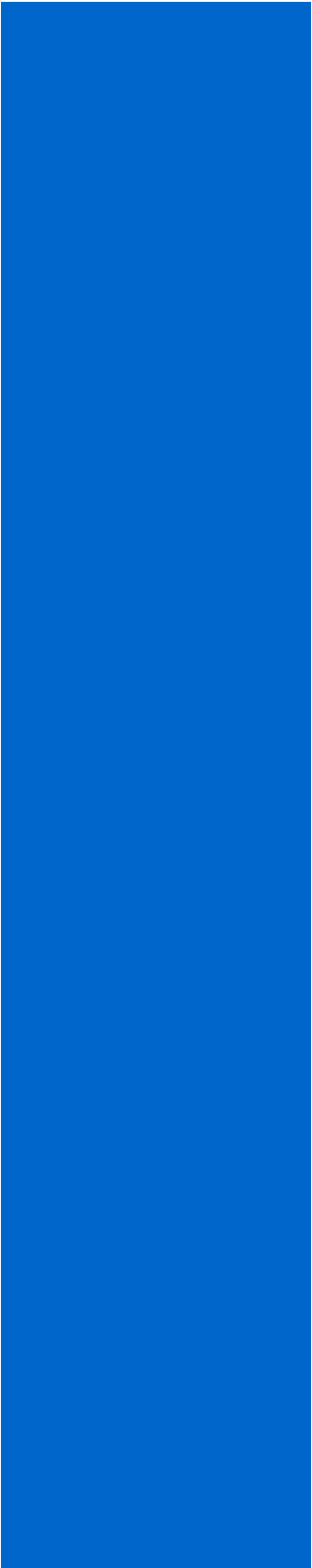
- **Sample Size Determination for Potential Patients**

If you need assistance with determining if a particular patient population exists in our geographical area, this Department can provide you a sample size estimate of the number of patients that meet your eligibility criteria. This service is useful when determining whether your site is feasible for participation in an upcoming clinical trial, completing a grant application, or simply determining if you can find suitable candidates for your newly developed research project. No approval of the HSREB is required. Remember: the outcome of your request will only produce the possible number of subjects; if you want identification of these potential subjects, you will need to follow the instructions listed under the next section.

- **Extracting a List of Potential Patients to Contact**

If you need to recruit subjects for your research study, this department can provide you with a list of names of potential patients that match your patient population/eligibility criteria for your research study. All names on the list have been verified that the patient has not "*withdrawn consent for contact for research purposes*". Your research study must be submitted and approved by the HSREB and also approved through the TRAQ system (TRAQ DSS FORM) prior to the release of the list of names.

For both types of services, advance discussions should occur with this Department ([decisionsupport@kgh.kari.net](mailto:decisionsupport@kgh.kari.net)) in advance of applying for funding/submitting to HSREB. Please contact David Barber (KGH Site ext. 3315 or [barberd@kgh.kari.net](mailto:barberd@kgh.kari.net)) if you have any questions. Along with your email request please include a brief description of your research project and the



specific patient population that you are interested in learning more about. In addition to forwarding this information you also need to read over the “*Kingston Health Sciences Centre’s Basic Rules of Confidentiality*” and complete the “*KHSC Data Request Form for Pulling Medical Records*”. If you are non-hospital staff, a “*Confidentiality Agreement for Accessing Information by Non-Hospital Staff*” needs also to be completed. A copy of your HSREB approval letter is required if you are requesting a list of potential subject names. Finally, please check off “KHSC-KGH Decision Support” and/or “KHSC-HDH Decision Support” within your TRAQ DSS FORM on the Approvals Tab for hospital departmental approval depending on the location(s) where your project is occurring.