**Preamble:**

The purpose of this policy is to ensure that Kingston Health Sciences Centre (KHSC) and Kingston General Health Research Institute (KGHRI) receive timely notification of actual or suspected (perceived) privacy breaches relating to research.

**Policy Statement:**

Under the *Personal Health Information Protection Act, 2004* (PHIPA), *Personal Information Protection and Electronic Documents Act*, 2000 (PIPEDA), and the *Freedom of Information and Protection of Privacy Act, 1990* (FIPPA), KHSC and KGHRI, along with our partner institutions, are mandated to protect confidential information relating to patients, employees and the business of the organization. This protection also extends to include confidential information related to research participants.

KHSC and KGHRI work collaboratively with our partner institutions and are responsible for ensuring that information to which it has access to is kept confidential and private and it reports privacy breaches as required by legislation in its capacity as a health information custodian or agent.

The procedures set out below apply to all hospital-based research projects, regardless of whether the projects were funded (received internal and/or external funding) or were un-funded.

**Definitions:**

**Agent**: An agent of a health information custodian includes anyone who is authorized by the health information custodian to do anything on behalf of the custodian with respect to personal health information.

**Board of Record**: The Research Ethics Board that is responsible for the ethical oversight of the research study.

**Breach:** The unauthorized collection, use, disclosure, retention, or destruction of confidential information in a manner that contravenes privacy legislation. Breaches can be accidental or intentional. This includes unauthorized access and/or viewing by an individual who is not involved in providing or assisting with research.

**Confidential Information:** Confidential information includes information, in any format, created or received in the course of conducting research, that is disclosed by one party (the “Discloser”) to the other party (the “Recipient”) which is identified by the Discloser, either orally or in writing, as confidential and is not intended for members of the public.

**Health Information Custodian:** Individuals or organizations who have custody or control of personal health information as a result of or in connection with performing the person’s or organization’s powers or duties pertaining to the provision of health care.

**Personal Health Information (PHI):** Personal health information means “identifying information” about an individual in oral or recorded form, if the information relates to: physical or mental health of the individual, including information that consists of the health history of the individual’s family; providing of health care to the individual, including the identification of a person as a provider of health care to the individual; a plan of service within the meaning of the Long-Term Care Act, 1994 for the individual; payments or eligibility for health care in respect of the individual; the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance; the individual’s health number; or identifying an individual’s substitute decision-maker.

**Personal Information (PI):** Information about an individual that identifies the individual or that can be linked or matched by a reasonably foreseeable method to other information that identifies the individual. Personal information can be information about a physician or other care provider, a hospital or university staff person, a research participant, or a research participant’s family member. Personal information does not include the name, title, contact information or designation of an individual that identifies the individual in a business, professional or official capacity.

**Procedure:**

1. Researchers, research staff, students and trainees who become aware of an actual privacy breach or suspected (perceived) privacy breach are required to notify KHSC’s Privacy Office in one of the two formats depending on whether or not they are KHSC employees or KHSC Physicians or they are Queen’s University (Queen’s) Faculty (non-physicians) or Queen’s, Providence Care or St. Lawrence College (SLC) employees, students or trainees who hold a KHSC research hospital appointment (RHA):

**KHSC Employees/Physicians**:

File a SAFE Report in KHSC’s SAFE Reporting system. The report should be filed with the following criteria selected:

* 1. General Incident Type: **ID/Documentation**
	2. Specific Incident Type: **Privacy Breach (either Lost/Found Documents, Theft or Unauthorized Access/Disclosure)**
	3. Check the check-box beside **“Is this privacy breach research-related?”**

Once the SAFE Report has been submitted, the KHSC Privacy Office and KGHRI are automatically notified through the SAFE Reporting system.

**Queen’s Faculty (non-physicians)/Queen’s, Providence Care, SLC Employees, Students or Trainees with RHA**:

Queen’s Faculty (non-physicians) and Queen’s/Providence Care/SLC employees, students, or trainees do not have access to KHSC’s SAFE Reporting system. Notification must occur directly to KHSC’s Privacy Office by email to privacy@kingstonhsc.ca. If there is a member of the research team who is a KHSC employee or KHSC Physician, this individual would be designated to file a SAFE Report in KHSC’s SAFE Reporting system on behalf of the Queen’s Faculty (non-physician) or Queen’s/Providence Care/SLC employee, student or trainee who discovered the privacy incident.

1. Once the notification to KHSC’s Privacy Office is received, KHSC’s Privacy Office will follow their privacy breach protocol to contain, investigate and, if possible, remediate the breach. KGHRI, partner institutions (if applicable), and the research team will cooperate with KHSC’s Privacy Office’s investigation and assist in containing and remediating the breach, if possible. It may be necessary to engage KHSC and/or partner institutions’ Information Management (or equivalent) department to assist with the investigation, containment and remediation.

KHSC’s Privacy Office will also confirm that KGHRI and the Board of Record have been notified of the privacy incident. If it is determined that the privacy breach also involves Providence Care, KHSC’s Privacy Office will notify Providence Care’s Privacy Office and a mutual decision will be made about which privacy office leads the investigation on behalf of the hospitals in consultation with the appropriate Board of Record. See Appendix A.

1. Researchers, research staff, students and trainees are also responsible for notifying KGHRI and the appropriate Board of Record.
2. KHSC’s Privacy Office in consultation with the researcher, KGHRI, and Board of Record, along with respective partner institutions’ Privacy Offices (if applicable) will determine whether the affected research participants are required to be notified and, if so, which party will do so.
3. KHSC’s Privacy Office, KGHRI and Board of Record, along with respective partner institutions’ Privacy Offices (if applicable) will also determine whether any other parties need to be notified (Information and Privacy Commissioner of Ontario, eHealth Ontario, Regulatory Colleges, Law Enforcement Agencies, Health Canada, Study Sponsors, other funding agencies, etc.).
4. The party designated to notify the affected research participants will do so and they will notify the KHSC’s Privacy Office, KGHRI, and Board of Record, along with respective partner institutions’ Privacy Offices (if applicable) after notification has occurred.
5. Once KHSC’s Privacy Office has determined that the privacy incident file is closed, the results of the investigation will be shared with KGHRI and Board of Record, along with respective partner institutions’ Privacy Offices (if applicable).

Authorizing Signature

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Dr. David Pichora,

President and Chief Executive Officer

**Related Policies:**

KHSC Policy 01-225: Privacy Breach Management

KHSC Policy 11-012: Research Hospital Appointment

KHSC Policy 11-150: Health Research