Procedure for Policy on Data Storage and Retention	Manual: Reference Number: *102-1*
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See related policy

See related Policies: Data Storage and Retention
Conflict of Interest
Scholarly Integrity
Intellectual Property
The Ethical Conduct of Research and Other Studies Involving Human Participants

Procedure

1.0 Research records must be retained in sufficient detail to enable the institution and the involved investigators to respond to questions about research accuracy, authenticity, compliance with pertinent contractual obligations, and institutional and externally imposed requirements and regulations governing the conduct of the research. The purpose of these procedures is to ensure that: (1) the authenticity of all data and other factual information generated in research can be verified; and (2) to ensure that any research records containing personal information and/or personal health information about research participants are stored in a manner which protects the privacy of such information in accordance with the applicable *Freedom of Information and Protection of Privacy* and *Health Information Protection* Acts.

2.0 Applications to the Research Ethics Board require a statement outlining the procedures investigators will use to securely store research records, including the length of time the research records will be stored, the location of storage, the identity of the person responsible for storage of research records, the procedures that will ensure secure storage, and the confidential and permanent means of destruction of data once the required data retention period has concluded.

3.0 The Principal Investigator (PI) and the RQHR are jointly responsible for the collection, maintenance, and retention of research data, in that:

3.1 Clinical trial data that is subject to Health Canada regulation is stored for a minimum of 25 years;

3.2 All other data must be stored for a minimum of 5 years from the date of completion of the study, unless otherwise stipulated by federal or provincial regulations, the terms of a research sponsorship agreement, or the terms of a funding body as stipulated in the funding agreement;

3.3 Hard copy files should be stored in a locked filing cabinet or otherwise secured within the Principal Investigator's office, or according to a method otherwise approved by the Research Ethics Board;

3.4 Electronic files should be stored on password-protected RQHR computers or network drives with limited access. For laptops and portable media (e.g., flash drives), at a minimum, files containing data and/or personal health information must be password-protected and encrypted to protect against unauthorized access. The user may instead opt to encrypt and password-protect the entire device itself;

3.5 Data retention periods specified in the approved research ethics application must be adhered to;

3.6 Following the data retention period, all data must be permanently and confidentially destroyed;

3.7 Hard copy data must be shredded. For RQHR staff and physicians, this may be accomplished by depositing data into a locked bin for confidential shredding by a private contractor;

3.8 Electronic files must be permanently removed from hard drives and external devices. Deleting files and emptying the recycle bin is not sufficient, as data recovery is still possible using sophisticated means. For data stored on non-RQHR computers or any external devices, third party software should be used to permanently overwrite deleted files or hard drives/devices should be permanently destroyed. For data stored on RQHR computers, the Information Technology department will permanently destroy the hard drive upon decommissioning; and

3.9 When an investigator leaves the RQHR, (s)he may take a copy of the research records related to his/her research. If a PI leaves the institution or a project is to be moved to another institution, Research and Performance Support must be notified of the location of the original research records. In some instances (e.g., where institution intellectual property or other interests are involved), such transfer may not be permitted, and any such agreement may require diligent retention by the recipient and continued access by the institution. The obligations of investigators set out in this policy and procedure continue to apply if an individual takes copies of research material to his/her new institution.