

# University Health Network Policy & Procedure Manual Research: Data Ownership, Stewardship & Security of Health Information

**Note that this policy is currently under review. Any questions regarding this policy may be directed to Katie Roposa, Director, Research Quality Integration via email at [katie.roposa@uhn.ca](mailto:katie.roposa@uhn.ca).**

## 1. Policy

University Health Network (UHN) is the [custodian/steward](#) for all research data for any research conducted under the auspices or within the jurisdiction of UHN.

UHN determines [ownership](#) based on the source of funding, contractual obligations, and regulatory requirements. UHN administers the rights of ownership, performs audits, and provides access controls to [research data](#).

The researcher is assigned as the [steward](#) for all research data generated from research in which he/she is engaged as [Principal Investigator](#). At UHN, this includes operational responsibilities and the responsible management of [research data](#). In the absence of the researcher, the department/division/program head assumes stewardship responsibilities.

As a steward of the research data, the researcher will ensure that the data is maintained in an accessible format. The researcher will ensure that any secondary uses of the data are consistent with any funding agreements, contractual obligations, legal and regulatory requirements including [consent](#) provisions where required.

UHN and its [research personnel](#) must protect data used for research purposes and maintain its privacy. In a modern environment with multiple methods of data storage and transmission, the obligation to protect data requires increased vigilance. (See [Privacy & Access](#) policy 1.40.007.)

Agreements are required when transferring data that is not a part of a larger contract or agreement involving intellectual property or study information.

### 1.1 Collection of Data from Humans (Data Banking)

Collection for quality assurance purposes should follow existing hospital protection of [personal health information \(PHI\)](#) as per [Privacy & Access](#) policy 1.40.007 and does not require research Institutional Authorization.

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Collection of data outside of existing records for future research purposes requires appropriate consent of the individuals. (See [Consent to Treatment](#) policy 3.20.001.)

Data collected in conjunction with biospecimens require Institutional Authorization as per [Institutional Authorization for Research Involving Humans](#) policy 40.20.008. Construction of storage and collection systems for data from humans outside of existing UHN mechanisms requires Institutional Authorization prior to commencement of a study. (See [Institutional Authorization for Research Involving Humans](#) policy 40.20.008.)

## 1.2 Personal Health Information (PHI)

[Research data](#) with [PHI](#) must be stored on the hospital servers. Data is not permitted to be stored on local drives. If it is absolutely essential to temporarily store research data on a laptop or portable memory device/media, that data must be properly [de-identified](#) and [encrypted](#). Local storage is allowed only under these conditions when absolutely necessary and for no longer than absolutely necessary. (See [Appropriate Use of Information & Information Technology](#) policy 1.40.012 and [Information Security](#) policy 1.40.028.)

Everyone at UHN is responsible for the protection of [research data](#) including [PHI](#).

## 1.3 Research Data Retention

[Research data](#) must be retained for the retention period required:

- by specific funding and regulatory agencies;
- by a publishing journal;
- by the terms of a research agreement;
- to protect intellectual property rights;
- by UHN in the event of a research misconduct allegation.

Researchers are responsible for storage/retention of research data at minimum for 10 years after the research project has ended or according to the list above, whichever is longer. A research project or activity should be regarded as having ended after (a) final reporting to the research sponsor, (b) final financial closeout of a sponsored research award, or (c) publication of research results, whichever is later.

Following the minimum retention period, retention of the research data will be reevaluated and, if appropriate, the data will be destroyed in a manner appropriate to the type of data and the medium in which it is stored. (See [Management, Retention & Destruction of UHN Records](#) policy 1.30.007.)

Data is to be stored in a manner that is retrievable during the retention period.

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## 1.4 Responsibilities

### 1.4.1 Researcher

- Ensures appropriate preparation and transfer of data into existing public repositories as required by funders and regulators. Where applicable, should request funding from the granting agency to cover the cost of preparation and transfer of data.
- Ensures retention and storage requirements are met for [research data](#).
- Facilitates access to data for auditing.
- Ensures use of hospital-[encrypted](#) devices such as USB keys and laptops for temporary storage of data.
- Ensures [PHI](#) is stored securely on UHN systems.
- Ensures use of a hospital-provided method of remote access to use PHI located on the hospital servers.
- Ensures appropriate handover of responsibilities upon leaving the institution.
- Ensures that all actions of members of their research teams in relation to data conform to UHN standards.
- Where PHI or other confidential information is handled:
  - a. Requires his/her research teams are trained in data management.
  - b. Ensures appropriate [consent](#) and agreements for sharing/transferring of data are in place.
  - c. Works with [de-identified](#) data at all times, except when identifiable data is absolutely required.

### 1.4.2 UHN

- Facilitates agreements and the sharing and protecting of data, where applicable.
- Administers the rights of data [ownership](#).
- Provides hard data backups of UHN information technology (IT) systems for disaster recovery purposes.
- Provides UHN IT systems, processes, and protection for handling data.
- Performs audits of research data against applicable standards.

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- Provides access controls to UHN IT systems housing research data.

## 2. Definitions

**Consent:** The mechanism through which permission is granted by the individual to allow the collection, use or disclosure of [personal information](#). Consent must be a voluntary agreement with a proposal or action.

**Copyright and related rights:** Copyright is a legal term describing rights given to creators for their literary and artistic works (including computer software). Related rights are granted to performing artists, producers of sound recordings and broadcasting organizations in their radio and television programmes.

**Custodianship:** An organizational plan of the roles and responsibilities of those overseeing the management of data across all stages of the data lifecycle, including its preservation (funding of such is a separate matter). At UHN, the organization itself is responsible for most parts of the data lifecycle, except for its discovery and production. The dissemination and long-term management are organizational issues. Where [personal information](#) (or [PHI](#)) is involved, stewardship includes the management of the data relative to the consent given.

**De-identification:** A process to remove the identifiable ties back to an individual. Items that must be removed to be considered de-identified include, but are not limited to, the name and/or initials of the subject, identifiers such as the Social Insurance Number (SIN) or Ontario Hospital Insurance Plan (OHIP) number, date of birth, last 3 digits of postal code, or any other data that might be used to identify the individual. Examples of such data include a rare condition in a small sample, items from which unique-to-the-individual information can be derived (i.e. tissue, genetic information).

**Encryption:** A layer of protection which adds capability for data protection in addition to access control, auditing, and authentication

**Institutional Authorization:** Authorization to perform research under the auspices of UHN. Granted on a per-protocol basis by the vice-president Research or designate.

**Ownership:** The relation of an owner to the object possessed, where possession has the right to transfer possession to others. The act of having and controlling an object/property/thing.

**Personal health information (PHI):** [Personal information](#) as it relates specifically to health care. It is information about the individual, whether living or deceased and whether in oral, graphical, pictorial or other recorded form. It is information that can identify an individual and that relates to matters such as the individual's physical or mental health, the provision of health care to an individual, payments or eligibility for health care in respect to the individual, the donation by the individual of a body part or

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bodily substance or sample, and, the individual's health number or other identifiers collected during the course of care.

Personal health information can be information about a physician or other care provider, a hospital staff person, a patient, or a patient's family member. Examples of personal health information include a name, medical record number, health insurance number, address, telephone number, date of birth, and, personal health information related to a patient's care such as blood type, x-rays, diagnoses, treatments, consultation notes, data derived from human tissue, etc.

**Personal information:** Factual or subjective information about an individual.

**Principal Investigator (PI):** The leader of a research project who is responsible for the conduct of the research, and for the actions of any member of the research team.

**Research data:** The factual records used as primary sources for research, and that are commonly accepted in the research community as necessary to validate research findings. Virtually all types of digital information or hardcopy media have the potential to be research data, if they are being used as a primary resource for research. Research data are not intellectual property, and thus cannot be patented or [copyrighted](#). (See [Intellectual Property Protection & Commercialization](#) policy 1.20.013.)

Research data include, but are not limited to, original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

**Research personnel:** All personnel, paid by UHN or other sources, involved in the conduct of research at UHN. This includes, but is not limited to, those personnel working in laboratory, administrative, clinical or support areas.

**Stewardship:** The day-to-day responsible management of a resource entrusted to one's care.

### 3. References

1. Health Canada Therapeutic Products Directorate (TPD) Regulations: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php>.
2. International Committee of Medical Journal Editors (ICMJE), Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals: <http://www.icmje.org/recommendations/>

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