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Research Records Stewardship Guidance Procedure

Office of Administrative Responsibility:	Vice-President (Research and Innovation)
Approver:	Vice-President (Research and Innovation)
Scope:	Compliance with this University procedure extends to all members of the University community.

OVERVIEW

The University and its members are responsible for the **stewardship** of the **research records** created, acquired, managed or preserved. Good stewardship procedures will ensure that research records are managed and preserved for future scholarship, that research records can be verified and that **confidential, personally identifying, identifiable** and/or **sensitive** information is appropriately safeguarded.

PURPOSE

- To provide principle-based guidance for research records stewardship
- To advise on best practices in research records management and preservation
- To define key considerations in the production, maintenance and protection of research data and records containing identifiable information on human participants
- To define key considerations and minimum requirements for research records retention

PROCEDURE

1. RESEARCH RECORDS

Research records must be appropriately managed for defined time periods or for reasonable longer periods [described below], and shared where appropriate. If research records are not designated for a permanent collection, the timing and process for their destruction should be documented. See Appendix A.

2. RESPONSIBILITY

The Principal Investigator (PI) is responsible for the collection, maintenance, confidentiality, and secure retention of research records until such time as the University may assume responsibility for their management and preservation. The PI is also responsible for ensuring that all personnel involved with the research understand and adhere to established practices that are consistent with these procedures.

3. CREATION AND RETENTION OF RESEARCH RECORDS

Different kinds of research records will require different standards for collection, maintenance, privacy and retention.

- a. In general, research records should be created, stored, used and retained in accordance with the highest standards of scientific and academic practice relative to the researcher's discipline or field.
- b. Research records must be retained in sufficient detail to enable the researchers and the University to respond to questions about research methods, rigour, accuracy and authenticity, to demonstrate that the results are reproducible and to document the relative contributions of the research team.
- c. Research records may contain sensitive or confidential information, separate and apart from personally identifiable information. That information must be appropriately managed and safeguarded. If called upon, the researcher, the University and any University employee who has access to the sensitive or confidential information in the course of a research project, must be able to show compliance with pertinent contractual obligations, and institutional and externally imposed requirements and regulations governing the conduct of the research.
- d. With regard to records of research involving humans, respect for privacy is a fundamental concern in the creation and retention of research records which contain identifiable information. Researchers and Research Ethics Boards (REBs) are expected

to identify and minimize privacy risks, keeping in mind that a matter that is not sensitive or embarrassing for the researcher may be so for the participant. The *Tri-Council Policy: Statement Ethical Conduct for Research Involving Humans (TCPS2)* discusses privacy and confidentiality and provides the framework for research ethics board review and approval. [See *UAPPOL Human Research Ethics Policy and Procedures*]. Further detail about stewardship of research records that contain identifiable information is contained in paragraph 5 of this Procedure.

4. MANAGING AND PRESERVING RESEARCH RECORDS

The University and its researchers each have roles and responsibilities in the management and stewardship of research records. The partnership between the University and researcher is essential for a complete lifecycle management of research records. Researchers depend on the University to enable their development of research records requiring the University to be responsive to the overall environment for research record management and stewardship. The University has a mandate to provide an environment supportive of the management and stewardship of research records while the researchers are expected to carry out this mandate through individual projects and programs.

- a. Institutional roles and responsibilities: The University's role is to provide an environment supportive of sound research records management and stewardship. This may include entering into or facilitating data sharing agreements. The substantial investment in research records, including the significant human, intellectual and financial capital, results in the production of valuable assets requiring proper management and stewardship. The University may assume responsibility for the long-term protection of these assets.
- b. Researcher roles and responsibilities: The researcher's role is to produce research records of high quality. He/she has a responsibility to manage research records using today's best practices.
- c. The value of research records can increase through their reuse or repurposing [see 4.d]. Maximizing the value of research records is conditional on making these records widely available for new uses.
- d. The University has an obligation to facilitate the advancement of knowledge in all disciplines by encouraging researchers to share data where appropriate. Sharing data strengthens our collective capacity to meet scholarly standards of openness by providing opportunities to further analyze, replicate, verify and refine research findings. Such opportunities enhance progress within fields of research, avoid duplication of primary collection of data, as well as support the expansion of inter-disciplinary research. Greater availability of research data will contribute to improved training for

graduate and undergraduate students and, through the secondary analysis of existing data, make possible significant economies of scale. In addition, institutions and researchers, whose work is publicly funded, have a special obligation to openness and accountability in research.

- e. Part of the environment that the University is to provide and support is preservation services. The transfer of stewardship responsibility for research records from the researcher to the University is articulated in Appendix A.
- f. The articulation of the primary stewardship responsibilities for all parties throughout the research lifecycle should be made at the very beginning of a research project in a Data Management Plan. Such plans are described in Appendix A.

5. IDENTIFIABLE INFORMATION

- a. For the purposes of this procedure, it is important to note that human research ethics applications require a statement outlining the procedures researchers 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, and the procedures that will ensure secure storage.
- b. Researchers, any members of the University community who have access to research records containing identifiable information, and the University will each take steps that are within their reasonable control to protect research records containing identifiable information; this will be done by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or destruction.
- c. Researchers and any other members of the University community who have access to research records containing identifiable information have a duty to treat research participants' identifiable information in a confidential manner and in accordance with relevant contracts, study participants' consents, Research Ethics Board(s) approval, legislation, and policies or procedures of the University.
- d. The Alberta *Health Information Act* sets out specific requirements concerning the use of health information in research. Among other things, following ethics approval (from a Research Ethics Board designated under the Act) and the decision by a custodian to disclose the health information, a researcher must enter into a formal agreement with the custodian. The data agreement will include any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and any requirement imposed by the custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information.

- e. The Alberta *Freedom of Information and Protection of Privacy Act* also states that a public body subject to that Act must enter into an agreement with a researcher before it discloses identifiable information to a researcher to use for research purposes.
- f. Ethical concerns regarding privacy decrease as it becomes more difficult (or impossible) to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group.
- g. The easiest way to protect participants is through the collection and use of **anonymous** or **anonymized** data, although this is not always possible or desirable. For example, after information is anonymized it is not possible to link new information to individuals within a dataset, or to return results to participants. A “next best” alternative is to use **de-identified** data: the data are provided to the researcher in de-identified form and the existing key code is accessible only to a custodian or trusted third party who is independent of the researcher. The last alternative is for researchers to collect data in identifiable form and take measures to de-identify the data as soon as possible. Where it is not feasible to use anonymous or anonymized data for research, the ethical duty of confidentiality and the use of appropriate measures to safeguard information become paramount. Researchers are expected to consult their Research Ethics Board if they are uncertain about whether information proposed for use in research is identifiable, anonymized or de-identified.
- h. Electronic storage and analysis of data may heighten risks of re-identification and researchers and REBs should be vigilant in their efforts to recognize and reduce these risks.
- i. Guidelines concerning classification of research records are contained in Appendix B.

6. RETENTION

Research record retention periods will vary depending on the research discipline, research purpose and type of records involved.

- a. Research records must be retained for not less than:
 - i. five (5) years after the end of a research project’s records collection and recording period;
 - ii. five (5) years from the submission of a final project report;

- iii. five (5) years from the date of publication of a report of the project research; or,
- iv. five (5) years from the date a degree related to a particular research project is awarded to a student

whichever occurs last.

b. The conditions for research records that must be retained for longer periods are:

- i. if required to protect intellectual property rights;
- ii. if the research records are deemed to have long-term value determined by the wider research community and the preservation services provided by the Institution;
- iii. if retention is required for the continuity of scientific research or if the research records are potentially useful for future research by the PI or other researchers;
- iv. if such research records are subject to specific federal or provincial regulations requiring longer retention periods. For example: *Canada's Food and Drug Regulations* require certain clinical trial records to be stored for fifteen (15) years;
- v. if required by the terms of a research sponsorship agreement; or,
- vi. if any allegations regarding the conduct of the research arise during the research activity, such as allegations of academic misconduct or conflict of interest.

c. Future use of research records may be subject to the provisions of applicable privacy legislation, contractual obligations or, for example, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*.

d. With regard to human participant research generally, records do not have to be destroyed, provided the researcher's Data Management Plan [see 4.f] has a clear statement about appropriate records management, storage and retention. For research involving health information, the agreement between the custodian and the researcher will determine data storage and management.

e. Research records must be stored securely and protected with all the precautions appropriate to their sensitivity and privacy.

7. FUNDING COUNCILS

Funding Councils may have specific policies and directives about sharing and preserving research data produced through projects they fund. Researchers should anticipate such requirements regarding research data and act accordingly. Some examples are:

- a. The Social Sciences and Humanities Research Council (SSHRC) Policy on Data Sharing states that all research data collected with the use of SSHRC funds must be preserved and made available for use by others within a reasonable period of time;
- b. Canadian Institutes of Health Research (CIHR) grantees must deposit bioinformatics, atomic and molecular coordinates data into the appropriate public database immediately upon publication of research results;
- c. CIHR grantees must retain original data sets arising from CIHR-funded research for a minimum of five years after the end of the grant. This applies to all data, whether published or not;
- d. Collections of animal, culture, plant or geological specimens, or archaeological artifacts (“collections”) collected by a grantee with Tri-Council grant funds are the property of the University.

8. DISPOSITION

Destruction of research records must be carried out so that sensitive, confidential and/or personal information cannot practicably be read or reconstructed. In some cases it may be advisable to document the manner and time of destruction.

DEFINITIONS

Any definitions listed in the following table apply to this document only with no implied or intended institution-wide use. [▲Top]	
Stewardship	The responsible management and caretaking of research records across the lifecycle of the records. For greater clarity, stewardship is different from ownership.
Research records	Research information assets supporting both research and operational needs. This includes administrative information and records produced for analytic or evidentiary purposes. Research records include those documents and records and materials captured by or for a researcher that are necessary to document,

	<p>reconstruct, evaluate, and validate research results and the events and processes leading to the acquisition of those results.</p> <p>Research records may be in many forms including but not limited to laboratory notebooks, survey documents, questionnaires, interview notes, transcripts, machine-generated data or performance outputs, recruitment materials, consent forms, correspondence, other documents, computer files, audio or video recordings, photographs including negatives, slides, x-ray films, samples of compounds, and components of organisms.</p> <p>With regard to research involving human participants or animal use, research records usually relate to the data collected about the subjects of the research, but may also include genomic sequencing and similar genetic information about animals used in research.</p>
Confidential	Information disclosed to a researcher with the ethical and/or legal obligation that it will be safeguarded from unauthorized access, use, disclosure, modification, loss or theft.
Personally identifying	Information that identifies a specific individual through direct identifiers (eg name, personal health number) or through a combination of indirect identifiers (eg, date of birth, unique personal characteristic, place of residence).
Identifiable	Information that may be reasonably expected to identify an individual, alone or in combination with other available information, is considered identifiable information (or information that is identifiable).
Sensitive	Personal information that is protected through confidentiality or anonymity.
Anonymous	Information that never had identifiers associated with it.
Anonymized	Information that is irrevocably stripped of direct identifiers and any other indirect identifiers that could readily enable someone to identify an individual through the use of those identifiers, and a code is not kept to allow future re-linkage and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

De-identify	To remove direct identifiers, and any indirect identifiers that could readily enable someone to identify an individual through the use of those identifiers, from data.
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RELATED POLICIES, FRAMEWORKS, AND PROCEDURES

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Research Policy (UAPPOL)	

RELATED LINKS

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Canada Food and Drug Regulations, Division 3 (Government of Canada)	
Canadian Institutes of Health Research (Government of Canada)	
Freedom of Information and Protection of Privacy Act (Government of Alberta)	
Natural Sciences and Engineering Research Council of Canada (Government of Canada)	
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Tri-Council Policy Statement: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) (Government of Canada)	