Sensitive Data Toolkit for Researchers

Part 3: Research Data Management Language for Informed Consent

Prepared by the Portage Network Sensitive Data Expert Group on behalf of the Canadian Association of Research Libraries (CARL)

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SERVICES PARTAGÉS POUR LES DONNÉES DE RECHERCHE
SHARED STEWARDSHIP OF RESEARCH DATA

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Introduction

The Sensitive Data Expert Group of the Portage Network has created a suite of tools for Canadian researchers. These tools have been created to help researchers understand how research data is involved in the research ethics process, and to address the evolution of research data management (RDM) practices such as data sharing and deposit in the context of existing research ethics frameworks.

This tool, Research Data Management Language for Informed Consent, is intended to assist researchers working with sensitive data in the development of tailored, deposit-friendly language for ethics approval and informed consent. The key principle of this tool is **Adaptation, Not Adoption**. Sample text is provided to address a number of informed consent considerations, including:

- Scope of Data Use
- Anonymity and Confidentiality
- Data Retention and Access
- Limitations to Data Withdrawal
- Future Use of Data
- Signature Acknowledgements

Please consult Part 1 of this toolkit, the Glossary of Terms for Sensitive Data used for Research Purposes, for key definitions. Please consult Part 2 of this toolkit, the Human Participant Research Data Risk Matrix, to determine the risk level of your data.

This tool has been informed by an environmental scan of secondary use of data policies, procedures, and forms at Mount Saint Vincent University: Harvard University; University of Toronto; The Hospital for Sick Children; Brock University; Utrecht University; and Queen's University.

The Portage Network's Sensitive Data Expert Group is composed of a broad membership from research communities - including research ethics professionals, representatives of funding agencies, and members of Indigenous organizations - with direct interests in sensitive research data. The group works together to develop practical guidance and tools for managing sensitive data in the Canadian landscape.

Research Data Management Language for Informed Consent

Scope of Data Use

The scope of future data use must be aligned with the risk level of the data, as per the Human Participant Research Data Risk Matrix, taking into consideration sensitivity, identifiability and downstream risks. Researchers should be specific about the scope of possible uses and mechanisms by which data may be obtained by persons outside of the research team (if applicable). Data uses are categorized as:

- **Defined use** - Data use will be limited to the specific project under consideration;
- **Extended use** - Data may be used in future research projects that are either an extension of the original project or that are in the same general area of research (e.g. breast cancer, diabetes, childhood trauma, poverty);
- **Broad use** - Data may be used in future research within or beyond the general area of research of the current study.

*Refer to the Human Participant Research Data Risk Matrix - the level of data risk will inform the language that researchers should use in informed consent forms.

**For data collected which are not anonymous, participants must be notified that their data may be used by others in the future. In higher-risk situations, this should be a formal opt-in; in lower risk situations, this can be simply a notification in the consent form.

Anonymity vs. Confidentiality

Only research that does not involve the collection of any direct and/or indirect identifiers that can be reasonably traced to individual respondents can be called anonymous. Otherwise, researchers have the obligation to establish measures to protect research participants from the possibility of being identified through their data. See the glossary definitions for further information.

Researchers are strongly encouraged to carefully consider, select, and adapt language in this section to suit the specific needs of their research.

- This study involves collection of anonymous data. This means that no personally identifying information will be collected, including your name or contact information, and that you cannot be identified from the data.

- This study involves collection of identifiable data. The research team will protect your personally identifiable information, including your name, so that no one will be able to connect your responses with any other information that identifies you. They will separate your name from your information as soon as possible, using instead an assigned number or code to match your study record with your answers.

- Federal or provincial laws or regulations, or university policy may require the researcher to show information to university, government officials, sponsors, or the REB who are responsible for monitoring the safety and integrity of this study. Any personal information that could identify you will be removed or changed before files are shared in any way, including with other researchers. Any information provided to the public will be in aggregated form only.

- You will not be identified in any publication from this study or in any data files shared with other researchers.

Data Retention and Access

Participants need to be informed about and consent to what data (e.g., their data in de-identified form) will be retained and made accessible for discovery and access. Decisions about how long data will be retained in a given repository, and/or preserved for long-term access, are generally the purview of repository managers and/or data curators. Researchers are encouraged to contact their chosen repository for more information, if needed.

Researchers are strongly encouraged to carefully consider, select, and adapt language in this section to suit the specific needs of their research.

- During the study, information from this research will only be accessed by the research staff. All personally identifying information collected about you will be destroyed once it is no longer needed for the study.

- The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator and/or selected members of the research team. Any information that can identify you will remain confidential.

- At the end of the study, your de-identified data may be deposited into one or more publicly-accessible scientific repositories, such as _____, through which researchers from around the world will have access to these data for future research.

- De-identified data will be retained indefinitely to facilitate requests from other researchers to verify results. Please note that anonymized data may be made available online on an open repository accessible to researchers around the world. This is common practice in research and required by many journals and funders.

Limitations to data withdrawal

While research participants must always have the right to withdraw participation from a study, the ability to withdraw their data is not absolute. Participants should be informed about their right to withdraw from a study, how to make such a request, how this will affect the data collected about them, and any limitations that may exist to fulfilling such a request. Generally speaking, participants need to be informed as to which of the following options is applicable to their data in a given study:

- they cannot withdraw their data (e.g., data are either anonymous, or identifiers have been irrevocably stripped)

- they can withdraw their data with limitations (e.g., by a certain date)

- they can withdraw their data with no limitations

Researchers are strongly encouraged to carefully consider, select, and adapt language in this section to suit the specific needs of their research.

- Research study participants may choose to no longer take part in the study at any time, however participant data may only be withdrawn up to and including _[insert date]_____, at which time _[describe action]_____ (e.g. identification will have been stripped and we will no longer be able to remove your data; data will be anonymized; de-identified data will be submitted to a research data repository; etc.)

- If you withdraw from the study, you do not have to state why. Please inform the researcher about your decision. All data already collected from or about you up until that moment will be used for the current and future research.

- You may withdraw from this optional study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information [and/or samples] collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data [and/or samples] will not be able to be withdrawn -- for example, where the data [and/or sample] are no longer identifiable (meaning they cannot be

linked in any way back to your identity) or where the data have been merged with other data.

- If you would like to request the withdrawal of any of your data [and/or samples], please let the researcher know.

Future Use of Data

Where possible, participants should be informed about future use of their data, including what data would be stored and made available, the scope of potential future use, as well as any specific limitations. Please note, data repositories have different requirements when it comes to future access to data. Please ensure participants are informed if:

1. Data will only be accessible to projects with REB approval
2. Data will only be accessible according to the terms of a data access agreement
3. Data will be broadly accessible without formal oversight

Researchers are strongly encouraged to carefully consider, select, and adapt language in this section to suit the specific needs of their research while protecting research participants. Please consult the Human Participant Research Data Risk Matrix in determining which level of access is appropriate.

- The data (personal information, biological samples, responses, etc.) you provide for this research study will be stored and may be used
    - in this research study only.
    - in future related research studies.
    - in future related or unrelated research studies.

  Prior to storage and future use, any personal identifying information will be removed from the data, and information/samples will not be linked back to you. Once this is completed, we will no longer be able to identify your specific data.

- Researchers outside of this specific study may request access to the collected dataset/samples for new research purposes. You will not be asked to provide additional informed consent for the use of your anonymous/anonymized data/samples for future research.

- Other researchers may request access to de-identified data in the future and may plan to link these data with other data which may render participants potentially identifiable. Access will only be granted if they agree to preserve the confidentiality of the information as requested in this form. If you have any questions about this, contact the Principal Investigator.

- Your decision to allow your information to be in the database is completely voluntary. While there may be no benefit to you, your information will help researchers to quickly identify individuals who may be suitable for a new research study. If you change your mind after agreeing to this, your information can be removed from the database. You will not be penalized in any way if you refuse to participate, or if you change your mind and ask that your information be removed.

- Your personal information and/or biological samples collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Signature Acknowledgements

Participants may be provided with a brief statement, summarizing what they are agreeing to, at the end of the consent form.

Researchers are strongly encouraged to carefully consider, select, and adapt language in this section to suit the specific needs of their research.

- I agree that research data gathered for the study may be deposited, published, or made available provided my name or other identifying information are not used.

- I understand that the research data, without any personal information that could identify me (not linked to me) may be shared with others.

- I agree that use of my research data/samples will be limited to my anonymized data only.

- I agree that use of my research data/samples will be for non-commercial use only.

- I understand that my de-identified data may be placed into a research data repository.

- In addition to the use of my data as described above, I agree to the following uses of my data (check all that apply):
    - **Extended use** - Data may be used in future research projects that are either an extension of the original project or that are in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research)
    - **Broad use** - Data may be used in future research within or beyond the general area of research of the current study.