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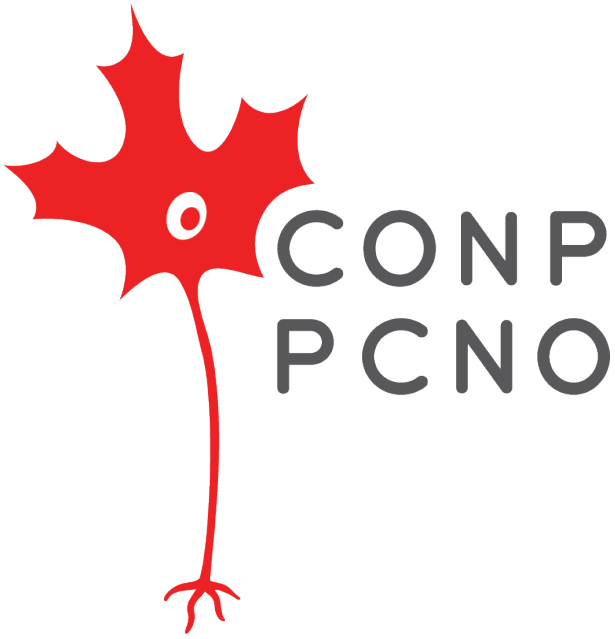

Canadian Open Neuroscience Platform
Plateforme Canadienne de Neurosciences Ouvertes

The CONP Consent Toolkit

By: Bartha Maria Knoppers, Michael Beauvais, Ann Cavoukian, John Clarkson, Lindsay Green-Noble, Judy Illes, Jason Karamchandani, Roland Nadler, Dylan Roskams-Edris, and Walter Stewart

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CONP Consent Toolkit

This consent toolkit is the product of extended discussions and careful drafting that considers both Canadian and international ethical frameworks and research practice. It provides general guidance to Canadian neuroscience researchers who wish to share de-identified data in an unrestricted manner with the scientific community and the public at large. The toolkit is a model for Canadian open-access neuroscience initiatives to adopt in developing their governance standards and also describes the minimum permissions required for researchers to submit data to the Canadian Open Neuroscience Platform (CONP) Portal.

In adapting this consent toolkit for your own research needs, we encourage you to mention to your research ethics board that your consent materials are modeled after those created by the CONP Ethics and Governance Committee. The Committee's members include internationally recognized experts in research ethics, neuroethics, data governance, and law. The Committee's members are Bartha Maria Knoppers (Chair), Alexander Bernier (Manager), Ann Cavoukian, John Clarkson, Lindsay Green-Noble, Judy Illes, Jason Karamchandani, Roland Nadler, Dylan Roskams-Edris, and Walter Stewart. Further feedback was graciously provided from members of the CONP community, in particular Patrick Bermudez, Marcel Farrés Franch, Jessica Royer, and Robert Zatorre.

In addition to the general guidance it presents, this document assists researchers in contributing datasets to the CONP Portal. The CONP accepts datasets in two situations:

1. Participants have prospectively consented to the sharing of their de-identified data through the CONP Portal.
2. Participants have not consented to the sharing of their data on the CONP Portal, but the consent given meets the core consent elements for retrospective consent.

Each of these situations will be explained.

Part 1. Core consent elements (prospective consent)

Researchers and/or clinicians should seek consent to the sharing of de-identified datasets through the CONP Portal prospectively. Depending on the circumstances, consent should be sought from either the prospective participant directly (first-person consent) or from their legally authorized representative (substitute consent). First-person consent is appropriate for adults with legal capacity. Substitute consent is for situations where the prospective participant lacks legal capacity either due to age (i.e., minors) or due to an inability to understand the nature and consequences of research participation (i.e., limited cognitive ability). In these circumstances, the prospective participant should be involved in the consent process to the fullest extent of their ability to do so.

In addition to the required consent elements common to research with human participants, prospective consent forms should include the following core elements to enable broad, open sharing via the CONP Portal:

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Table 1. Core consent elements for contributing datasets to the CONP Portal.

	To contribute datasets to the CONP Portal, participants should consent to:
Data generation	Generation of participant data for research purposes
De-identification (coding, anonymization, and synthetic data generation)	De-identification of their data, which may consist of a combination of the following processes: Coding – the removal of direct identifiers (e.g., name; health insurance number) and replaced with a code whose key is kept in a secure location Anonymization – the permanent removal of direct identifiers without the conservation of any keys Data synthesis – the creation of a dataset with similar statistical properties as the original dataset but without a one-to-one match for every variable
CONP Portal	Sharing of de-identified data via the CONP Portal, an open-access platform that researchers the world over may access
Commercial use	Use of de-identified data for commercial purposes
Data withdrawal	Not possible to withdraw data that has already been shared
Re-identification	Low risk that the participant could be re-identified in the future

If any of the elements in Table 1 have not been included in the informed consent documents, datasets should not be uploaded to the CONP Portal. In such circumstances, we recommend you examine the retrospective filter below. If doubts still remain or you have questions about the suitability of these consent elements for your research, please consult with your local research ethics board.

Note: Researchers who want to repurpose the above guidance to establish the terms of data deposit for a different open science platform should replace the phrase “CONP Portal” in the above template with the name of the concerned open science platform.

We recognize that some research projects may choose to have a tiered consent model, whereby participants consent to only certain data types being publicly shared via the CONP Portal or other open data repository. In such circumstances, the essential consent elements are only required with respect to those data types. It is the researcher’s responsibility to ensure that data segmentation is appropriately managed so that only those data types for which consent to open data sharing has been given are shared.

See Annex 1 for suggested clauses to include in the informed consent documentation.

Part 2. Retrospective consent filter

Use the filter below to determine if the consent already obtained from participants will permit you to include the data on the CONP Portal.

Step 1: Answer the following questions.

Have your participants consented to:	Yes	No
Deposit of de-identified data in open-access databases?		
Commercial use?		

Step 2: If all your responses in step 1 were "yes", your data can be submitted for inclusion on the CONP Portal. If any of the responses were "no", answer the following questions.

	Yes	No
Have your participants consented to be re-contacted?		
Is it feasible (i.e., not onerous to the degree of jeopardizing your research) to re-contact and consent your participants for inclusion on the CONP Portal?		

Step 3: If both answers in step 2 were "yes", re-contact your participants and obtain their consent using the example consent clauses in Annex 1. Otherwise, answer the following question. (Note: Only those participants who were re-contacted and gave appropriate consent can be included in the dataset included on the CONP Portal. If you have recontacted your participants and they have withheld consent, you are unlikely to obtain a waiver.)

	Yes	No
Are you able to apply to your research ethics board for a waiver, i.e., an authorization to alter the initial consent parameters?		

Step 4: If the answer in step 3 was "yes", apply to your research ethics board for a waiver. If the answer was "no", your data cannot be included on the CONP Portal.

Annex 1. Example consent clauses for the essential consent elements.

The example consent clauses are marked with CC0 1.0 Universal			
	Essential elements	**Example of consent clause language:**	**Alternative consent clause** [1]**:**
Data generation	The generation of participant data for research purposes	You are being asked to consent to [*include relevant procedure, e.g., imaging*] procedure(s) that will generate data about your [*include relevant data types, e.g., cognitive performance*] for research purposes. [*If questionnaires are also included...*] You will also be asked questions about [*include description of the types of questions, e.g., personal biographical information, health status, etc.*]	N/A
De-identification (coding, anonymization, and synthetic data generation)	Removal of direct and indirect identifiers, the restructuring of data, and the generation of synthetic data for open sharing	To protect your privacy and to facilitate the broadest possible, public sharing of the data that you and other participants contribute, your name, date of birth and other directly identifying information will not be shared. Some data, [*e.g., name; date of birth; occupation; etc.*], will be replaced by a code. Other data that we believe may allow others to determine who you are, such as your [*include relevant feature, e.g., facial features*] will be irreversibly changed through a family of processes called anonymization so that you cannot be identified. Other information, such as [*include relevant data, e.g., age group; location*], will be pooled together with those of other participants for high-level summaries.	Your privacy is very important to us, and we will take appropriate measures to protect it. We will not disclose any information about you like your name, your date of birth, your address, or your contact information to unauthorized persons. All personal identifying information will be replaced with a unique code. Before researchers have access to your data, we will de-identify it. This means we take out names, dates of birth [*include others, if any*] and other personal details. Your participation in this research project and any information obtained within this research project that can identify you will remain confidential, except as required by law [*circumstances in which confidential information can be released by law should be explained to the participant*].

The example consent clauses are marked with CC0 1.0 Universal			
	Essential elements	**Example of consent clause language:**	**Alternative consent clause [1]:**
CONP Portal	Sharing of de-identified data via the CONP Portal, an open-access platform that researchers the world over may access	After having gone through the described de-identification process, a dataset made of your de-identified data and those of other participants will be uploaded to [*specify the online platform or give a list of potential options if known, e.g., Zenodo, LORIS, etc.*]. The link to the dataset will then be included on the Canadian Open Neuroscience Platform (CONP) Portal to be openly shared with the scientific community. As an Open Science platform, CONP aims to make scientific data as easily accessible as possible to the scientific community while respecting your privacy. CONP is publicly available to anyone with internet access. Researchers from around the world will use the CONP Portal to access the de-identified data from this research study and other studies. This maximizes the potential for this project's research data to be used for additional research that may lead to important scientific discoveries.	With your consent, we will share de-identified information with other researchers from around the world who would use it to improve patient care or advance scientific knowledge, for clinical and/or general research purposes. Your information will be shared with others through open-access databases, such as the Canadian Open Neuroscience Platform (CONP). CONP is publicly available to anyone with internet access. General information, such as age, race, or sex, or your de-identified [*specify data type, e.g., MRI images*] may be shared in these types of databases.
Commercial use	Use of de-identified data for commercial purposes	It is possible that future research conducted using datasets that include both your de-identified data and those of others will lead to the development of commercial products. These may include new therapeutics, diagnostic tests, or even software programs. In such cases, no part of the revenue generated from their development or sale will be shared.	Some of the research done with the information stored in the databases may one day lead to the development of software, tests, drugs, or other commercial products. If this happens, you will not receive any of the profits.

The example consent clauses are marked with CC0 1.0 Universal			
	Essential elements	**Example of consent clause language:**	**Alternative consent clause** [1]**:**
Data withdrawal	Not possible to withdraw data that has already been shared	The choice to participate is always yours. You may withdraw from the study at any time. If you withdraw, no additional data will be collected from you. We will continue to use any data already collected unless you tell us otherwise. Once data have been de-identified and shared via CONP, they cannot be deleted. Your privacy is important to us and your data will continue to benefit from the privacy protections we use for all participants.	You are free to withdraw from the project at any stage. If you withdraw before testing and data is collected, we will not continue. If you withdraw after testing and data is collected, we will use any information already collected unless you tell us not to. However, if your data has already been shared it may not be possible to retrieve or remove all your data. You can withdraw your data at any time by contacting [*name of relevant person*] free of charge at [*information*]. Data sent to other researchers around the world cannot be withdrawn if already used or published.
Re-identification	Low risk that the participant could be re-identified in the future	Your privacy will be protected through advanced de-identification techniques. Despite this, this is always a small risk that your shared data may one day enable someone to identify you. For example, someone could use information in your clinical record to match you in a dataset. This is difficult to do because of the de-identification measures. Extensive sharing of personal information through social media or genealogical websites may also make it easier to re-identify you. With technological advances, however, it may become less difficult. Unable to foresee such advances, we use today's best protections. In the remote chance that you are re-identified, you or your relatives may suffer a loss of privacy or potentially be subject to discrimination	Some participants worry about being identified as someone taking part in the project. The chance of this happening is extremely small [*consider including an estimation of such risk, such as "i.e., less than 1%"*], and we will do everything we can to prevent this from happening. Much like fingerprints, it is possible to identify someone if certain pieces of information are put together. While we use very strict data security measures to protect your privacy, there is always a small risk that your data may lead to you being re-identified. As technology advances, there may be new ways of linking data back to you that we cannot foresee today. Like other medical information, this may one day affect your insurability or your employment.

1. Modified from the Global Alliance for Genomics and Health's model consent clauses.