



## Guidelines: Informed Consent Wording for Administrative Data Linking

### 1. Document Purpose

This document has been created by Health Data Research Network (HDRN) Canada's Privacy Team with the goal of providing guidance on what to include in consent forms informing participants of data linking to administrative data. The linkage may be one-time (e.g., data collected for a vaccine study is linked to administrative data so that the vaccine study dataset can be enhanced with variables from administrative data) or ongoing (e.g., a genomic study dataset is integrated into a data platform so the genomic study data can be used for multiple purposes).

Importantly, this guidance assumes that before the study data (full or subset) is transferred to the secure research environment, an agreement between the principal investigator and institution/secure research environment that governs the sharing of data will be established. In other words, the text related to informed consent is not the only binding text for the data sharing arrangement. Participants should also be informed that anyone accessing, working with, or linking to the data would be part of a verified and approved research team, and thus bound by all the governing policy guiding the project.

Addressing the following topics should help to streamline data requests that involve multiple jurisdictions.

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### 2. Data Linking Defined

Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2 2018)<sup>1</sup> defines data linkage as “*the merging or analysis of two or more separate data sets (e.g., health information and education information about the same individuals) for research purposes.*” The TCPS also states that “*Where data linkage of different sources of information is involved, it could give rise to new forms of identifiable information that would raise issues of privacy and confidentiality when used in research and would therefore require Research Ethics Board (REB) review.*”

### 3. REB Approval for Data Linkage

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<sup>1</sup> Government of Canada. 2018. “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018).” Retrieved February 19, 2021 ([https://ethics.gc.ca/eng/policy-politique/tcps2-eptc2\\_2018.html](https://ethics.gc.ca/eng/policy-politique/tcps2-eptc2_2018.html)).



According to TCPS2 Article 5.7: *Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:*

- a. *the data linkage is essential to the research; and*
- b. *appropriate security measures will be implemented to safeguard information.*

Ethics applications for studies that involve data linking activities must address the issues raised by TCPS above. The bodies that steward administrative data may, however, have additional criteria that must be met.

#### 4. Topics for Inclusion in Consent Forms When Seeking to Link Data

In addition to topics that are required by the approving REB, the topics listed below in Table 1 are to be included, where relevant, in the participant consent form for studies that seek to link data in order to meet the requirements of data stewards. In the 'Example Text' boxes of Table 1, the text in **[brackets and bold font]** are to be filled in by the researcher with the relevant information about their research study. The Appendix to this document illustrates how text related to the topics could be brought together in a form – paper or online – that is presented to research participants when seeking their consent for data linkage. Researchers should also have accessible versions (large print, simple language, etc.) of their consent forms available to their participants.

These topics, and the way in which they are presented, address the *Seven Guiding Principles for Meaningful Consent* as outlined by the Office of the Privacy Commissioner of Canada<sup>2</sup>:

1. Emphasize key elements
2. Allow individuals to control the level of detail they get and when
3. Provide individuals with clear options to say 'yes' or 'no'
4. Be innovative and creative
5. Consider the consumer's perspective (i.e., can be understood by target audience)
6. Make consent a dynamic and ongoing process
7. Be accountable: Stand ready to demonstrate compliance

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<sup>2</sup> Anon. 2018. "Guidelines for Obtaining Meaningful Consent." *Office of the Privacy Commissioner of Canada*. Retrieved October 28, 2020 ([https://www.priv.gc.ca/en/privacy-topics/collecting-personal-information/consent/gl\\_omc\\_201805/](https://www.priv.gc.ca/en/privacy-topics/collecting-personal-information/consent/gl_omc_201805/)).



**Table 1: Data Linking Consent Topics for Inclusion**

Data Linking Consent Topic	Regulatory Explanation	Lay Language of Requirement	Example Text
Data types and linking activity	The types of data that are to be linked should be clearly outlined and justification for data linking activities must be clearly communicated.	Describe the general types of data sources to be linked and provide an explanation of why data linkage is necessary to answer the research question.	“Information about me, that I have given to the researcher(s), will be combined with other information about me found in <b>[type]</b> hospital records in order to answer the question of ...”  OR  “I understand that my CT scan results will be linked to data from a previous research study <b>[provide study title]</b> that I participated in.”
Linkage options	Potential participants must be informed whether their participation in the research study is dependent on their consent to data linkage.	Inform participants whether linkage is optional or required for participation in the study.	“You do not have to consent to data linkage to participate in this study. If you do not consent to linkage, <b>[researcher’s description of whether the person can still be part of the study or not, and direct statement of whether it will/will not affect services: e.g., you will not receive the experimental vaccine OR the placebo, or your genetic information will still be analyzed but it will not be used for any purpose beyond your own diagnosis and care].</b> ”
Use of personal (unique) identifiers	If any personal identifiers are required for the linking activity these must be clearly detailed and specifically consented to in the form (e.g., name, personal health number). A justification	State the personal information that will be used to link data sets.	“I consent to my personal health information, including my <b>[data elements in question, such as health card number and date of birth]</b> , being released to <b>[Organization X]</b> for <b>[Organization X]</b> to locate information about me that is held in its <b>[database name]</b> database.”



Data Linking Consent Topic	Regulatory Explanation	Lay Language of Requirement	Example Text
	<p>for their collection should also be included in the consent form.</p> <p>Information about what happens after data linkage is helpful in allowing participants to make an informed decision. For example, details on how the data is held, the creation of a crosswalk file, how long it is held, etc.</p>		<p>“The information found about me in the <b>[database name]</b> database will be combined with the information about me that I have given to the researcher(s) and that combined information will be used for purposes of this study.”</p>
Linkage process	<p>The secure linkage process should be explained to participants.</p>	<p>Explain how data is linked to protect the security of the participant's data.</p>	<p>“We will use your health card number to locate information about you in other records. The researchers will ensure that the appropriate data sharing agreements are in place to protect your privacy and reduce the risk of identification by anyone other than those researchers working directly with the <b>[X database]</b>. Your information may also be linked with other information about you in other administrative databases such as those from other health institutions (if you visited another hospital, for example) or government organizations. Linking this information will be done in a way that your identity is protected and is only known to some members of the <b>[X]</b> research team.”</p>



Data Linking Consent Topic	Regulatory Explanation	Lay Language of Requirement	Example Text
Stewards conducting linkage	<p>Any new research partners involved in the lifecycle of the study data for linking or other activities are to be listed.</p> <p>The organization conducting the linking activities should be named so that the participant will know where their data are stored. Research partners and their location should also be outlined including registries that permit future unspecified use for qualified researchers.</p> <p>Data stewards, in the context of this document, refers to the organizations handling the data for linkage.</p>	<p>Provide the names of the data stewards combining the data for linkage.</p> <p>Some stewards have the authority to hold linked data for unspecified use.</p>	<p>“I consent to <b>[Organization X and location]</b> releasing this information about me from its <b>[database name]</b> database to the study researchers for this <b>[study name]</b>.”</p> <p><b>Note:</b> If the research team plans to link data with other data centres/entities, the participant should be clearly informed.</p> <p>“I consent to my data from <b>[name data centre and location/entity]</b> being combined with the data from <b>[name other data centre and location/entity]</b>.”</p>
Linking from multiple stewards	<p>It should be clearly explained to the participant whether data from multiple provinces/territories are being linked, or whether data from one or more provinces/territories are being linked to national repositories. If possible, provide participants with relevant laws or policies.</p>	<p>Explain that data sharing across provincial/territorial borders may potentially introduce additional risk to data protection as it becomes subject to different legislation, policies, practices, safeguards, etc. than those where the research was conducted.</p>	<p>“Because this study involves multiple provinces/territories <b>[or repository names]</b>, your information will need to be accessed and used in these provinces/territories. While Canadian federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information, not all provinces/territories <b>[or repository names]</b> have the exact same laws. Privacy protection may be applied differently in different provinces/territories. <b>[Researcher should provide the main provincial/territorial policies being followed.]</b>”</p>



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Linking to genomic data	<p>As explained by the Panel on Research Ethics (PRE), “addressing material incidental findings in practice is a complex and challenging issue for researchers and research ethics boards (REBs). Article 3.4 of the TCPS 2 requires researchers to disclose material incidental findings to the participants, within the limits of consent provided by the participants or their authorized third party.” The PRE recently developed a <a href="#">How to Address Material Incidental Findings: Guidance in Applying TCPS2 (2018) Article 3.4</a><sup>3</sup> that are to be followed for research activities taking place in Canada.</p> <p>In addition, article 9.22<sup>4</sup> of the TCPS2 (2018) requires REB review</p>	<p>Explain that genomic/genetic data linking may produce unique risks of harm than other types of data. The reason for high risk and measures to limit this risk must be outlined to the research participants.</p> <p>If there are any consequences that may result from the data linking that will affect how data results will be shared with participants, this must also be clearly explained.</p>	<p>“I understand that my genetic data will be linked with other information about me found in <b>[type]</b> hospital records in order to answer the question of <b>[...]</b>”</p> <p><b>Note:</b> Any additional consequences or communication about findings will be determined by the REB.<sup>5</sup></p>

<sup>3</sup> How to Address Material Incidental Findings: Guidance in Applying TCPS2 (2018) Article 3.4  
[https://ethics.gc.ca/eng/documents/incidental\\_findings\\_en.pdf](https://ethics.gc.ca/eng/documents/incidental_findings_en.pdf)

<sup>5</sup> Government of Canada. 2018. “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018) Chapter 9.” Retrieved February 19, 2021 ([https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_chapter9-chapitre9.html](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter9-chapitre9.html)).

<sup>4</sup> See Thorogood, Adrian, Gratien Dalpé, and Bartha Maria Knoppers. “Return of Individual Genomic Research Results: Are Laws and Policies Keeping Step?” *European Journal of Human Genetics* 27, no. 4 (April 1, 2019): 535–46. <https://doi.org/10.1038/s41431-018-0311-3>.



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	<p>for researchers when seeks data linkage of two or more anonymous data sets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Indigenous community or a segment of the Indigenous community at large."</p>		
<p>Future contact with participants</p>	<p>If it is anticipated that future contact with participants is desired (for the return of material incidental findings, to acquire consent from participants who were only able to provide assent initially for example, to conduct a follow up study, to expand on the existing study) then this must be addressed.</p> <p>The Panel on Research Ethics (PRE) developed a <i>Guidance on how to address Material Incidental Findings</i> that must be followed for research activities taking place in Canada.</p>	<p>If there are plans to contact research participants in future, you must seek the permission of the participant to make this contact.</p>	<p>"Yes, I may be contacted in the future for the purpose of <b>[clarification of purpose by researcher]</b>."</p> <p>"No, I do not wish to be contacted about the project in the future."</p>



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Linked data years of inclusion	The time period, if known and appropriate for the study topic, for the data about the individual to be linked should be outlined.	Describe the years of data that will be included in the linkage process. This description could include retroactive linkage and linkage for the time period of the study.	"I give permission to the study team to link information held about me from <b>[database name]</b> database dating back <b>[XX]</b> years before I joined the study, as well as to information obtained about me during this study."
Intended future use of linked data	Future unspecified uses of data that cannot be identified to the participant (e.g., for publishing, auditing, etc.) must be disclosed. Depending on your jurisdiction, some data stewards only permit data to be used for the specified purpose.	Inform participants that publishers may request data sets used in the study to be made available.  Clearly explain any plans for usage, publication, etc. of linked data in the future.	"Results from the study that do not include any personal information (i.e., cannot be identified to you) may be shared with researchers and industry (commercial) partners from around the world. The aim of these future studies is to benefit people in the future by improving our understanding of particular health conditions. This may include sharing of future study results that are unknown at this time. Study results may also be added to public databases (e.g., available on the internet, published, or presented at scientific meetings)."





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Data storage /disclosure/ access outside of Canada	<p>Any limits to confidentiality and security must be clearly communicated and must not be overpromised.</p> <p>Data storage /disclosure/ access outside of Canada (and any associated risks) should be disclosed and outlined.</p> <p>The storage of data outside of Canada may be subject to the foreign jurisdiction's laws which could result in unanticipated uses of that data.</p>	<p>Explain that storage, disclosure, and access to data outside of Canada is subject to different laws and this may affect their privacy and the confidentiality of their data.</p>	<p>"I consent to the researchers <b>[disclosing]</b>, <b>[permitting access to]</b>, or <b>[storing]</b> information about me outside Canada. <b>[Only include if applicable.]</b> Canadian federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. Laws in other countries may not be as strict as those in Canada, so when your information is sent to places outside of Canada, you may not be afforded the same rights <b>[include brief summary of jurisdiction's relevant legislation if possible]</b>. We believe that the chance of adverse events will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect them."</p>
Withdrawing linked data	<p>Any limits to withdrawing from a study or correcting errors in data should be outlined for the entire project. However, there may be additional limits how and when this can be done with linked data.</p>	<p>Provide information on how and when a participant may choose to withdraw from a study.</p> <p>Explain the limitations about the point when a participant can and cannot withdraw from the study and about the limits of removing linked data.</p>	<p>"You may withdraw your permission to use your personal health information for this study at any time by letting the doctor/researcher who invited you into this study know. However, this would also mean that you withdraw from the study going forward.</p> <p>Any personal information obtained before you withdrew and that now cannot be identified to you cannot be removed due to risk of identification. However, no further information about you will be collected or included in the study after you withdraw your permission."</p>



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Data Retention, reuse, and destruction*	<p>Retention, reuse, and destruction plans for data should be detailed.</p> <p>If the plan is to retain the data indefinitely this should be stated.</p> <p>Any plans to store data at partner sites that may be involved in the linkage process should also be mentioned.</p>	<p>Explain to participants how the data will be stored, reused, or destroyed after the research project closes. There may be specific information for partner sites that will need to be shared about linked data.</p>	<p>“Linked personal information will be held in secure storage for three years after the close of the study.”</p> <p>“<b>[Organization X]</b> will hold my <b>[personal health numbers]</b> for <b>[time period]</b> after completing the necessary file for linking data and then <b>[destroy/return]</b> the personal data.”</p>

\*The consent form should include details about this topic in general for the whole study as it is not limited specifically to data linkage.



## Appendix

### Example: Wording for Administrative Data Linking Informed Consent

The text below demonstrates how the data linking consent topics and example text found in Table 1 could be synthesized in an informed consent form to address data linkage to administrative data for a fictional study.

In this fictional example, the study lead is seeking informed consent for one-time linkage to create a new enhanced data set primarily consisting of clinical trial data with added variables from administrative data holdings. Research Ethics Board (and Data Provider, if applicable) approval of the text would be required before use. **This text would be used in addition to other consent form requirements** and does not take the place of any consent or other requirements imposed by the REB.

The portions in bold font are essential to be communicated but are likely to be covered in existing consent templates. If they are already addressed, please delete them so that the consent text will remain as succinct as possible. The portions in brackets [] are to be completed by the researcher for the project if using this form as a base.

[General information about study]

#### ***Data Linking section that would be included in the informed consent information***

We require your permission to transfer potentially identifiable personal health information collected about you to [name organization(s) and location] so that we can link the data we collect during the study with information in the administrative databases held by [that/those] organizations. Linkage of your data will allow us to meet the study objectives explained earlier in this form.

At [name organization(s)] the data we collect about you during this trial may be linked with other information about you [where applicable in any of the following examples] including information about hospital visits, physician services, home care services, and medications you received, your personal health information from this study may also be linked with data about social services that you receive, immigration status, and interactions with the justice system.

The linked data will be stored in [name province/territory/state/supranational entities] and only accessed as set out in the consent form and as approved by the Research Ethics Board.

Linking of data will be done in a way that your identity is protected and is unlikely to be known by anyone other than those directly part of the [X] research team. The appropriate data sharing agreements will be in place to ensure that your data privacy is protected and reduce the chance that anyone other than those working directly with the [X database] could identify you. **The privacy and the confidentiality of your data are very important to us, and we will make every effort to protect them.**



**You may withhold or withdraw your permission for the use of your personal health information for this study at any time by letting the [doctor/researcher] who invited you into this study know. However, this would also mean that you withdraw from the study. Your study data that was recorded and anonymized before you withdrew will continue to be used to protect the integrity of the research, but no information will be collected or shared after you withdraw your permission.**

By signing below, I authorize the linking activities described in this consent form.

- I consent to my personal health information, including my [data elements in question, such as health card number and date of birth], being released to Organization [X] so that Organization [X] can locate information about me that is held in its [database name(s)] database.
- I consent to Organization [X] [at location] performing data linkage and releasing the information about me from its databases to the [study name/title] researchers [*where applicable*: and for future unspecified use for qualified researchers].
- [*where applicable*] I consent to my data being [stored and/or disclosed and/or accessed] outside of Canada [specify jurisdiction].