

Guidance Document	Open Access/Open Data
Effective Review	Delegated & Full Board (NMREB and HSREB)
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Transparency, reproducibility, and accessibility are becoming increasingly important considerations with respect to research dissemination. As such, the Tri-Council has released a requirement that all publically funded research be made available in an open access repository within 12 months of publication (see [Western Libraries](#) for more information). Many journals are also now requiring raw data sets to be included with publication submissions. This policy change has ethical implications for participants engaging in research:

- What information is being collected?
- How is it being used?
- Who will have access to it?
- How are participants providing informed consent to share their data?

Researchers must ensure that participants are informed of the data security and confidentiality measures in place to protect their data. If data will be made available to journals and/or other researchers (e.g., for replication studies and/or re-analysis for different research questions) then participants **must** be informed of this in the Letter of Information and Consent (LOI/C), as well as what type of information will be shared. It is important to note that the strict confidentiality practices as outlined in the LOI/C pertain to the IDENTIFIABLE information rather than the anonymized data (i.e., where there are no identifiers or code to re-link identification). Also, as per institutional policies, only identifiable information must be deleted after the data retention period (i.e., Western 7 years; London hospitals 15 years; and Health Canada 15 years); anonymized data may be retained indefinitely.

Researchers are encouraged to be mindful of the language included in the LOI/C to avoid restricting themselves from sharing anonymized data later on in the research life cycle. Researchers should consider what information participants need to receive in order to give informed consent prior to submitting a protocol for ethics review, as well as what information might be requested by a journal in order to promote transparency and reproducibility.

Some examples of LOI/C language regarding open data include:

- **CLINICAL DATA**
For the reasons of transparency and education, it is strongly encouraged by many medical journals and other authorities to publish the anonymized data from clinical studies for public use (anonymized means no data which can identify you would ever be published). This data is visible to researchers or the general public after the study is over. Researchers may use this data to improve knowledge about [insert topic here].

We will publish the anonymized data from this study. [Consider including some examples of what anonymized data would like like.] You should note that there will be NO personal identifiers, such as your [insert as appropriate: name, address, date of birth, etc.] in this list. Nothing in published

dataset would ever identify you specifically. There are guidelines for publishing safe, anonymized data and the researchers will be following these.

[insert sample table of anonymized dataset for participants' information]

If you are interested in the background behind Open Data, we invite you to start at the British Medical Journal's Open Data website at: www.bmj.com/open-data"

- **OTHER QUANTITATIVE DATA**

"All identifiable information will be deleted from the dataset collected so that individual participant's anonymity will be protected. The de-identified data will be accessible by the study investigators as well as the broader scientific community. More specifically, the data [will/may be posted on specific database OR made available to other researchers upon publication] so that data may be inspected and analyzed by other researchers. The data that will be shared on [insert database/publication] will not contain any information that can identify you."

In addition, special considerations will be needed in qualitative research. That is, at which point are qualitative data anonymized? Depending on the research methodologies and participant samples, this may be a difficult determination to make and may require negotiation with participants during informed consent and throughout the data collection/dissemination process. Researchers must always be sensitive to the participants' rights and only share that which has been consented to be shared, and a plan for how this will be determined will need to be included in the ethics submission and LOI/C.

NOTE:

Researchers who have already collected data under an REB approved protocol that restricts access to sharing data with journals, etc. must comply with the parameters agreed upon in the signed consent documentation. For more information, or to request the REB to review your specific case, please contact the Office of Human Research Ethics.