Retrospective Consent Form Template for Open Access Data Sharing

This consent form template was created by the Metaresearch and Open Science Program at the Ottawa Heart Research Institute and the Brain-Heart Interconnectome ARCHIMEDES Team. This working draft was adapted from the OHSN-REB Informed Consent Form Update Template and will continue to be reviewed and refined to meet the evolving needs of the research community.

This template is intended:

1. For researchers seeking to obtain consent from research participants to share study data as openly as possible, through a public website that anyone can access. This approach furthers open science principles in disclosing the aims, risks, and benefits of sharing research participants' data in open access and obtaining their affirmative acceptance of such data sharing.

2. For situations where research participants are consenting to the sharing and secondary use of data about them that was previously generated for prior clinical or research purposes (i.e., retrospective consent).

It should be used as a separate consent form, either to supplement an additional wave of data collection within an ongoing study, or to obtain a new consent to the sharing of their research data ("re-consent"). Researchers should generally only recontact participants for re-consent if the participant agreed to be re-contacted (e.g., for inclusion in other further studies) or with the permission of the competent research ethics board.

When sharing data in open access, the following controls should apply to data collected from research participants:

Privacy is partly safeguarded through data de-identification. In addition to removing direct identifiers, before sharing data in controlled access, research teams should also follow best practices to remove or modify other aspects of data that might contribute to a significant risk of research participant re-identification. It should be made clear to participants that there will nonetheless remain a residual risk of re-identification.

Participants also need to be informed of the practical limits on the direct oversight of open access research data, and that it may not be possible to remove data from public websites once released.

Consent to sharing data in open access is premised on the communication of associated risks to research participants and their acceptance thereof. Though control of downstream data use is not possible after its public release, researchers should still make their best efforts to encourage responsible use of coded study data through website policies and by respecting participant withdrawal requests, where possible.

When referring to participant data, the term "**coded**" is recommended here because it effectively communicates that steps have been taken to reduce the risk of re-identification and that there also remains a residual risk of re-identification. It is defined in the Tri-Council Policy Statement (TCPS-2) and is commonly understood across Canadian health research contexts and jurisdictions. Researchers are discouraged from replacing the term coded with alternative terms such as "de-identified," "anonymized," or "anonymous" when seeking consent to share coded data in open access, as these terms can suggest that the data carries little or no residual risk of participant re-identification.

TIPS FOR WRITING AND IMPLEMENTING THE CONSENT

- **Delete this instructional page**.
- Only use logos that are applicable to your study.
- Use plain (lay) language that is easy for a non-medical person to understand:
  - Use short sentences and sections, and simple words, avoiding scientific or technical vocabulary, expressions, and explanations.
  - Avoid repetition of information unless doing so aids the participant in understanding the section they are reading and make sure there are no conflicts in what is written across the form.
  - Ensure that the final form is properly formatted and free of spelling or grammar errors.
  - Aim for grade 8 (age ~13) reading level, generally, and no more than grade 10 (age ~15) in any circumstance.
  - If applicable, the study drug should be named.
- Define all acronyms and abbreviations when they first appear.
- Use the term "study doctor" when referring to physicians involved in the clinical trial/study, to ensure that there is no confusion with the treating or primary care doctors.
- If assistance is provided during the consent process, or if consent is obtained from a substitute decision maker, more information, including the role or relationship of the impartial witness/interpreter/substitute decision maker, should be noted in the medical record and/or study record. Other aspects of the informed consent form (ICF) may also need to be modified.
- The language of these clauses is tailored to capable adult research participants, both healthy and having a disease or disorder. Additional language and safeguards may be required to share data from paediatric populations, adults not legally capable of providing informed consent on their own behalf (i.e., incapable adults), and other populations with individuated data governance needs.
- The summary page (below) is intended as an example. Integrate its content to the applicable institutional template which you are using to develop your consent form, as appropriate.

HOW TO USE THIS TEMPLATE

- *Turquoise italicized highlighting* indicates instructions to the consent form authors. **Delete** from the final draft.
- *Blue italics* within sentences indicate that protocol-specific details need to be inserted, such as drug/intervention name, options for protocol details, etc. **Replace** these with the details in regular font.
- Suggested text/examples are provided throughout the ICF. Any that are not relevant to a given protocol **should be removed**.

REMINDER: The informed consent form is only one component of the informed consent process. Verbal explanations, audio-visual support, time for consideration and the opportunity to ask questions ensure that participants fully understand the information in the ICF.

Retrospective Consent Form Template for Open Access Data Sharing

Study Title*: insert study title as written on the protocol*
REB Number: *insert number*
Sponsor Study ID: *insert sponsor's study ID if applicable*
Study Doctor/Primary Investigator: *insert name, department, and telephone or pager number*
Sponsor/Funder(s): *insert the name of the Sponsor or, if applicable, the funder(s) of the research*

[*Note: A 24-hour, 7-day a week phone number is required for all studies that include greater than minimal risk research procedures or interventions*.]

Emergency Contact Number (24 hours / 7 days a week): _____
Non-Emergency contact numbers are at the end of this document in the section entitled "Whom should I contact if I have questions or concerns?".

Ce formulaire de consentement est disponible en français sur demande.

Summary

- What are we asking your consent to do?
  We would like to ask for your consent to share your coded study data in open access.

  "**Coded**" means that information that directly identifies you (e.g., your name, your civic address, and your hospital number) will be removed and replaced with a unique, random code.

  "**Open access**" means making your coded study data available through a public website, for anyone around the world to freely access, use, and download as part of future health research.

- Why is data sharing important?

  Sharing your coded study data may contribute to many different research projects and their results could ultimately help improve the health of others in the future.

- How will we share your data?

  If you agree, your coded study data will be available on a public website for free. Anyone will be able to access, view, and use the data as part of health research. While we intend to make your study data available for health research only, there remains a residual risk that your data may be used for other purposes unrelated to research.

[If known, include details regarding the repository/website/platform where data will be made openly available and the data steward, i.e., the organization responsible (e.g., name, where it is located, and any other relevant information). If mentioning a specific website, clarify that data may be shared on additional platforms].

[If you will be sharing data through the ARCHIMEDES platform, replace the language in brackets above with the following: Your coded study data will be shared in the open access ARCHIMEDES database. The Ottawa Heart Institute Research Corporation (OHIRC) will act as the steward of your data, and share your data using servers that McGill University provides. OHIRC and McGill implement safeguards, such as secure data storage, staff training, and data use policies, both to communicate limitations on data use, and to mitigate the risk of data being misused.]

What are we asking you to do?

You [*are/were*] a [*current/past*] participant in a study called [*name of study*], which is looking at [*type of cancer/illness/disease*]. The purpose of the study was to [*briefly describe in a manner that is consistent with information in the original ICF*].

When you took part in our study, we collected information on [*list the collected data*]. This data has been used by the research team to [*describe the original study in general terms*].

Your coded study data can also be useful for future health research. We would like to ask your consent to share your coded study data in open access. "**Coding**" means that information that directly identifies you (e.g., your name, your civic address, and your hospital number) will be removed and replaced with a unique code, which is typically a long, random string of letters and numbers.

"**Open access**" means making your coded study data available through a public website, for anyone around the world to freely access, use, and download. Making your coded study data more easily accessible and readily available can facilitate research that may improve people's health.

What data about me will be shared?

If you agree, your coded study data from the following categories will be shared on an open access website: [*describe the categories of information that will be shared. These might include demographic information, information about biospecimens, genetic information, phenotypic information, health information, photographs, videos, audio recordings, images (e.g., MRI, X-Ray, etc.)*].

How will my privacy be protected?

To protect your privacy, we will code your data before making it available in open access. The link between this code and your identity will be stored securely by the study team and will only be accessible to them. In addition, we will remove other data that presents a significant risk of causing you to be re-identified through its combination with publicly available information. Website policies will also include terms related to the protection of privacy.[*Describe other mechanisms used to reduce the privacy risks of particularly sensitive data types listed above, where applicable*.].

[If you will be sharing data through ARCHIMEDES, replace the language in brackets above with the following: For example, addresses, and identification numbers such as hospital codes and your social insurance number will be removed. Software tools will be used to remove identification numbers and facial features from your MRI images, to better protect your privacy. [Remove the foregoing sentence if your study is not collecting MRI images.].

There remains a possibility that someone could identify you using your coded study data. This risk will increase over time as technology advances and new ways of understanding information evolve. For example, there may be new ways of linking information back to you that we cannot foresee now. If you are re-identified, you, your family, or your community may experience discrimination on the part of employers, insurers, or other third parties.

How will my data be stored and for how long?

Your study data will be shared through a website that is available to the general public and may be held indefinity. The study data will be accessible to all categories of users, for use as part of health research. Users may download copies of your data. Further, copies of the data could be shared on other public websites, possibly forever.

[*If applicable, include details regarding the data steward, i.e., the organization or repository that is responsible for hosting the data on a public website (e.g., name, where it is located, published research location, and any other relevant information).*]

[*If you will be sharing data through ARCHIMEDES, replace the language in brackets above with the following: Your study data will be shared in the open access ARCHIMEDES database. The Ottawa Heart Institute Research Corporation (OHIRC) will act as the steward of your data, and share your data using servers that McGill University provides. OHIRC and McGill implement safeguards to communicate limitations on data use, and to mitigate the risk of data being misused. These safeguards include: requiring personnel to undergo privacy training and to keep such training up-to-date; using web analytics to identify potential misuses of data that is held on the public website, communicating permissible uses of the data to users through website policies; storing the data using secure hardware; and implementing policies and processes to respond to privacy incidents and to data withdrawal requests.*]

In the future, it is possible that the responsibilities for the stewardship of your data will be transferred to a public website managed by a different organization. This will not affect the conditions according to which your study data can be accessed or used.

How will my data be used?

Your coded study data will be available on a public website for free. Anyone can use it as part of future health research.

Your study data may be shared, used, and downloaded by researchers from Canada or elsewhere in the world, and from all types of organizations, including academic institutions, public bodies, for-profit companies, and nonprofits. Researchers may use your data for both commercial and non-commercial research purposes (i.e., the outputs of the research can be translated into commercial products).

Website policies will require that users only use data for research purposes. However, it is not possible to guarantee that everyone will respect these policies, or to monitor how data is actually used. Therefore, it is possible that your study data could be used for unauthorized purposes, including non-research purposes. *[Remove or modify to reflect actual website policy.]*

We will not be able to ask permission from you or your study doctor for each specific research project. We will not be able to give you reports or specific information about the exact types of research that are done with your study data. Nonetheless, the results of the research that are performed using your data, and that of others, will be made available to the public online, and in academic publications.

In addition, the study team may also share an anonymized subset of your study data through open access databases. **"Anonymization"** means that the information is irrevocably stripped of direct identifiers, no code is retained that would allow your data to be linked back to you, and the risk of re-identification from your remaining indirect identifiers is low. This data is shared publicly and can be used for any purpose.

Will I benefit from sharing my data?

You will not receive any direct benefit from sharing your study data. However, sharing your data may contribute to many different research projects. The results of these studies could help to improve the health of others in the future.

It is possible that your study data will be used by commercial organizations and some of the research done with your coded study data may one day lead to the development of software, tests, drugs, or other commercial products. If this happens, you will not be informed or compensated.

What risks are involved in sharing my data?

Data about you that is shared through the ARCHIMEDES platform could be used for future purposes that you would not agree with, including non-research purposes that do not respect ARCHIMEDES policies.

Further, there is a risk that you be re-identified through the use of your study data (as described above).

There may be other risks involved in participating in ARCHIMEDES that are unknown today, but that could materialize in the future.

Can I change my mind and withdraw my data?

If, at a later date, you change your mind and no longer wish to have us store or share your coded study data in open access, you should contact [*insert contact info*]. We will do our best to honor your request and remove any copies of your data from the public website. However, this may not always be possible. For example, if we no longer have a way to identify which study data belongs to you, we will not be able to retrieve them. Also, if researchers or others have already downloaded copies of your data, or have published the data on other websites, it will not be possible to destroy those copies. It is never possible to guarantee the complete removal of data that has been publicly shared on the Internet.

How does the new information affect my participation in future research within this study?

Whether or not you agree to share your previously collected study data does not affect your participation in the main study. Choosing to share this data is your choice and will not affect your participation in other research studies, nor affect the medical care you receive.

Is there anything else I should know?

If you have any questions, you should discuss them with the study team. You should take as much time as you want to make an informed decision about whether you wish to participate.

What are my rights as a participant?

By providing your consent to participate in this study, you do not give up any of your legal rights in relation to the investigators, sponsor, or involved institutions concerning potential compensation, nor does this consent form relieve the investigators, sponsor, or involved institutions of their legal and professional responsibilities.

The new information in this consent form has been reviewed by [*name that ethics board that reviewed this study.*]

Whom should I contact if I have questions or concerns?

If you have questions about sharing data in an open access database, you should talk to your study doctor/coordinator/main contact [name and contact information].

Principal Investigator Name	Telephone

Contacts:
If you have questions about your rights as a participant or about ethical issues related to the data sharing topics in this document, you can talk to someone who is not involved in this specific study by contacting the [*name the research ethics board responsible for the oversight of this data, and list the contact information of its Chairperson or local equivalent*].

NOTE: include the signature page only when the new information requires signed consent (see the consent form update guidelines for criteria). If a signature is not required, delete the signature page.

Study Title: *insert study title as written on the protocol*

SIGNATURES

- I understand the information within this informed consent form.
- I have read, or someone has read to me, each page of this informed consent form.
- I understand that when my coded study data are shared in open access, there are safeguards in place to help protect my privacy. However, there remains a risk and possibility that someone could identify me.
- I understand that my coded study data will be shared on a public website that anyone can access for future health research purposes.
- I understand that a preference not to share my coded study data will not affect the medical care I receive, nor my participation in any other research studies.
- I understand that I do not give up any of my legal rights by signing this informed consent form.
- The intended research and data sharing have been explained to me. I have had the opportunity to discuss them and to ask questions. All my questions have been answered to my satisfaction.

Signature of Participant	Printed Name	Date

Investigator or Delegate Statement
I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in continuing to take part in this study.

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date

Participant Assistance

Complete the following declaration only **if the participant is unable to read:**

- The informed consent form was accurately explained to, and apparently understood by, the participant.
- Informed consent was freely given by the participant.

Signature of Impartial Witness	Printed Name	Date

Complete the following declaration only **if the participant has limited proficiency in the language in which the consent form update is written and interpretation was provided** as follows:

- The informed consent discussion was interpreted by an interpreter.
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:
By signing the consent form, I attest that I provided a faithful interpretation for any discussion that took place in my presence and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter	Printed Name	Date

[*Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.*]