Retrospective Consent Form Template for Open Access Data Sharing in ARCHIMEDES

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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 template is intended:

1. For researchers seeking to obtain consent from research participants to share their study data as openly as possible, through the public ARCHIMEDES 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. In choosing an appropriate data release tier, researchers should consider both the identifiability of the data and whether it reveals sensitive attributes about the research participants.

2. For situations where research participants are consenting to the sharing and secondary use of data about them that was previously collected for prior 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 open 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. For example, such limitations could apply where the users of the data have copied it to other websites, or where linkage logs enabling participant withdrawal are no longer available.

- 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 other 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**.
- Insert applicable institutional logo(s) into the header of the first page as well as on all signature pages, or as per local institutional requirements.
- 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.
- Insert institutionally required sections or language if and where applicable (e.g., conflicts of interest, return of incidental findings, etc.).

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 the data types shared, options for protocol details, etc. **Replace** these with the details in regular font.
- Suggested text/examples are provided throughout the ICF. Any template language that is not relevant to a given protocol **should be removed or modified**.

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: *insert the name of the sponsor of the research, if applicable*
Funder(s): *insert name(s) of the funder(s) of the research, if applicable*

[*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?".

What am I being asked 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 [*is/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 through the open access ARCHIMEDES database.

"**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.

Your decision to share your coded study data in ARCHIMEDES' open access database is voluntary. Choosing not to share your coded study data will not affect your access to healthcare or treatment, your participation in the main study, nor your participation in other research studies.

You should take as much time as you want to make an informed decision about whether you wish to participate.

What data about me will be shared?

If you agree, your coded study data from the following categories will be shared through the open access ARCHIMEDES 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.)*].

[If this research involves the linkage of data from multiple clinical or research databases or data repositories, provide details about which data will be linked together, the sources of that data, and how privacy will be preserved in performing data linkage].

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 [*name of site*] study team and will only be accessible to them. It will not be available to other third parties. 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.

We will use data de-identification methods appropriate to each data type collected. The methods chosen will reflect the state of the art at the time that data is prepared for release. For example, we will remove dates, addresses, and identification numbers such as hospital codes and your social insurance numbers from all data types. For imaging data, we will use software tools 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:]*.

[*Describe the mechanisms used to reduce the privacy risks associated with other sensitive data types collected, where applicable*.].

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.

What risks are involved in sharing my data?

We will not ask permission from you for each specific research project. 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.

Although there are physical, technical, and organizational safeguards in place, there is a risk that someone who is not authorized may access the data that ARCHIMEDES has stored about you.

Further, there is a risk that you could be re-identified through the use of your data.

The release of data outside Canada may increase the risks to your privacy, because the information privacy laws in other countries may not be as strict as those in Canada.

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

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.

We will not 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.

Will I receive payment for sharing my data?

You will not be paid for sharing your coded study data through ARCHIMEDES.

It is possible that your study data will be shared with or 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, treatments, or other products that are sold commercially. If this happens, you will not be informed or compensated.

How will my data be stored and for how long?

Your coded study data will be shared through the open access ARCHIMEDES website, which is available to the general public. This data can be held on servers, including cloud servers, both in Canada and elsewhere in the world. It will be kept for as long as it remains useful for health research purposes, possibly forever.

The Ottawa Heart Institute Research Corporation (OHIRC) will act as the steward of your data. OHIRC provides technical and organizational support to researchers in uploading, curating, and re-using data from multiple different studies together as part of future research.

OHIRC implements 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, instead of or in addition to ARCHIMEDES. 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 the public ARCHIMEDES website for free. Anyone can use it as part of future health research. Further, copies of the data could be shared on other public websites, possibly forever.

Your study data may be shared, used, and downloaded onto local hardware 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).

A for-profit company, for example, could be a pharmaceutical or a biotechnology company that wants to make a new drug, test a currently approved drug and/or develop a new way to treat or diagnose disease. It could also be a diagnostic, medical device or digital health technology company that wants to develop new ways of detecting, diagnosing or monitoring a disease.

Health-related studies may include, but are not limited to research conducted to:

- find out more about the causes and progression of diseases and conditions;
- find out how new treatment options affect diseases and conditions;
- develop and test methods to diagnose different diseases and conditions;
- learn more about health patterns, treatments and/or outcomes;
- improve clinical-decision making tools;
- support imaging research, such as developing or improving tools that analyze medical images (e.g., MRIs, CT scans, X-rays);
- develop, train and test artificial intelligence or machine-learning models; or
- other purposes, not yet identified, as research and technology are continuously evolving.

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.]*

[If molecular, genetic, or genomic research are anticipated, include the following language, or equivalent language, as is relevant to your research site and study:]

Researchers may also conduct **molecular, genetic or genomic research** using your data, as further described below:

Molecular Research on Data:
Molecular data refers to information about the tiny building blocks and processes inside your cells that help your body function. This includes data about your DNA (genetic material), RNA (which helps turn genes into proteins), proteins (which carry out most of the body's work), and other small molecules involved in how your body grows, repairs itself, and responds to illness. By analyzing molecular data, researchers aim to better understand the underlying mechanisms of health and illness, which may lead to new approaches for diagnosing, treating, or preventing disease.

Genetic Research on Data:
Genetic data is information about your DNA—the set of instructions in your body that you inherit from your biological parents. This data can show things like your risk for certain health conditions, how your body might respond to medications, or traits like eye or hair colour. By analyzing genetic data, researchers aim to better understand how genes affect health and disease, which can help to develop new ways to prevent, detect and treat these diseases.

Genomic Research on Data:
Genomic data is information about your entire set of DNA, also called your genome. It includes

all of your genes, as well as the parts of your DNA that help control how those genes work. By analyzing genomic data, researchers aim to understand how different genes work together, how they influence health and disease, and how people may respond differently to treatments.

What data about me will be shared openly, without restriction?

In addition, ARCHIMEDES and/or 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. For example, it could include aggregated information about multiple research participants, or minimal demographic or clinical information about you.

Can I change my mind and withdraw my data?

It is your choice whether or not to let researchers share your coded study data for future research. If you say "yes" now, you can still change your mind later at any time. If, at a later date, you change your mind and no longer wish to have us store your coded study data in ARCHIMEDES for future research use, 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 ARCHIMEDES 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 used or 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.

What are my rights as a participant?

By providing your consent to participate, 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.

Whom should I contact if I have questions or concerns?

If you have questions or concerns about sharing data on the open access ARCHIMEDES website, you should talk to the research team or the person at your institution who oversees the research study you are participating in.

Principal Investigator Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to ARCHIMEDES, 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*].

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

SIGNATURES

- I have read, or someone has read to me, each page of this informed consent form, including the risks, benefits, and my rights as a participant.
- 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 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 participation is voluntary and my decision will not affect the medical care I receive, nor my participation in any other research studies.
- I do not give up any of my legal rights by signing this informed consent form.
- I have had the opportunity to ask questions. All my questions have been answered to my satisfaction.
- I agree for the coded study data to be deposited into the ARCHIMEDES open access database for future research use as explained in this consent form.
- I will be given a signed and dated copy of this consent form.

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 depositing their coded study data on the ARCHIMEDES open access website for future research use.

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

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

Interpreter Declaration and Signature:

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:

- A sight translation of this document was provided by the interpreter.
- The informed consent discussion was interpreted by an interpreter.

By signing the consent form, I attest that I provided a faithful sight translation of this document and accurate interpretation of any discussion that took place in my presence.

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.*]