Western Research

Western University
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Guidance Document	HSREB Repository (Databases and Biobanks) Letter of Information and Consent (LOI/C) Form
Effective Review	Delegated
Version Date	1 January 2025

Legend

Blue text: Guidance and/or instructions
Black text: Wording that should be used *as applicable*
Red text: Language that should not be included
Yellow Highlight: Biobank Specific information

When writing the consent, please remember to:

- Use plain (lay) language that is easy for a non-medical person to understand. An 8th grade reading level is recommended.
- Remove unnecessary repetition throughout the form; if technical words are used a simple definition in lay terms should be included beside the terminology in brackets.
- Please use "second person" voice - i.e., "You will be asked to ..."
- Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended).
- Define all acronyms and abbreviations when they first appear.
- Use the term 'participant' instead of 'subject' at all instances to emphasize the voluntary nature of the participation.
- Ensure that the final form is properly formatted and free of spelling or grammar errors.
- Keep the footer simple and short. It should only include the version date, pagination as "page x of y", and initials on every page.
- After all edits have been made, all text should be black.
- The participant must be provided with a copy of the entire consent document and this should be stated. Example: This letter is for you to keep or You will be given a copy of consent document once it has been signed.
- Institutional logos/letter head should be reflected in this document

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Letter of Information and Consent [Sub-Group if applicable]

Repository Title [as it appears on Protocol]:

Name of Principal Investigator [include institutional affiliation]:

Contact Information:

Co-Investigators:
Listing co-investigators and/or staff is optional but discouraged. If you choose to enter the names and titles of co-investigators keep in mind that at any point there is a change in the co-investigator, the consent form will require revision, review and approval by the REB.

Funding [or Sponsor if not investigator-initiated]:

Conflict of Interest: Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the individual beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, honoraria, profit from selling data or samples, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.

If SDM involved, insert:
In this Consent document, "you" always refers to the study participant. If you are a substitute decision maker (SDM) (i.e. someone who makes the decision of participation on behalf of a participant), please remember that "you" refers to the study patient. If an SDM is needed for this study, you will be asked to review and sign this consent form on behalf of the participant.

Introduction: You are being invited to participate in a research repository because you [explain why participant is eligible. E.g., are a healthy volunteer, are a cancer patient of Dr. X, are having surgery for condition Y, have been referred to clinic Z]. A repository is a collection of data [*and/or biological specimens like blood or tissue*] to be used for future research.

INSERT ONLY IF NECESSARY: ……. [insert name of Hospital or Institution] and the investigator Dr. … [insert Locally Responsible Investigator's name] are under contract with the Sponsor of this study and are receiving compensation to cover the costs of the repository.

Why Is This Repository being established?

This repository is being created to … Explain in layman's terms what the database will be used for and what it will not be used for. We anticipate enrolling [*insert number*] participants from this site.

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What is involved in participating in this repository?
If you volunteer to have your personal health information added to this repository, we will ask you to do the following things:
Describe the procedures chronologically using simple language, short sentences and short paragraphs. Medical and scientific terms should be defined and explained.
e.g. Agree to the collection of your personal health information from your medical chart; agree to your personal health information being kept in the database for xx years [or indefinitely]; agree to being contacted by the researcher about participation in future studies *or agree not to be contacted*, agree to have left over tissue from your surgery frozen and shared with, have XmL of blood collected now, and in annually for the next xx years; complete annual questionnaires online etc.

There are no medical benefits to you from your taking part in this repository. However, by participating, you may assist us in finding out more about [*insert what is appropriate e.g. disease x*]
Choosing not to participate in this database will in no way affect your care or treatment [relevant only for patient LOI/C, not healthy participants].

Who Will Have Access To Your Data [and Samples]?

By having your personal health information added to a research database there is the potential for a breach of confidentiality. Every effort will be taken to ensure that your information is kept private. The only people who will have access to your directly identifiable information such as your name and contact information are [Insert the scope of all people who will have access to the data]. These people understand the laws regarding privacy and have signed a confidentiality agreement. The data will be securely stored [Insert location/platform].

We wish to use your [*de-identified, identifiable, anonymous, anonymized*] data [*and/or biological specimens*] for future research related to [*scope*]. While such research is not planned at this time, it is possible that we may use [*and/or share your data with other researchers {at this institution/in Canada/around the world}*] in the future. Once data is shared, it cannot be witehdrawn [*or if it can be, the mechanism to do so*]. It is unknown at this time what the risks of any future research are [*if there are known risks such as to genetic research, please state the risks. Any risk of re-identification or incidental findings and how they will be managed need to be disclosed*].

We will continue to collect your information for [duration *e.g. one time, 10 years etc.]* and retain it [period of time *e.g. indefinitely, duration in years*]. Your identifiable information will further be retained for 15 years after the database closes.

If a research study wants to use samples and/or data from this repository, our team will assess the request and require that the research be approved by a research ethics board.

For the purposes of ensuring the proper monitoring of the research database, it is possible that a member of the Western Health Sciences Health Sciences Research Ethics Board or the Quality

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Assurance and Education Officers from the Hospital's Office of Research Services may consult your research data and medical records. By signing this consent form, you give permission for such access.

If using a third party for data collection, storage, or transfer (for example Qualtrics, REDCap, NVIVO etc.) please include the following information (at a minimum), as applicable:
- Use of 3rd party
- Name of 3rd party
- Link to 3rd party's privacy policy
- Country where data is stored using 3rd party (do not need to include Western storage location once exported from 3rd party platform)
- Identify risks (i.e. nothing over the internet is ever 100% safe)

Will You Receive Any Compensation for Participating?
You will receive [value and method of delivery *e.g.$10 in cash at the time of your visit, $20 each year that you respond to questionnaires via an Amazon eGift card sent to your email, no compensation*]

What Are Your Rights As A Participant?

If you volunteer to be part of this repository, you may change your mind and withdraw at any time without consequence. Indicate whether the participant has the option of removing data already collected. For example, *You have the option of removing your data [and/or samples] from the repository but if it/they has/have already been utilized in research or shared with other researchers we will not be able to withdraw them.*

Whom Do You Call If You Have Questions?

If you have any questions about the research database now or later, please contact [insert name of investigator or staff and title]

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics that supports Western's research ethics boards (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. An REB is a group of people who oversee the ethical conduct of research studies. The REB is not part of the study team. Everything that you discuss will be kept confidential.

Or

If this is a study that requires Lawson oversight:
The Letter of Information should include the following language for St. Joseph's Health Care London as a contact outside of the research team:

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If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 61234.

The Letter of Information should include the following language for London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

Include this section with the rest of the LOI document, but on its own page.

Study Title
PI Name

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to take part in this study.

_____	_____	_____
Print Name of Participant	Signature	Date *(DD-MMM-YYYY)*

WHEN YOU INTEND TO RECONTACT FOR FUTURE RESEARCH

If you wish to ask participants to consent to future contact for additional studies, please provide check boxes before the "Participant's Signature" block for participants to accept or decline to be contacted for other studies in the future. See example below:

CONTACT FOR FUTURE STUDIES

Please check the appropriate box below and initial:

___ I agree to be contacted for future research studies (but understand that I will not be contacted in all instances where my data *and/or samples* will be used)

___ I do NOT agree to be contacted for future research studies

The person obtaining consent must also sign the consent form. Please insert the following:

My signature means that I have explained the study to the participant named above. I have answered all questions.

_____	_____	_____
Print Name of Person Obtaining Consent	Signature	Date*(DD-MMM-YYYY)*

If you are including people who require a substitute decision maker, insert the following:

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☐ Your signature on this form indicates that you are acting as a substitute decision maker(s) for the participant and the study has been explained to you and all your questions have been answered to your satisfaction. You agree to allow the person you represent to take part in the study. You know that the person you represent can leave the study any time.

Print Name of Substitute Decision Maker	Signature	Date *(DD-MMM-YYYY)*

Relationship to Participant

If you are including people with communication difficulties, insert the following:

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator	Signature	Date *(DD-MMM-YYYY)*

Language

If you are including illiterate people (those who cannot read English, add the following:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date *(DD-MMM-YYYY)*

Relationship to Participant