University of Manitoba | Human Research Ethics

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Guidelines to Create a Recruitment Repository for Future Studies

Summary

More and more researchers are collecting different types of participant data to store in data **repositories** (e.g. databases) for future unspecified use. This includes the collection of identifiable contact and other information from potential participants for recruitment in future research studies.

In order to ensure that ethical principles are maintained with respect to the creation of these repositories and the collection and storage of these data, the TCPS (2022) includes a new provision governing **broad consent** (Article 3.13).

Data Repositories

Data are stored in **repositories**, which have "a known governance framework that 'must ensure safe storage, preservation, and curation of the data' and human biological materials". The creation of a repository requires REB review and approval and is subject to continuing research ethics review.

Where data or human biological materials are being stored for use in future unspecified research, the researcher, the relevant authority of the repository, and future researchers share the responsibility of ensuring that the terms of participant consent are respected (Respect for Persons) and that participant privacy and confidentiality, as well as participant welfare are protected (Concern for Welfare) throughout the life of the research project.

You may already have a repository set up in connection with a research study. As part of the continuing ethics review process, the REB Chair may ask that you create a new protocol with respect to the repository if they think the data connected to the repository is better managed separately.

Broad Consent

Broad consent is defined in Article 3.13 as "an indication of agreement by an individual, or their authorized third party, for the storage and use of their **data and human biological materials** for all types of future unspecified research, subject to specific restrictions".

Broad consent includes the following elements:

- is for future unspecified research,
- may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry,
- applies to the storage and secondary use of participants' data and human biological materials collected for research purposes, and
- occurs in the context of future research using data and human biological materials with no direct contact or intervention with participants at that time.

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Broad consent, like other forms of consent, must be free, informed, and ongoing and must include the following information:

- potential benefits of the research,
- potential risks of the research,
- how participant interests will be protected,
- any limitations to those protections,
- potential uses of the data, and
- limitations to the range of uses, if known at the time.

Purpose of the Guide

This guidance document has been created specifically for repositories that will collect contact and other identifiable information from current or potential participants for use in future recruitment of research participants,

The creation of a repository under the auspices of the University of Manitoba requires UM REB review and is subject to continuing research ethics review, in accordance with a proportionate approach to research ethics review (Article 6.14).

Appropriate mechanisms and procedures should be clearly outlined in the governance of the repository to ensure that subsequent use of the data is in accordance with the original terms of participant consent.

When seeking consent for a specific research project at the same time as seeking consent for storage of data for future unspecified research, prospective participants must be provided with an option to consent to each separately, either through separate consent forms or separate sections on the same form.

Where the data are from a specific or unique community or group, researchers and repositories may be required to further consult with, or seek permissions from, such groups, or to respect existing agreements.

Protocol Submission Requirements

The text in **black** is the question as worded in the RAS system. The text in **green** clarifies what the Research Ethics Board (REB) is looking for.

Sections and/or questions not listed below can be answered 'N/A' if they are not applicable to your repository.

Purpose of the Research

- Provide a **brief** statement about the repository project written in **lay** language.
    - Explain that this protocol is to create a repository of potential participants for recruitment for future studies.
- In point form, list the research question(s) and objectives for this research study..
    - Indicate N/A.
- Describe the research methods.
    - Indicate N/A.

- Briefly describe chronologically what the research team will ask participants to do after consent has been obtained.
    - Here appropriate mechanisms and procedures should be clearly outlined regarding the governance of the repository to ensure that subsequent use of the data is in accordance with the original terms of participant consent.
    - Details should include:
        - whether any additional information (i.e., demographic information) will be collected. Outline how this additional information will be collected and used.
        - how team members will have access to the data to recruit for future studies.
- Where will the study take place?
    - If the consent process will take place on-line, specify the platform to be used.
    - If the consent process will happen in-person, specify where the meeting to discuss/obtain consent will happen. If participants have the option to choose the location, indicate this choice provide examples of the types of locations (e.g., coffee shop, participant's home, another public place).
- How much time will study participants be expected to dedicate to the research?
    - Indicate N/A.
- Type of Study
    - Indicate 'Other' then add Repository.

Research Personnel

- Protocol Personnel Table
    - Include all individuals who will have access to the database. This section will require continued updating to reflect the addition of other researchers who are either:
        - accessing the repository, or
        - recruiting people for the repository.
- For each team member listed above, describe (as applicable) how they will interact with research participants and/or access raw data.
    - Outline who will be responsible for managing the repository and allowing/removing researcher access to the repository.
- What type of data will each individual have access to?
    - State how access to the database will be restricted and specify who will have direct access.
    - Specify whom the information may be shared with (for example, other researchers at the same institution; researchers in other institutions).
    - State the type of information (for example, name, phone number) that may be provided to/shared with other researchers.
    - Team members accessing directly identifying information should be named in the consent form. Students, RAs, study coordinators, and those in similar roles should be identified by their role only and should not be named directly.
- All team members who engage with participants and/or raw data are required to complete CORE training and PHIA training (if appropriate). All team members (other

than the PI, Co-PI, and Advisor) must complete an Oath of Confidentiality. If any team member requires alternative training, provide a justification and describe the training that will be completed.
    - All team members who engage with participants and/or the repository are required to complete CORE training and UM's Privacy Training for Researchers and upload certificates into their RAS profile.
    - All team members (other than the PI and Advisor) must sign an Oath of Confidentiality. Template Oaths are available **here**.

Participants

- What are the inclusion criteria to participate in the study?
    - List the inclusion criteria.
    - If there are inclusion criteria that may change over time (e.g. age range limits), you must describe the process you will implement to remove excluded participants from the repository. This information must be included in the consent form.
- Describe how prospective participants will be identified, who will contact them, and the process of doing so.
    - Outline all recruitment strategies. Include recruitment from specific research projects, as relevant/applicable.
    - Best Practice: Create a standard method for recruiting participants for the repository. Outline this method here. For future studies, reference the repository protocol number to streamline and ensure consistency in the recruitment process.
    - Upload any scripts, posters, social media posts etc. that will be used to recruit for the repository.

Consent Process

- Describe the consent process including how consent will be obtained.
    - Outline when and how participants will be consented.
    - Best Practice: Create a standard method for consenting participants for the repository. Outline this method here. For future studies, reference the repository protocol number to streamline and ensure consistency in the consent process.
- Consent forms:
    - To seek broad consent for the storage and future unspecified use of data and human biological materials, researchers must provide prospective participants, or authorized third parties, with applicable information as set out in **Article 3.2**, as well as the following details, as appropriate to the particular research project:

        a. the type, identifiability, and amount of data being collected and stored for re-use, and for what potential purpose;
        b. the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;
        c. a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);
        d. the risks and potential benefits of storage of data, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;
        e. access to a general description of the repository and its governance;

f. a statement regarding participants' preferred method to being re-contacted for additional future research;
g. whether the data could be shared with researchers who are not subject to the TCPS;
h. whether linkage of data gathered in the research with other data about participants – either contained in public or personal records – is anticipated (**Article 5.3**); and
i. separate options for consenting to participate in a specific research project and for consenting to the storage of data for future unspecified research.

Similar to consent for a specific research project, the broad consent process must focus on what is relevant to an individual participant's decision-making process. Not all the listed elements are required for all research. It is up to the REB to consider whether all elements listed, or additional elements, are necessary to the consent process of the research project.

Where future communication is contemplated (e.g., re-contact, follow-up with participants, return of research results), researchers should invite participants to maintain and update their contact information with a designated individual. As the elements of informed consent may change over time, repositories and researchers have a duty to provide participants who wish it, with information relevant to their consent throughout the storage and use of their data for research (**Article 3.3**). This includes providing participants with options about obtaining information and details of the research and/or repository. Moreover, ensuring that appropriate mechanisms to maintain informed and ongoing consent are in place is an important consideration in the context of evolving capacity (Article 3.3).

Data

Refer to the **Data Storage Guidelines** for more information on proper storage options. Due to the nature of the data, it will be identifiable. Therefore, proper safeguards need to be in place to protect the data.

- Add the repository under 'Other Data Mediums'. Specify how long identifying information will be retained and how it will be destroyed, keeping privacy and confidentiality in mind.
- If applicable, indicate when/if the source data will be deleted or destroyed (e.g., paper forms, data from the intake platform)
- Add the storage and destruction of consent forms under 'Other Data Mediums'.
- If you will be collecting demographic information, please state 'Yes' under the survey/questionnaire question and answer the following questions accordingly.

- Will data be transferred from one site to another? This includes data collected in the field or off-site.
  - Discuss how data will be transferred to the repository if you are collecting the information in-person.
  - If data will be collected on a platform different than what is used for long-term storage, outline how this transfer of data will take place.

- Will data be shared/transferred between research team members (e.g., student PIs/advisors, research assistant/PI, PI/co-Is)?
    - Discuss how data will be transferred between research members.
    - Best Practice: Create a standard method for accessing and removing data from the repository. Outline this method here. For future studies, reference the repository protocol number to streamline and ensure consistency in the data transfer process.

Withdrawing

- How and when will you inform participants about the withdrawal process?
    - Keep this information consistent with the consent form, which should clearly outline how participants can withdraw from the repository.
- Indicate what participants should do to withdraw from the study at any point. Include information on who they contact and how the contact should be made.
    - Describe how participants can withdraw from the repository at any point in time.
- Indicate what will be done with the participants' data when they withdraw.
    - The information should be destroyed as soon as possible. If you anticipate any limitations to your ability to destroy these data (e.g. program issues), indicate the limitations here and in the consent form.

Other Approvals

- If approvals will be needed from other organizations or groups to post or send recruitment material, state this here.
- Attach any scripts that will be used to request distribution of recruitment material or any approval letters/emails that are available.