University of Manitoba | Human Research Ethics

Human Ethics - Fort Garry
66 Chancellors Circle
Winnipeg, MB R3T 2N2
humanethics@umanitoba.ca

Start Here!

What You Need to Know Before Submitting Your Fort Garry Human Ethics Protocol

Considerable preparation is required before submitting your ethics protocol for approval. The following information will help you get started.

Note: Students and Post Doctoral Fellows require an Advisor/Supervisor to sign off on their protocol.

	Required Certification
	TCPS2 CORE Certificate • All team members interacting with participants and/or accessing raw data, whether those data are anonymous, anonymized, coded, or identifiable, must complete the most recent **TCPS2: CORE** training and **upload** the Certificate of Completion to their RAS profile. • You will not be able to submit your protocol if you or anyone on your team has not uploaded the CORE Certificate. • **CORE training** is a self-paced virtual training completed online. When creating your CORE account, use your UM email address. • In some cases, alternative ethics training may be provided. Please contact humanethics@umanitoba.ca for more information.
	UM Privacy Certificate of Completion /UM Pledge of Confidentiality • All team members must complete the **UM's Privacy Training for Researchers.** • **Module 1**: Satisfies the UM requirement for PHIA Training • **Module 2:** Required **in addition to Module 1**, for UM faculty/staff/students accessing **WRHA records and facilities** for research purposes • If you are a UM faculty member, student or staff you **must access** the training through **UM Learn**. If you do not have a position at UM, you can access the training through the **Access and Privacy website**. • Ensure your training is up to date.

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	• For more information, visit the **Access and Privacy Office's Website**
	Required Documents **All participant-facing documents must be final versions and uploaded to your protocol.** If you upload a draft document, you must provide justification and indicate in your protocol that you will submit an amendment and upload the final version. **Proofread** all participant-facing documents and **correct all errors** before submission.
	Oath of Confidentiality • With the exception of the Principal Investigator, Co-Principal Investigator, and Advisor, all team members who will interact with participants and/or have access to the data must sign an Oath of Confidentiality. CORE training is not a substitute for an Oath of Confidentiality. • The research project title written in the oath must be consistent with the protocol title. • A template can be found on **our website**.
	Recruitment material (e.g. posters, social media posts, telephone and email scripts, etc.) • See the **Participant Recruitment Guideline** for more information. • Recruitment material must be submitted as **individual documents**. Do not submit as a single document containing all the material. • Note that the PI's name must be included in all material. The name of the research lab or group without the PI's name is not sufficient.
	Consent Forms • Ensure that all verbatim statements written in bold in the Consent Form Template are included in the form. • Templates can be found on **our website**. • All applicable information must be included in your consent form per Article 3.2 of the TCPS2. • If you are recruiting minors, assent forms may be required. • If you intend to share data stored at UM with a team member outside UM and/or if you intend to transfer data to another location, this must be clearly outlined in your consent form.

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	Data Collection Tools (e.g. survey questions, interview or focus group guide, etc.)
	• Survey, interview, focus group, and observation materials must be uploaded under the Data tab. Any additional data collection tools can be uploaded under the Attachments tab.
	• You will need to provide data storage information on all data that you are collecting. See the **Data Storage Guidelines for Research with Human Participants** for more information.
	• If you intend to conduct your research through a virtual platform, see the **Virtual Platforms Guidelines** for security tips and data storage information.
	• Research Data Management (RDM) is an important component of ethical research practice. Consider completing a data management plan (DMP) along with your ethics submission to ensure you have considered all aspects of data management, including storage, sharing and access for your upcoming research project.
	  ○ Resources:
	  ▪ **DMP Assistant** (A Canadian data management planning tool)
	  ▪ **RDM Support at UM**

	Participant Guidance material – if applicable (e.g. instruction scripts, videos) • Upload your videos to OneDrive and provide a document with a link to the file in your protocol. If the video is not created yet, upload the script that will be used.

NOTE: Failure to provide the required documentation will result in the submission being returned to the Principal Investigator.

REB approval applies to the ethical acceptability of the research and does not, in itself, constitute authorization for the research to proceed (TCPS 2, Article 6.3, Application).

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As you prepare your protocol submission, you must consider whether other consultations or approvals are required before your research can begin. Start any other approval processes **before** submitting to the REB for ethics review. Please note that this is not an exhaustive list.

	Possible Consultations and Approvals
	Approvals from Indigenous communities or other organizations • If you require additional approvals from Indigenous communities or other organizations, you must upload the script that you will use to reach out to these communities/organizations in your protocol submission. • Once received, evidence of support (e.g., email thread, screenshot of chat, letter of support) from communities or organizations must be uploaded into RAS through the amendment process.
	Data or Material Sharing/Transfer Agreement • Sharing or transferring data or material to/with anyone who is not an employee or student at UM may require a data/material sharing agreement. • For more information, email **researchcontracts@umanitoba.ca**
	Research Agreements and Memoranda of Understanding • Researchers working with external third parties including Indigenous communities may formalize their partnership through a Research Agreement or a Memorandum of Understanding. For more information, email **researchcontracts@umanitoba.ca**
	Archives • If you intend to archive your data, contact the intended archive to confirm that the data will be accepted and inquire about requirements for the deposit.
	Information Security and Compliance • If you are using an application or an online service that is not currently licensed by the UM, please contact Information Security & Compliance to have a Threat Risk Assessment conducted. Threat Risk Assessments address information security risks and recommend best practice security controls. This applies to any third-party application or web service that stores, processes, or transmits UM information that is classified as Internal, Protected, or Restricted.

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	• Contact **infosec@umanitoba.ca** or use the **TRA Intake Form** • Upload the Threat Risk Assessment PDF or email thread with IST approving the platform/software under the Attachments tab of your protocol.
	Survey Review Committee • If recruiting UM faculty, staff, and/or students through any UM listserv, review and approval by the **Survey Review Committee** may be required. • UM's Access and Privacy Office deem any survey with open-text fields as confidential data (not anonymous). Once open-ended responses have been reviewed and identifiable data removed, the data are considered anonymized. • If you have any questions about FIPPA or PHIA, contact the **Access and Privacy Office**.
	Shared Health Research Impact Application • All research studies conducted within an affiliated Shared Health/WRHA facility, program, or service must be submitted for **institutional assessment**.
	Provincial Health Research Privacy Committee Review (PHRPC) • **PHRPC** reviews all health research projects that request or require use of personal health information held by any Manitoba trustee, including government and government agencies.

Your protocol is a living document. Please refer to it regularly throughout the course of your research to ensure you are complying with what has been approved.