

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 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 A section of the sectio
contact humanethics@umanitoba.ca for more information.
UM PHIA Certificate/UM PHIA Pledges
If you will be collecting personal health information, all team members
must complete the UM's PHIA training , which has been specifically
created for UM researchers and is available through UM Learn.
Please note that the UM REB cannot accept PHIA training from any
other institution (i.e., WRHA, HSC, St. Boniface) as each institution
develops its own training and pledge based on its specific policies and
procedures.

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.
- Templates can be found <u>here</u>.

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 <u>Consent</u>
 Form <u>Template</u> are included in the form.
- 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.

<u>Data Collection Tools (e.g. survey questions, interview or focus group guide, etc.)</u>

- 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
- You will need to provide data storage information on all data that you are collecting. See the <u>Data Storage Guidelines for Research with</u> <u>Human Participants</u> for more information.
- If you intend to conduct your research through a virtual platform, see the <u>Virtual Platforms Guidelines</u> for security tips and data storage information.

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 <u>being returned</u> 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).

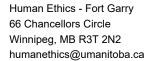


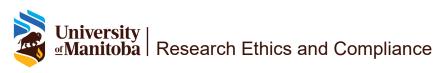
As you prepare your protocol submission, you must consider whether other consultations or approvals are required before your research can begin. Start any other approval processes **before** submitting to the REB for ethics review. Please note that this is not an exhaustive list.

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.



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	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 <u>researchcontracts@umanitoba.ca</u>
	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 <u>researchcontracts@umanitoba.ca</u>
	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.
	 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 listsery,
	review and approval by the <u>Survey Review Committee</u> is 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.





In your consent form, you will need to <u>create a FIPPA notification</u> <u>statement</u> .Contact the <u>Access and Privacy Office</u> if you have any questions.
 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.