

Guidance Document	Multi-Jurisdictional Research
Effective Review	NMREB and HSREB; Delegated & Full Board
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Introduction:

Many researchers engage in multi-jurisdictional research; that is, research being conducted outside of their home institution. For example, researchers collaborate with colleagues at other institutions. Researchers also conduct research at institutions other than their home institution. Tri-Council Policy Statement (2nd Ed.; 2014) Chapter 8 indicates each institution is responsible for reviewing research conducted under their auspices unless an appropriate Board of Record agreement has otherwise been established. At Western University, this includes research conducted by Western’s own faculty, staff and students, and research conducted by external researchers using Western’s resources.

Western University’s Research Ethics Boards (Western’s REBs) have established the following guidelines to assist Western researchers and external researchers determine when Western’s REB oversight is needed. Western’s REB oversight includes a formal application submitted for full board or delegated review that follows Western’s REB submission procedures (i.e., WREM initial application, continuing ethics reviews, study closures, etc.). If, after reviewing the below information, it is not clear whether a project requires Western’s REB oversight, the Office of Human Research Ethics (OHRE) should be contacted for discussion.

Please note that Western affiliated researchers are responsible for upholding Western’s ethical standards in all projects, even those in which they are involved only peripherally. Researchers are reminded to consider the TCPS2 core principles in all collaborations: respect for persons, concern for welfare, and justice. If it is determined that Western affiliated researchers are acting contrary to ethical standards, the University may prevent future collaborations.

Guidelines for Western affiliated researchers involved in multi-jurisdictional projects:

Western’s formal REB oversight **IS** required when the Western affiliated researcher:

- Has direct involvement in the project (i.e., recruitment and consent, data collection, analysis/storage of identifiable information, etc.), regardless of study location unless an appropriate Board of Record agreement has otherwise been established;
- Has a conflict of interest in the project (e.g., financial gain, commercialization);
- Is conducting the project as part of their academic degree (e.g., Honour’s thesis, Master’s thesis, PhD dissertation, or equivalent), regardless of study location unless an appropriate Board of Record agreement has otherwise been established.

Western’s formal **REB oversight is generally not required** when the Western affiliated researcher has only a peripheral role on an external project (e.g. conceptual development, recruitment without consent*, de-identified analysis, manuscript review, knowledge user not directly involved in the project, etc.) and the project has ethical oversight at the collaborators’ institution(s). If a researcher is unsure of whether Western’s REB oversight is required on a particular project, Western affiliated researchers are asked to submit an abbreviated Multi-Jurisdictional application, via WREM, for administrative review. The OHRE, in determining whether Western’s REB oversight is required on a particular project, will consider all the relevant factors, including whether:

- (a) There is REB oversight and approval for the project at the collaborating institution;
- (b) The OHRE is satisfied that the researcher’s role for the project is peripheral;
- (c) There is an agreement that clearly defines the role of the researcher;
- (d) The OHRE is satisfied that the project meets Western’s ethical standards; and

- (e) The OHRE is satisfied that the project meets the requirements of the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans.

*This refers to instances where a Western affiliated researcher will distribute recruitment material or seek participants who will ultimately be consented and enrolled by another institution with appropriate REB oversight. There would be no local research procedures or data collection. This may be the Western researcher's only role or this may be in addition to other peripheral roles.

Guidelines for researchers not affiliated with Western:

- If a researcher, external to Western, has obtained REB approval from their home institution and would like to conduct their research using Western resources (e.g., faculty, staff, students, posters, email lists, office space, laboratory, clinic, etc.):
 - The external researcher will be required to submit to the OHRE, via email, their institutional REB approval letter(s) and approved study materials (study protocol, letters of information/consents, email templates, survey template, etc.) for administrative Western REB review.
 - Upon review of these materials, the OHRE may acknowledge on behalf of the appropriate Western REB (i.e., Non-Medical Research Ethics Board (NMREB) or Health Sciences Research Ethics Board (HSREB)) that this research is taking place and that the NMREB/HSREB does not have any major objections to the manner in which it will be conducted.
 - Note: Western's REBs reserve the right to request full review via WREM (i.e., with local PI) as needed.

*Except when contacted through publicly available contact information.

Tips for Submitting Multi-Jurisdictional Research for Western's REBs review/approval:

Scenario #1: Western affiliated researcher collaborating with researchers at other institutions where each PI is responsible for one local site:

- a. Researcher must determine whether the study requires a NMREB or HSREB application, and the study may require full board or delegated review.
- b. Western's REB is responsible for reviewing and approving the local (i.e., Western PI's) study documents, including recruitment, letter of information and consent form (LOI/C), and other site-specific materials.
- c. The LOI/C should be clear if any other collaborators will have access to the study records (e.g., de-identified data) collected by the Western affiliated PI.

Scenario #2: Western affiliated researcher collaborating with researchers at other institutions using one LOI/C:

- a. Researcher must determine whether the study requires a NMREB or HSREB application, and the study may require full board or delegated review.
- b. It is recommended that each institutions' logo be added to the document.
- c. Each REB should be listed as having access to the study-related records.
- d. If applicable, the confidentiality section should also be clear that researchers at several institutions will have access to their data. The default is that identifiable study records be retained and accessed only by the investigators responsible for its collection. Participants

need to be informed of who will have access to their information, and to what information they will have access.

- e. If there is a local London site (and/or a site that is being led by the Western PI), Western's OHRE should be listed as the primary point of contact for any questions regarding study conduct or participants' rights.

Scenario #3: If a project has already received REB approval at another institution and also requires Western's REB oversight:

- a. A local, Western affiliated PI is required to submit a Western REB application.
- b. Researcher must determine whether the study requires a NMREB or HSREB application, and the study may require full board or delegated review.
- c. The Western REB application must include all approved documents and approval letters from the other REB(s).
- d. The study procedures and activities being conducted under Western's jurisdiction (i.e., Western collaborator roles and responsibilities) must be described in the applicable sections of the Western REB application.
- e. Any applicable documents that will be used in the activities carried out by the Western collaborator (e.g., recruitment materials, consent documents, etc.) must be updated as needed to meet Western REB's guidelines and submitted for approval in the Western REB application.

Scenario #4: If Western REB oversight is needed on a project that will need to be submitted to another REB (e.g., Western researcher collecting data at another institution):

- a. The Western PI must submit the application to Western as per usual (i.e., researcher must determine whether the study requires a NMREB or HSREB application, and the study may require full board or delegated review).
- b. If Western PI is aware of any site specific requirements at the other institution, they should be included in the application/study documents (e.g., LOI/C information) submitted to Western.
- c. In order to obtain approval from the other institution's REB, researchers may be requested to modify the Western-approved materials. If so, researchers must contact Western's REB to determine if these changes require an amendment to the Western REB application.

General considerations:

- a. Researchers should submit to subsequent REB(s) following approval at the lead site.
- b. To minimize review time, researchers are encouraged to contact each REB early to determine what is required at each institution.
- c. Institutional Recommendation: When data and/or biological material is transferred between collaborators/institutions, a Data Transfer Agreement (DTA) or Material Transfer Agreement (MTA) between participating institutions will be required. Contact Research Western's Contracts Coordinator for more information.