

UWO - HSREB	GUIDELINE	2-G-024	Page 1 of 2
EFFECTIVE: February 1, 2005 REVISED: February 1, 2007	The Ontario Cancer Research Ethics Board (OCREB) and the Health Sciences REB (HSREB) at The University of Western Ontario.		

The University of Western Ontario and the Lawson Health Research Institute (LHRI) are committed to ensuring that cancer patients attending London hospitals have the opportunity to participate in multi-centred, time-sensitive, competitive enrollment cancer clinical trials. In an effort to facilitate this process, The University of Western Ontario and the Lawson Health Research Institute have agreed to sanction the use of the Ontario Cancer Research Ethics Board (OCREB) in lieu of Western's Health Sciences Research Ethics Board (HSREB).

Conditions:

- The acceptance of OCREB as an alternate research ethics board is limited to the ethical review of **new multi-centre cancer clinical trials** where the study sponsor has identified OCREB as the preferred research ethics board provincially; and, where Western and/or LHRI investigators are leading and/or participating in these trials. **All other types of research previously approved by OCREB must still obtain approval from Western's HSREB. E.g. epidemiological, tissue use, non-clinical.**
- Ongoing cancer clinical trials currently under review by, or approved by, Western's HSREB will remain under the jurisdiction of Western's HSREB until the completion of the trial.
- The University of Western Ontario and the Lawson Health Research Institute retain the right to require ethical approval from Western's HSREB for studies previously approved by OCREB if, in their opinion, circumstances warrant it.
- Western's Health Sciences Research Ethics Board accepts no responsibility for the conduct of research conducted under the auspices of OCREB, for which Western's HSREB has not issued an approval notice.

A) Procedures re New Multi-Centre Clinical Cancer Trials:

- 1) Western's Office of Research Ethics will collect and maintain a record of approval information relating to OCREB approved cancer clinical trials.
 - a) All records and correspondence will use the OCREB approval number as a reference.
 - b) The Office of Research Ethics will not issue a HSREB approval or file number for those records.
 - c) The Office of Research Ethics will provide to LHRI at least annually, a list of the OCREB approvals they have on file, with a request to confirm whether or not the study is still active.
- 2) Researchers with protocols that have been reviewed and approved by OCREB must notify the Office of Research Ethics at Western and the Lawson Health Science Research Institute prior to starting the study.
- 3) The local investigator must provide a copy of the following to **both** the Office of Research Ethics at Western and the Lawson Health Research Institute.
 - a) **prior to starting the study.**
 - i) the OCREB approval notice for the local centre
 - ii) the completed and approved OCREB protocol submission form
 - iii) the approved informed consent documentation for the local site that reflects the personnel and procedures at the local site
 - b) **during the course of the study**
 - i) any subsequent OCREB approval notices
 - ii) an end of study notification or report
- 4) Instructions for submitting information to the Office of Research Ethics and LHRI:
 - a) Do not include a covering letter.
 - b) The documents should be bundled with the top sheet being a plain piece of paper with OCREB written in large letters and the OCREB file number. The OCREB approval notice should be the next item.
 - c) All documents submitted must include the OCREB file number.
 - d) Do not send sponsor documents; adverse event reports; safety reports; reports of violations or deviations; or requests for revisions or updated approvals.

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B) Procedures re other types of research (e.g. epidemiological, tissue use, non-clinical):

- 1) Research studies, other than new, multi-centre clinical cancer trials, that have been reviewed and approved by OCREB must still obtain approval from Western's Health Sciences REB prior to starting the study locally.
- 2) The local investigator must provide the following to the Office of Research Ethics at Western.
 - a) **prior to starting the study (4 copies).**
 - i) Western's HSREB **OCREB Supplemental Form (2-F-003):**
 - ii) the completed and approved **OCREB submission form**
 - iii) a copy of the OCREB approval notice and any comments relating to the OCREB ethics and scientific review
 - iv) (If appropriate) Informed consent documentation that reflects the personnel and procedures at the local site e.g.
 - local letterhead
 - number of local participants
 - names and contact information for local investigators and/or staff
 - names and contact information for local person that participants may contact if they have any questions regarding the conduct of the study and their rights as a research participant i.e. Vice President Research, Lawson Health Research Institute, (519) 667-6649
 - v) if data is being sent off-site, a description of where data etc will be sent and under what conditions e.g. all data will be de-identified and sent to central site at Cancer Care Ontario
 - b) **during the course of the study (1 copy)**
 - i) Reports of Serious Adverse Events – Local and Non-Local including the loss or compromising of data
 - ii) Reports of deviations and waivers
 - iii) Requests for revisions and amendments – unless revisions and amendments refer solely to the local site e.g. change in local investigator, the revisions should not be submitted to the UWO HSREB until after OCREB approval.
 - iv) Requests for Updated Approvals
 - v) Annual Surveillance Reporting

Prior review and approval by OCREB should result in a very well prepared HSREB submission that will require few modifications and can easily pass through the UWO HSREB process in a timely manner. It is quite likely that the submission will be processed by delegated (expedited) review.

Please note that the decision as to whether or not OCREB acts as the REB of Record resides with the institution and the Office of Research Ethics not the researcher.

***For information about OCREB and its policies and procedures check the OCREB web site.
http://www.ocrn.on.ca/ethics_AboutOCREB.htm***