Lakeridge Health
1 Hospital Court
Oshawa, ON L1G 2B9

Title	**LAKERIDGE HEALTH RESEARCH ETHICS BOARD PROCESS FOR RESEARCH ETHICS**
Effective Date	2015-Nov-02

Process for Research Ethics

Any research involving human participants that is conducted within Lakeridge Health must be reviewed and approved by the Lakeridge Health Research Ethics Board.

The approval process at Lakeridge Health (LH) is two pronged, REB and Administrative.

REB

A submission to the Lakeridge Health REB will consist of completion of the *Lakeridge Health Research Application Form*.

Principal Investigator: A Lakeridge Health Site Principal Investigator is required for all studies. They are responsible for all research activities at LH. Students/trainees cannot be listed at the PI. The LH REB Application requires the signature of the LH Site PI.

LH Site Program Director: The LH REB Application requires the signature of the Program Director. The signature indicates agreement that the Division/Department/Program supports the research project and that the PI is qualified by education, training, and experience to perform his/he role in the study.

Application: The first two pages of the application form outline the submission requirements in detail. All applicable areas of the application form must be signed before submission. Incomplete applications will not be processed and will be returned to the Principal Investigator.

Submissions will follow the REB schedule. An electronic copy is to be submitted to the Research Liaison. A submission package will consist of:

a) *Lakeridge Health Research Ethics Board Application*
b) Full protocol/proposal
c) Consent Forms/Information Letters (must be specific; checklist and guidelines available)
d) Other REB letters of approval (if applicable)
e) Recruitment information (flyer, phone script, wallet cards) (if applicable)
f) Investigator Brochure (if applicable)
g) Health Canada No Objection Letter (if applicable)
h) Study Contract/Agreement
i) *Research Team Form* and all supporting documents:
    j) Lakeridge Health Confidentiality Agreement
    k) Research Confidentiality Agreement

Lakeridge Health
1 Hospital Court
Oshawa, ON L1G 2B9

*If supporting documents have been previously submitted, contact Research Liaison to verify they are up-to-date. All research team members are required to complete the TCPS2 Tutorial (as per the *research team form*).

The Research Liaison will screen the package for completeness. The study is assigned a research identification number (RID#). All initial approvals are reviewed full Board. The PI will be requested to attend Research Ethics Board meeting as per REB schedule to avoid any delays in approval.

Administrative

Administrative approval requires approval of the department impact, resource utilization (including sufficient funds to cover all expenses related to the study), and execution of a research Contract/Agreement. A Department Impact Form must be completed for all studies conducted at Lakeridge Health, regardless of whether or not the impact is financial in nature. If there is not an impact to declare, this must be indicated on the form.

All studies **require** one of the following agreements (unless specified otherwise):

1. Data Sharing Agreement- Data is being transferred from Lakeridge Health to another institution
2. Collaboration Agreement- Funds are being transferred or LH is investing in resources outside of regular practice
3. A Clinical Trial Agreement (CTA)

Agreements outline roles and responsibilities, insurance, indemnification, budget, privacy, confidentiality etc. Agreements shall be forwarded to the Research Office. If an agreement is required, one will be drafted and forwarded by the Research Office once informed.

All applicable areas of the application form must be signed. The LH Site PI's Program Director is required to sign directly on the form in the non-industry research section along with signoff from any other departments/units that will be involved in the research. Industry sponsored research will be requested the same via the *Department Impact Forms*. These signatures are required to verify the Director(s) are aware of the proposal and support the submission for research approval at Lakeridge Health.

Notification to Commence

Once REB and Administrative approval are in place, a '*Notification to Commence*' is issued with a date of commencement.

After the submission has been reviewed by the Research Ethics Board:

A research review rating form is issued with REB comments/ requested changes.

An itemized response is prepared to respond to the REBs questions/comments and documents are amended as required and submitted to the Research Liaison.

REB APPROVAL IN PLACE	**ADMINISTRATIVE APPROVAL IN PLACE** **(Contract/Agreement and DIA Process Complete)**

Once REB and Administrative approval are in place, a '*Notification to Commence*' is issued with a date of commencement.

- Submit an Annual Renewal each year
- Submit amendments for any changes to the application/study protocol/consent
- Report all unanticipated problems
- Report all protocol deviations

Submit a Study Closure Form to the Research Liaison