SRHC Research Ethics Board Submission Requirements*

New Research Requiring REB Review:

- Research Ethics Board Study Application Form (must be signed)
- Informed consent form (electronic copy in Word format using the SRHC/CTO ICF template)
- Research Protocol
- Written Information to be Provided to the Study Participant (e.g. educational materials, advertisements/recruitment materials, questionnaires)
- Investigator's Brochure / Product Monograph / Device Manual
- FDA or Sponsor Significant Risk (SR) or Non-Significant Risk (NSR) Determination (applicable for FDA regulated device trials)
- Additional Safety Information (Serious Adverse Events/toxicology data)
- Local Qualified/Principal Investigator curriculum vitae (signed and dated)
- Study Budget

For Research Office Only:

- Departmental Impact Analysis Forms
- Clinical Trial Agreement (CTA)
- Data Sharing Agreement
- Material Transfer Agreement
- Grant Account Initiation Form

Ongoing/Continuing Review of REB Approved Research (as per SRHC Research and REB SOPs):

- Reporting of unanticipated problems
- New safety information (e.g. Investigator's Brochure (IB) updates)
- REB Annual Renewal Form
- REB Study Closure Form

Revised documents such as those listed below should be accompanied with a summary of changes and rationale:

- Protocol/amendment(s)
- Informed consent form
- Any written information provided to participants
- Advertisement for subject recruitment (if used)

***NOTE: Some requirements may not be applicable due to the type of research**

Contact Information:

Research Office: Southlake Village, 640 Grace St., North Side Entrance, 5th Floor, North Corridor

Mailing Address: 596 Davis Dr., Newmarket, Ontario L3Y 2P9

SRHC Internal Mail: Box #102 (Research Dept.)

REB Administrator: Sharon Villani, svillani@southlakeregional.org, 905-895-4521 ext. 6638
Research Ethics Assistant: Cristina Chitu, cchitu@southlakeregional.org, 905-895-4521 ext. 6237

REB Submission Email: rebsubmissions@southlakeregional.org