SOUTHLAKE
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SRHC REB Submission Requirements*

New Research:

- Research Ethics Board Study Application Form (must be signed)
- Informed consent form (electronic copy in Word format using the mandatory SRHC ICF templates)
- 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)
- Study Budget (draft is acceptable if not finalized)
- Local Qualified/Principal Investigator curriculum vitae (signed and dated)
- Research Training Certificates (as per SRHC REB Mandatory Research Training Policy)

Ongoing/Continuing Review:

- REB Amendment, Notifications, Ongoing Communications Form (signed)
- Revised documents Protocol/amendment(s) with summary of changes/rationale
- Informed consent form (clean copy and tracked changes to version previously approved by the REB)
- Any new written information provided to participants
- Reporting of unanticipated problems
- New safety information (e.g. Investigator's Brochure (IB) updates)
- REB Annual Renewal Form
- REB Study Closure Form
- Change to Study Personnel

Send REB Submissions to: **rebsubmissions@southlake.ca**

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NOTE: Not all requirements listed above may be applicable.