



**Get in, loser.
We're going to Canada**



A wide-angle photograph of the Toronto skyline at dusk. The city lights are on, and the lights are reflected in the water of Lake Ontario. The CN Tower is a prominent feature in the center. The sky is a deep blue, and the water is a calm, dark blue.

Implementing the **ACHQC** ABDOMINAL CORE HEALTH QUALITY COLLABORATIVE into Canada

Megan Melland-Smith, MD

Lessons Learned

- What are the cross-border data sharing rules?
- Secure strong leadership
- Legal Expertise
- Secure Funding
- Set your self up for success
- Commitment
- Patience





No Database

What are the rules?



Canadian personal health information (PHI)



**NORTH YORK
GENERAL**

**Proud to be Recognized
through the ACS
National Surgical Quality
Improvement Program**



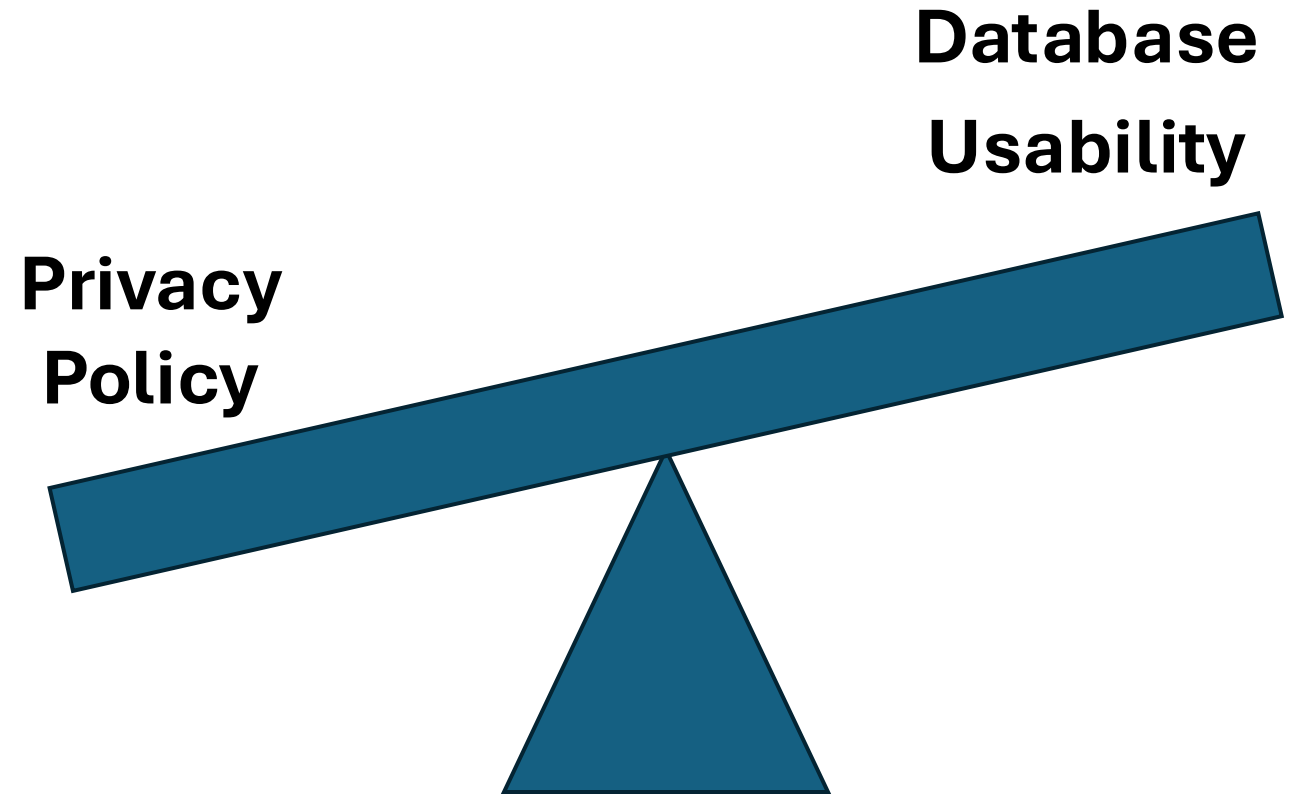
ISHLT A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease



What are the rules?

- De-identify the data **X**
- Opt-out consent **X**

Manual date entry, prospectively collected



Strong Leadership




CANADIAN ASSOCIATION OF
General Surgeons



CANADIAN
HERNIA
SOCIETY

SOCIÉTÉ
CANADIENNE
DE CHIRURGIE
HERNIAIRE

About Us



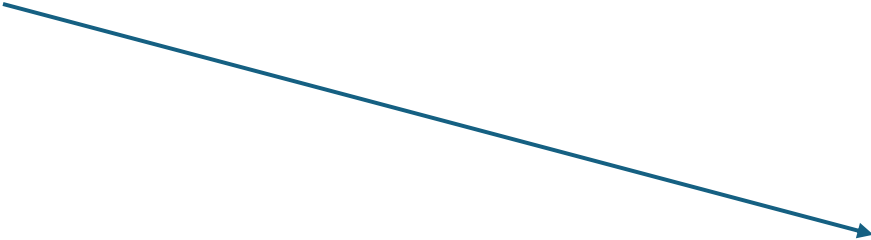
Advancing Hernia Care and Research in Canada.

Carol Broderick
CEO CAGS



Legal Expertise

- Interviewed 3 lawyers/law firms
- 2 quotes



Small independent lawyer: \$3000

OSLER

ACHQC Database – Canada Project	
“Canadianizing” the existing Participation Agreement	\$10,080
Revising/commenting on an existing “Privacy Policy and FAQs”	\$10,080
Review of existing vendor agreements. Includes providing a list of minimum requirements for compliance with applicable Canadian laws. Does not include comments on or revisions to individual vendor agreements, which would require additional conflicts checks and will require a separate fee estimate following Osler being provided with the existing agreements for review.	\$5,040
Drafting a new patient consent document	\$4,200
Reviewing and commenting on the de-identification processes for compliance with Canadian thresholds	\$5,040
Total	\$49,040




Funded: \$40,000

Secure Funding

- Pitched our idea to industry → Ethicon, Cook, BD
- Grant proposal for \$50,000
- BD Unrestricted Education Grant
 - Requested Canada wide dissemination including Quebec
- Osler → Additional \$50,000 for Quebec



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STEINBERG FAMILY TOWER

 NORTH YORK GENERAL

The Important People



Rita Reynolds
Chief Privacy & Freedom of
Information Officer



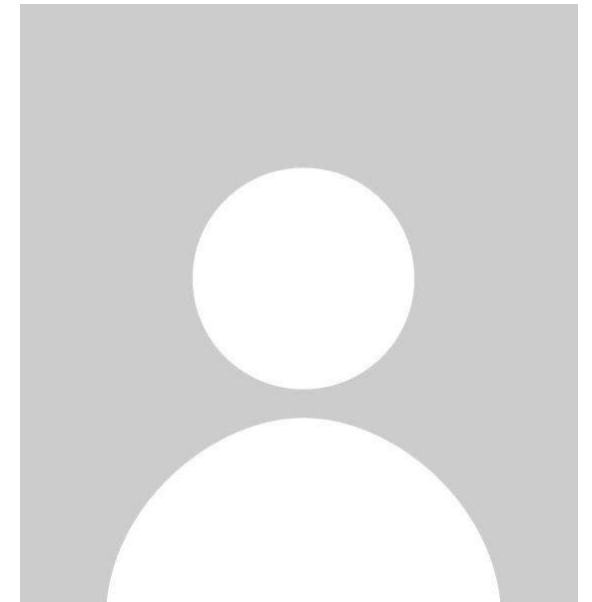
Research Ethics Board

Naomi Margo
Osborne Margo Health Law & Policy

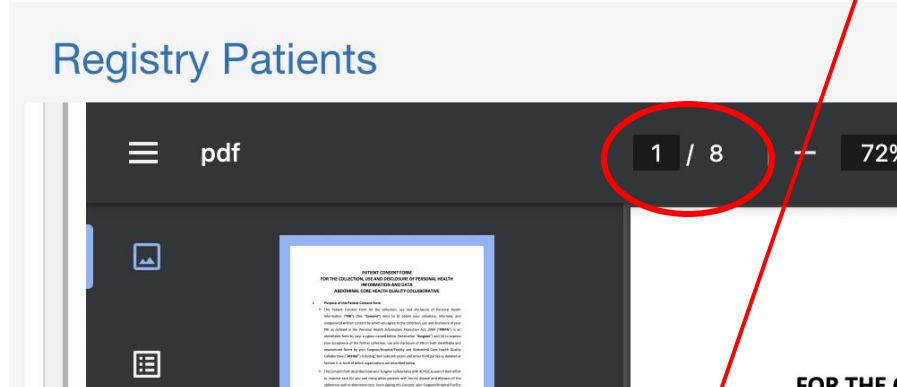


Quote: \$15,000-ish

Howard Haenel
ACHQC Lawyer



Canadianize it



- ACHQC is affiliated in Canada with the Canadian Hernia Society (“CHS”), a not-for-profit society of hernia surgeons and other medical professionals interested in the care and treatment of hernias and other abdominal diseases in Canada. Among other things, the CHS provides a professional forum for education and research for the advancement of hernia care. CHS has surgeon members across Canada who may participate in the Abdominal Core Health Quality Collaborative as it expands across Canada.
- The CHS surgeon members participating in the ACHQC Hernia Patient Registry will be in charge of obtaining, maintaining, and storing the digitalized Consent forms of all patients registered in the ACHQC Hernia Patient Registry. Further information is available at <https://www.canadianherniasociety.ca>.

e-sign

- 1 PRINT YOUR NAME**
- 2 SIGN YOUR NAME**
- 3 CONFIRM**

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CAN vs USA Healthcare



Canadians are privileged/independent contractors subject to hospital oversight



Hospitals are not-for-profit corporations, subject to **extensive government regulation**



Very cognizant of risk exposure of providing data to the US, even if anonymized



Provincial privacy legislation unique to each province

Secure Funding

Invoice

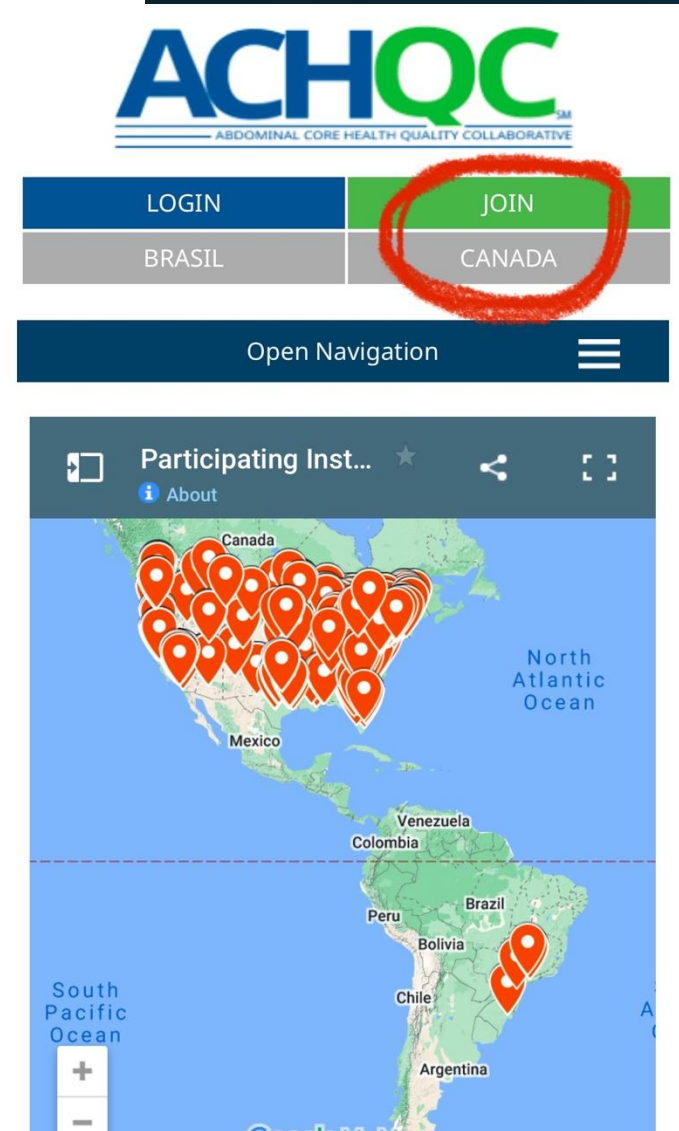
Date: December 8, 2024
 Due Date: January 8, 2025
 Invoice # **Canadian Hernia Society
 ACHQC Agreements
 CHS-01-24**

Date (m/d/y)	Service	Time Spent	Charge
Page 2 cont.			\$
08/30/24	Attend extensive mtg w. RR of NYGH re comments on PA (1.6), update client & ACHQC same (0.2).	1.8 hrs	
09/09-10/24	Revising PA to incorp NYGH comments & engage in f/u. Drafting further revisions to PA & Consent, draft explanatory comments for same, finalize drafts, draft corr. to NYGH & ACHQC, & client.	2.8 hrs	
09/11-13/24	Review/draft reply to NYGH corr., draft corr. to ACHQC on agmts. Draft f/u corr. to ACHQC.	1.5 hrs	
09/16/24	Attend client mtg w. ACHQC re both agmts. and Next steps. Review ACHQC changes in prep.	1.2 hrs	
09/18/24	Review/draft reply to NYGH corr. re REB approval.	0.5 hrs	
09/23/24	Call w. NYGH re privacy compliance comments, f/u Research review.	2.0 hrs	
09/26/24	Attend mtg w. ACHQC counsel re NYGH comments; Review TCPS guidelines for same, draft sum for NYGH & ACHQC counsel, update client corr.	1.9 hrs	
09/30/24	Attend mtg. w. client re ACHQC research data practices & next steps; draft f/u corr. to ACHQC.	0.7 hrs	
10/01/24	Attend mtg w. ACHQC counsel re PA and ICF.	0.7 hrs	
10/11/24	Review draft PA and Consent changes, draft further revisions, note comments, draft ACHQC corr.	1.4 hrs	
10/17/24	Draft NYGH corr. re final agmts/next steps, review agmts for same, draft f/u ACHQC corr.	0.4 hrs***	
Invoice cont. on next page			
		Total Fees	

Total Fees	\$16,441.50
Expenses	N/A
Subtotal	\$16,441.50
HST	\$2,137.40
Total	\$ 18,578.90

Set Yourself Up For Success

- Start small → 1 Province, 1 hospital
- NYGH 6-month pilot period
- Surgeon onboarding webinars
- Discuss at national meetings - Canadian Surgery Forum 2025



Commitment

- Enrollment since **Dec 21, 2024**
 - Clinic
 - Block room/outside the OR
- Every patient has consented YES
- Enrolling surgeons: 1.....3 pending



patients enrolled to date: 48



Future Goals

- Expand across Ontario → 10 UofT Hospitals, Shouldice
- Expand to provinces that house CHS surgeons
- Join the embedded Randomized Controlled Trials
 - “NOPIOIDS” DUA submitted
- Run our own RCT



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Take Home Points

- Don't take no for an answer
- Be aware of “Big powerful” law firms
- Leadership from a body to take this on together
- Start small
- Patience, patience, patience





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Thank you

mmellandsmith88@gmail.com



CAN vs USA Healthcare

Canadians are privileged/independent contractors subject to hospital oversight

Hospitals are not-for-profit corporations, subject to **extensive government regulation**

CAN vs USA Healthcare

Very cognizant of risk exposure of providing data to the US, even if anonymized

- Ensure informed patient consent process addresses all concerns

Provincial privacy legislation unique to each province

- Re-do some of the work when expanding to each province

What are the rules?

- Canadian personal health information (PHI) to a data system housed in the US
- Privacy policy vs usability
- Prospectively collected data → Must use PHI, not de-identified data
- No role for de-identification

