



McGill

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April 4, 2017

Dr. Gillian Bartlett
Department of Family Medicine
5858 Chemin de la Cote des Neiges – Suite 300
Montreal, Quebec H3S 1Z1

RE: IRB Study Number A04-E32-16B

Evaluating the gap between research ethics review and data sharing in pediatric infrastructure science: a case of big data and little ethics?

Dear Dr. Bartlett,

Thank you for submitting an application for Continuing Review for the above-referenced study.

The study progress report was reviewed and full Board re-approval was provided on April 3, 2017. The ethics certification renewal is valid from **April 28, 2017 to April 27, 2018**.

The Investigator is reminded of the requirement to report all IRB approved protocol and consent form modifications to the Research Ethics Offices (REOs) for the participating hospital sites. Please contact the individual hospital REOs for instructions on how to proceed. Research funds may be withheld and / or the study's data may be revoked for failing to comply with this requirement.

Should any modification or unanticipated development occur prior to the next review, please notify the IRB promptly.

Sincerely,

Serge Gauthier, MD
Interim Co-Chair
Institutional Review Board

cc: V. Rahimzadeh
A04-E32-16B

The completed form is to be submitted electronically to submit2irb.med@mcgill.ca. The continuing review form must be received at least **one (1) month** before the expiration of the last ethics approval. If you require additional information, please visit the IRB website at: <http://www.mcgill.ca/medresearch/ethics/> or by calling 514-398-3124.

Principal Investigator Gillian Bartlett
Faculty and Department Medicine/Family Medicine
Study Coordinator, if applicable NA
Address: 5858 Cotes des Neiges, Suite 300, Montreal H3S 1Z1
E-mail gillian.bartlett@mcgill.ca Telephone: 514-399-9100

Study Title Evaluating the gap between research ethics review and data sharing in pediatric infrastructure science: a case of big data and little ethics? +

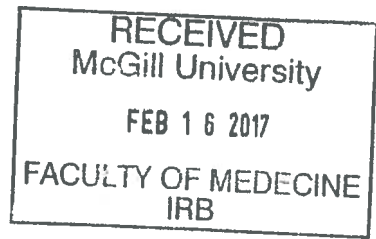
Grant title, if different from study title.

IRB Study Number A04-E32-16B Date of last approval 4-29-16

Has there been a change or addition to the financial support for this study? YES NO

If yes, please specify the changes/additions.

Status of the Protocol Active enrolment When did this study begin? 9-1-16
 Recruitment complete
 Recruitment on hold
 Data analysis
 Secondary Analysis only
 Inactive/dormant**



**If the study is inactive/dormant (i.e., there are no participants enrolled in the study and no study activity is occurring), please specify the reason:

If the study is actively enrolling participants, or if enrolment is complete, please answer the following questions:

Study sample size: ~40 Total number enrolled in the study: 3

Number of participants that have completed this study:

Total number of participants withdrawn

Projected date of completion of study enrolment:

Projected date of study completion:

Please provide a brief description of what has occurred since the IRB's last ethics approval.

A systematic literature review has been conducted and a manuscript prepared for publication as a precursor to field work planned as part of this doctoral thesis. Participants have been identified, and preliminary email notifications sent to local investigators that will be included in the study. Due to participant availability and emerging scholarly advancements in the field of data governance/ethics, the sequence of study activities and projected timelines for completion have been modified accordingly. The majority of fieldwork for the study on

Has the study revealed any new findings or knowledge relevant to the potential benefits and/or study risks that may influence participants' willingness to continue in the study?
 YES
 NO
 N/A

Has this new information been communicated to participants?
 YES
 NO
 N/A

If applicable, please describe the findings.

Has an amendment(s) to the protocol been submitted to the IRB in the past year?
 YES
 NO

What is the version date of the most recent IRB- approved protocol?

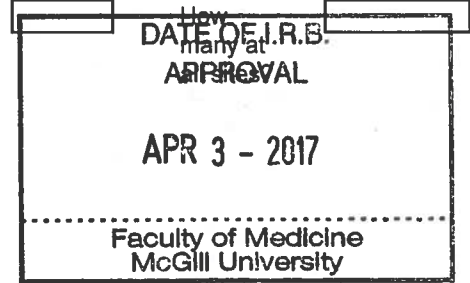
Has the consent form(s) been revised in the past year?
 YES
 NO
 N/A

Have consent form modifications been reported to the IRB?
 YES NO
 N/A

Version date/s of the most recently approved consent form(s):

Have any adverse events occurred since the last approval?
 YES
 NO
 N/A

If yes, how many at McGill sites?



Have the adverse events been reported to the IRB? If no, submit all adverse events with this form.
 YES NO N/A

Have there been any publications?
 YES
 NO

If yes, append list: Rahimzadeh V. Sharing outside the sandbox? A child's right to an open future for data sharing. (2016). In: +

SIGNATURES

Principal Investigator

Gillian Bartlett

Digitally signed by Gillian Bartlett
Date: 2017.02.16 12:13:47 +01'00'

Date

IRB Chair

Date