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| **INFORMED CONSENT—Research ethics review policy actor** | |
| **TITLE** | Evaluating the gap between research ethics review and data sharing in pediatric infrastructure science: a case of big data and little ethics? |
| **INVESTIGATORS** | Vasiliki Rahimzadeh, PhD Candidate  Department of Family Medicine; Centre of Genomics and Policy  McGill University  [Vasiliki.rahimzadeh@mail.mcgill.ca](mailto:Vasiliki.rahimzadeh@mail.mcgill.ca)  514-887-7030  Gillian Bartlett, PhD (co-supervisor)  Associate Professor, Department of Family Medicine  McGill University  Bartha Maria Knoppers, PhD (co-supervisor)  Director, Centre of Genomics and Policy  McGill University |
| **FUNDING** | Vanier Canada Graduate Scholarship 2015-2016 |

**Purpose**

You have been identified as a policy actor involved in research ethics review policy and governance in Canada. As such, you are being asked to participate in Part II of a two-part study that aims to develop a policy for ethically responsible sharing of pediatric genomic and associated clinical data in Canada. Your insight will help us better understand the values and priorities of policy makers towards shaping governance of clinical innovation in pediatric genomics.

**Background**

Biomedical research in genomics has increasingly become data-intensive and requires collaboration between researchers and research institutions, often across Canada and the world. The promises of personalized medicine through the use of new genetic sequencing technologies can only be realized through widespread sharing of research data among collaborators. Like all research that involves human participants in Canada, genetic research requires approval from an institutional research ethics board (REB). Understanding how REB procedures affect scientific collaboration in fields like genomics is therefore important for accelerating clinical innovation in this field in Canada. Genomic research involving children can accentuate this need, as their inability to consent makes them a vulnerable population that requires special protections yet should nevertheless benefit from scientific advances.

**Research Problem**

This PhD thesis explores the relationship between research ethics review processes and genomic data sharing for studies that involve children across Canada. Little empirical research to date quantifies the resource demands of existing ethics review procedures for pediatric genomic research in Canada, nor what impact they have on data sharing and collaboration among researchers in this field.

Your perspectives and participation in this study is requested to meet the second of two objectives outlined in this thesis: to develop a Canadian policy framework that identifies the ethical, legal, social and scientific priorities necessary for sharing pediatric research data.

**Study procedures**

You will be asked to participate in Part II of a two-part study that will require approximately **120 min of your time over the course of 1 year (12 months)**. In order to meet the proposed objectives stated above, your participation as a policy maker involved in research ethics review will involve the following:

*Part II. Policy Delphi*

* 4 online surveys (approx. 30 min each)

**Benefits and Risks**

While there may not be any direct benefit to you or the patient advocacy group you represent, your participation in Part II of the study may help to inform future ethics review policies for pediatric genomic research in Canada. We do not anticipate that *Part II* of this study poses any significant risk to you according to the Tri Council Policy Statement: Ethical Conduct of Research Involving Humans 2(2014). The online surveys will take approximately 120 minutes total (30 minutes of your time per survey), and are entirely anonymous. They will be administered sequentially over the course of 1 year. All subsequent survey questions will be based on your responses to the first survey, and those of other key stakeholders in the pediatric genomic research community who participate in this study. This method of research is called a Policy Delphi.

**Withdrawal**

To withdraw from the study, please contact the study lead, Vaso Rahimzadeh either by phone (514-887-7030) OR email ([vasiliki.rahimzadeh@mail.mcgill.ca](mailto:vasiliki.rahimzadeh@mail.mcgill.ca)).

**Confidentiality**

All survey data will be kept in a qualitative database using N’Vivo software licensed privately to investigators VR, GB and BMK. All data will be password protected to limit access only to the 3 investigators listed above. Moreover, all surveys responses administered online in *Part II* will remain strictly anonymous. This means no personally identifying information will be collected linking you to your survey responses. You will be notified immediately by email in the event of any privacy breach experienced by the N’Vivo software, and the subsequent relocation of this data to an alternatively secured platform.

**Subject Rights**

As a research participant in this study:

* you have the right to ask questions at any time
* your study participation is entirely voluntary
* your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled
* you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled

**Signature**

By signing this consent form, you acknowledge that the study has been explained to you, and your questions regarding the scope, purpose and extent of your participation have been answered to your satisfaction.

I agree to participate in this study, and acknowledge that I do not waive any of my rights by signing this consent. I will also receive a copy of this signed consent form for my records.

Participant Name Date

Witness Name Date