Author's response to reviews

Title: Comparison of paediatric health research consent forms in Canada: working towards best practices

Authors:

Edward S Dove (edward.dove@mail.mcgill.ca)
Denise Avard (denise.avard@mcgill.ca)
Lee Black (lee.black@mcgill.ca)
Bartha M Knoppers (bartha.knoppers@mcgill.ca)

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Adrian Aldcroft
Executive Editor, BMC Medical Ethics

RE: “Comparison of paediatric health research consent forms in Canada: working towards best practices”

Dear Dr. Aldcroft:

Please find attached our research article manuscript for consideration to be published in BMC Medical Ethics.

The manuscript empirically explores a critical question in current paediatric health research: how paediatric consent operates in practice to accord with current and emerging legal and socio-ethical issues, norms, and requirements. Over the past year, we have analysed paediatric consent forms from various health research projects across Canada to see how they addressed generally required elements of informed consent, as well as key issues in paediatric research (e.g. scope of consent of the parent and/or child, return of research results and incidental findings, retention of and access to the child’s data and/or samples). After examining areas of concordance and discordance, our manuscript proposes novel best practices for drafting paediatric health research consent forms to improve current gaps and facilitate harmonised and yet contextualised approaches to paediatric health research ethics.

Our manuscript would appeal to BMC Medical Ethics’ international readership. To the best of our knowledge, we believe this is the largest qualitative study undertaken of paediatric research consent forms to date and that our discussion of legal and emerging socio-ethical issues, as well as the best practices, fills a current gap in the literature and has resonance on a global scale.

I would like to confirm that the manuscript has not been published previously and is not under consideration for publication elsewhere.

As per a request made by Ms. Abigail Quiniquini of the BioMed Central Journal Editorial Office on June 21, 2012 for a statement on ethical approval in the manuscript, we declare here in this cover letter and in the manuscript that no ethical approval was sought in connection with the study as, in accordance with McGill University and Canadian ethics guidelines, there was no research involving human subjects or research on information containing personally identifiable information.
Thank you in advance for your consideration of the manuscript. On behalf of the co-authors, Denise Avard, Lee Black, and Bartha M. Knoppers, we look forward to hearing from you.

Sincerely,

Edward S. Dove, B.C.L, LL.B.
Researcher
Centre of Genomics and Policy (http://www.genomicsandpolicy.org/)
Department of Human Genetics, Faculty of Medicine, McGill University
740 Dr. Penfield Avenue, Suite 5200, Montreal, QC., Canada H3A 0G1