## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

#### **ARTICLE DETAILS**

TITLE (PROVISIONAL)	The Queensland Family Cohort: Study Protocol
AUTHORS	Borg, Danielle; Rae, Kym; Fiveash, Corrine; Schagen, Johanna; James-McAlpine, Janelle; Friedlander, Frances; Thurston, Claire; Oliveri, Maria; Harmey, Theresa; Cavanagh, Erika; Edwards, Christopher; Fontanarosa, Davide; Perkins, Tony; de Zubicaray, Greig; Moritz, Karen; Kumar, Sailesh; Clifton, Vicki

# **VERSION 1 – REVIEW**

REVIEWER	Mohan, Diwakar		
REVIEWER			
	John Hopkins Bloomberg, International Health		
REVIEW RETURNED	21-Nov-2020		
GENERAL COMMENTS	Thank you for the opportunity to review your manuscript. The study appears to be very well thought out and co-created with a wide variety of stakeholders including the consumers / participants. There are some minor spelling and grammatical errors and would be good if these can be rectified.		
	<ul> <li>Minor suggestions</li> <li>The sources of bias due to consent process have been outlined in great detail. If circumstances permit, it might be a useful to collection data on demographics of those who refuse to participate and their reasons for refusal.</li> <li>in the section on unexpected findings, there is no mention or discussion of what the procedure protocol is to address any discoveries that may be potentially linked to criminal activities or harm to others. This could include sexual or physical abuse of the participants or others connected to them. '</li> <li>Figure on page 36 does not seem to have a label and seems to go beyond the margins. Feel free to include only if the figure is important.</li> <li>Please include table information at the top of the table rather than the bottom.</li> <li>The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.</li> </ul>		

### **VERSION 1 – AUTHOR RESPONSE**

Reviewer 1 comment: Thank you for the opportunity to review your manuscript. The study appears to be very well thought out and co-created with a wide variety of stakeholders including the consumers / participants. There are some minor spelling and grammatical errors and would be good if these can be rectified. Authors Response: Thank you for this comment. We have scanned the document, corrected errors, removed superfluous words, and changed tense as detailed in the table and marked copy of the main document.

Reviewer 1 comment: The sources of bias due to consent process have been outlined in great detail. If circumstances permit, it might be a useful to collection data on demographics of those who refuse to participate and their reasons for refusal.

Authors Response: Thank you for this comment. While we agree that obtaining demographic information and understanding why a family refuses to participate in a longitudinal study over pregnancy would be of great benefit, unfortunately, our ethics does not allow for questioning or follow up of individuals who decline participation in the study. This has now been clearly defined to ensure the correct interpretation for the reader in the main document.

Reviewer 1 comment: in the section on unexpected findings, there is no mention or discussion of what the procedure protocol is to address any discoveries that may be potentially linked to criminal activities or harm to others. This could include sexual or physical abuse of the participants or others connected to them.

Authors Response: Thank you for this comment. Participants are advised when consenting that if disclosures are required by law (criminal) or if the Research

Midwife identifies that participant healthcare requires urgent attention (for e.g. medical, indications of partner, child abuse, bereavement) they have a duty of care to disclose or escalate the matter as required. This has now been detailed in the main document.

Reviewer 1 comment: Figure on page 36 does not seem to have a label and seems to go beyond the margins. Feel free to include only if the figure is important.

Authors Response: Thank you for this comment. Figure 1 on Page 37 was increased in size to allow for the easy interpretation for the reader. We have uploaded a jpeg file to the correct resolution and size as requested.

Reviewer 1 comment: Please include table information at the top of the table rather than the bottom. Authors Response: Thank you for this comment. We have now corrected this formatting to ensure the Table information is at the top of the table rather than the bottom.

Reviewer	Comment	Text Changes	Location
			in
			Document
1	Figure	Relabelled Figure 1 to Figure 1 Legend	Page 17,
	Formatting		18
2	Grammar and Text Changes	Changed was to were	Page 6
		Added and	Page 6
		Removed for example	Page 7
		Corrected approximately	Page 8
		Shortened sentence removed which and added This	Page 8
		Changed has been to will be	Page 9
		Corrected 2020 to 2021	Page 9
		Removed undertook their antenatal care to are	Page 9
		booked to deliver	
		Changed were to will be	Page 9
		Added pilot	Page 9

### Overall Change Summary (document changes in red)

		Changed are to will be	Dogo 0
		Changed are to will be Removed During and recent	Page 9
		Removed During and recent	Page 10
		Changed was to will be	Page 10
		Changed were to will be	Page 10
		Added for pregnant participant only	Page 10
		Added from mother	Page 10
		Changed was collected to will be	Page 11
		Changed were collected to will be	Page 11
		Added three	Page 11
		Added the	Page 12
		Removed to	Page 12
		Removed have	Page 12
		Added are	Page 12
		Added pilot	Page 12
		Added multisite	Page 12
		Removed are likely to with may	Page 13
		Added pilot	Page 13
		Changed were to will be	Page 13
		Changed have been to be	Page 13
		Changed were to are	Page 13
		Added may	Page 13
		Changed failed to fail	Page 13
		Changed this committee meet to this committee will	Page 13
		meet	
		Added will	Page 14
		Added their application along with their planned	Page 14
		Corrected 2020 to 2021	Page 14
		Corrected QLD to QFC	Page 14
		Changed are to will be	Page 14
		Changed are to to will	Page 14
		Corrected gender diverse to LGBTQIA+ members	Page 15
		Corrected rate from 6 to 10.6%	Page 15
		Added Qiagen	Page 27
		Corrected REDCap	Page 28
2	Source of Bias	Although all potential pilot participants will	Page 13
		be approached and followed-up using phone calls or	
		SMS reminders, selection bias may be introduced for	
		potential participants who are linguistically diverse	
		and may fail to respond to follow-up attempts [30,	
		31]. Moreover, while we acknowledge that	
		understanding the reason and demographics of	
		families who do not consent to participant in this study	
		would be of benefit, under the ethics approval for the	
		pilot study, we are unable to follow-up or question a	
		participant once they refuse contact.	
2	Unexpected	Participants are advised during the consenting	Page 14
	Findings	process that if disclosures are required by law, or	
	-	there are health concerns during routine appointments	
		that require urgent care, that it is the duty of care of	

		the research midwives' to disclose or escalate the issue as appropriate.	
2	Figure Formatting	Reduced the size of Figure 1	Page 35
2	Table information	Moved table information to the top of the table Table 2, Table 3, Supplementary table 1	Page 20 Page 24 Page 36

We thank BMJ Open for their time, assistance, and support. We look forward to your response.