CONFIDENTIAL WHEN COMPLETE

CHildbirth Acquired Perineal TRauma Study

A cohort study

INFORMED CONSENT FORM

Version 2.0; 01-June-2023

Principal Investigator: **Ana Yepes**

Study ID: _____/____

Thank you for agreeing to participate in the Chapter Cohort Study. Please read this consent form carefully and put your initials in each box **(do not tick the boxes please)**.

		Please initial inside each box to indicate your consent
1	I confirm that I have read and understood the Participant Information Leaflet (version 2.0 dated 01- Jun - 2023) for the Chapter Cohort Study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason why and that my treatment or legal rights will not be affected. However, any information given up to that point can be used in the study results.	☐
3	I agree that my local research team will provide the study organisers at the University of Birmingham with some personal information about me and my baby that is relevant for the study and for any future long term follow up analysis, if it is undertaken. My data will be stored at the University of Birmingham.	☐
4	I understand that all information collected from me for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. This information will be stored securely by the University of Birmingham, which is the data controller for the Chapter Study, for a minimum period of 25 years.	☐

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5	I understand that relevant sections of my medical notes and those of my baby (both paper and electronic) and data collected during the study will be looked at by individuals from the research team, representatives of the sponsor, the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
6	I understand that my contact information held by the NHS will be used to keep in touch with me and follow up of my status when relevant for the purposes of this study.	☐
7	I understand that the information collected about me may be used to support other related research in the future, and may be shared anonymously with other researchers.	☐
8	I understand that any information I give may be included in the study summary or other published documents, but my identity will be protected.	☐
9	I agree to being contacted by researchers for the Chapter Observational Study at approximately 6 weeks, 6 months and 12 months after my baby's birth. This contact may be via post, telephone call, email or text message via the details provided on the contact information form.	☐
10	I agree to my General Practitioner being informed of my participation in the study and contacted if necessary.	☐
11	OPTIONAL: I am willing to be contacted in the future for further research in this area. I understand that I am still free to decline later if contacted. If I DO NOT initial this box, I understand I have consented to be included in the Chapter Cohort Study, but DO NOT want to be contacted in the future.	☐
12	For the purposes of Chapter and projects related Chapter, I agree to the information held and maintained by NHS Digital, together with current and future NHS bodies, being used in the future to provide information about my long-term health status. For this purpose, I agree to the University of Birmingham holding my name, address, date of birth and NHS Number.	☐
13	I agree to take part in the Chapter Cohort Study.	☐

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Name of participant:
(please print clearly) _____

Signature: _____

Date: _____

Name of person taking consent: _____
(please print clearly)

Signature: _____

Date: _____

When completed please note: Original to be filed in the Investigator's Site File; one copy for participant; one copy to be kept with patient's hospital record