PCN-CRP ID:

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PCN-CRP Supplementary information and Consent Form

PCN-CRP Sub-study 4: Exploring new preterm birth predictors for inclusion in the QUiPP v.3 clinical decision support tool.

This sheet provides more information about PCN-CRP sub-study 4 and should be given to you with the main PCN-CRP participant information sheet v2.0 dated 26/02/2025 and main PCN-CRP Consent Form v2.0 dated 26/02/2025.

The QUiPP app is a tool which is commonly used in practice to help doctors and midwives to assess a woman's chances of having her baby early. This helps when deciding what treatments, if any, should be offered, and to reassure women when early birth is unlikely. The app makes this calculation using the woman's risk factors, the length of her cervix and/or the result of a swab test called fetal fibronectin. Cervical length scans and fetal fibronectin are not always available, so we want to make the QUiPP app more flexible by including other predictive tests. One of these is a vaginal swab test called Actim® Partus, which detects the presence of a protein called phosphorylated insulin-like growth factor binding protein-1 (phIGFBP-1). This test is now commonly used when women have symptoms that might be preterm labour. If you took part in this sub-study, you would not have to have any additional tests or treatments. We just ask for your permission to collect information about you, any factors that made you more at risk of having a baby early, the care you have had, and what happened to you and your baby.

Some hospitals are also offering a test which measures the stiffness of the cervix using a medical device called Pregnolia. Your midwife or doctor would have told you whether this test was available in your hospital. During the course of a pregnancy the cervix becomes softer, and a very soft cervix may be an indication of a higher risk of preterm birth. With the Pregnolia test, a small probe is placed against the cervix through a speculum and three measurements are taken. The device has been used for measuring cervical stiffness in over two thousand women, and no serious side effects have been reported so far. The procedure takes less than 30 seconds and it should not be uncomfortable. If you had this test and experienced any discomfort or pain, we will ask you to rate it between 0-10. You can take part in sub-study 4 without also agreeing to the Pregnolia test. More information about this test can be found on the additional Pregnolia leaflet you will be given, and the Pregnolia website: https://en.pregnolia.com/schwangere. Scan this QR code to go to the website:

Please continue overleaf/-

Please initial in boxes

I confirm that I have read and understand the above information for PCN-CRP Sub-study 4: Exploring new preterm birth predictors for inclusion in the QUiPP v.3 clinical decision support tool and have had the opportunity to ask questions. ☐

I understand that taking part in this PCN-CRP sub-study involves collection of information about the pregnancy care I have been offered and received during this pregnancy, including tests designed to predict my chances of preterm birth, and I agree to this. ☐

I understand this may involve a test for cervical stiffness (Pregnolia), and I agree to this. YES ☐ NO ☐

(only sites offering Pregnolia)

Signatures

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of Person taking consent	Signature	Date

When complete: copies - 1 for participant, 1 for researcher site file, 1 to be kept in medical notes.