OCCS Study

Norfolk and Norwich University Hospitals NHS Foundation Trust

Informed Consent Form – OCCS Study

The informed consent form should always be accompanied by a Participant Information Sheet

Study Title:

OCCS Study - Comparing the impact of oral and transdermal oestrogen on cortisol binding globulin and cortisol levels before short synacthen test

IRAS project Id: 356003

Participant Name:

Participant Identification number:

Participant email:

Please read the following statements and initial each box if you agree:

Statement	Initials
I confirm that I have read and understood the Participant Information Sheet dated..... (version.....)	
I understand that I will be required to stop taking oestrogen for 6 weeks as part of this study and in line with standard clinical care at NNUH. (This does not apply to participants not taking any form of oestrogen)	
I have had the opportunity to ask questions and received satisfactory answers.	
I understand that my participation is voluntary and that I can withdraw at any time.	
I understand that my anonymised data will be used for research purposes only.	
I agree to provide blood and salivary samples for analysis as part of the study. (9 blood samples and 7 salivary samples in total over the whole 7-week study).	
I agree to participate in the Short Synatchen Tests.	
I agree to my anonymised data being published in scientific research articles.	
I agree to provide information about my oestrogen use, including the type and dosage, if applicable.	
I wish to receive a summary of the study results upon its completion.	

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands what they are freely consenting to.

Signatures:

Participant Name:

Signature:.....
Date:

Researcher Name:
Signature:.....
Date:

Study contact details for further information:

Main Researcher	Mr. Rupen Limachya Trainee Clinical Scientist/Biochemist Email: rupen.limachya@nnuh.nhs.uk
Study Supervisor	Dr. Allison Chipchase Consultant Clinical Scientist Email: allison.chipchase@nnuh.nhs.uk
Study Sponsor	Julie Dawson Research Services Manager Research Operations Office (NNUH) Quadram Institute, Rosalind Franklin Road Norwich, NR4 7UQ office.rd@nnuh.nhs.uk

Filing instructions when completed:

- 1 (copy) for patient
- 1 (copy) for medical notes
- 1 (original) to be filed in the OCCS Study File