DEPARTMENT OF PSYCHIATRY
NEUROSCIENCES BUILDING
WARNEFORD HOSPITAL
OXFORD OX3 7JX, U.K.
www.psych.ox.ac.uk

Principal Investigator: Prof Catherine Harmer
Email: catherine.harmer@psych.ox.ac.uk
Tel: +44 (0)1865 618326
Primary Researcher: Michael Colwell, DPhil Student
Tel: +44 (0)1865 618 303
Email: michael.colwell@psych.ox.ac.uk

Participant Consent Form – The effect of seven day fenfluramine administration on cognition in healthy volunteers

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PARTICIPANT CONSENT FORM

CUREC Approval Reference: R69642/RE001

The effect of seven day fenfluramine administration on cognition in healthy volunteers

Purpose of Study: To investigate the effects of fenfluramine on cognitive ability, comparing the effects of the drug with placebo.

		Please initial each box
1	I confirm that I have read and understand the information sheet version _____ dated _____ for the above study. I have had the opportunity to consider the information carefully, ask questions and have had these questions answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences or academic penalty.	☐
3	I have been advised about the potential risks associated with taking part in this research and have taken these into consideration before consenting to participate.	☐
4	I have been advised as to what I need to do for this research (especially with regard to drug intake) and I agree to follow the instructions given to me.	☐
5	I understand that blood and urine samples will be taken to assess my eligibility criteria for the study. I understand my urine sample will used to assess pregnancy status (if appropriate) and current drug use. I understand my blood samples will be used as standard screening to check physical health (liver function, urea, and electrolytes. I understand that the samples will be destroyed after completion of the eligibility assessment, or if I withdraw my consent.	☐
6	I understand that saliva samples will be taken during the study and that these samples will be tested for cortisol levels. I understand that the samples will be destroyed after study has ended, or if I withdraw my consent.	☐
7	To the best of my knowledge, I do not meet any of the exclusion criteria outlined in the information sheet for this research. If this changes at a later date during study participation, I agree to notify the researchers immediately.	☐

8	I understand that data collected during the study may be looked at by designated individuals from the University of Oxford. I give permission for these individuals to access my data.	☐
9	I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	☐
10	I consent to answering screening questions to confirm my eligibility to take part.	☐
11	I agree for data collected in this study to be shared with other researchers, including those working outside of the UK and the EU, to be used in other research studies. I understand that any data shared will be anonymised so that I cannot be identified.	☐
12	I understand how this research will be written up and published.	☐
13	I understand that this project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee.	☐
14	I understand how to raise a concern or make a complaint.	☐
15	I understand that all information will be kept strictly confidential except in the rare circumstance in which it is judged that I, or someone else, is at immediate risk of serious harm.	☐
16	I understand that I have been advised not to drink alcohol or carry out activities requiring full alertness (such as driving) during the week of drug/placebo administration if I am aware of any impairment.	☐
17	I agree to take part in the study	☐
Optional:	I agree for my contact details to be kept in a secure database for the purpose of contacting me about future studies. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	☐

_____	dd / mm / yyyy	_____
Name of Participant	Date	Signature
_____	dd / mm / yyyy	_____
Name of person taking consent	Date	Signature