

Scotland A Research Ethics Committee

Research Ethics Service 2nd Floor Waverley Gate 2-4 Waterloo Place Edinburgh EH1 3EG Tel: 0131 465 5680 www.hra.nhs.uk

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22 February 2022

Prof Simon Thomas Professor of Clinical Pharmacology and Therapeutics Newcastle Hospitals NHS Foundation Trust Medical Toxicology Centre Newcastle University Newcastle NE2 4HH

Dear Professor Thomas

Study title:	Identification and characterization of the clinical toxicology of novel psychoactive substances (NPS) by laboratory analysis of biological samples from recreational drug users
	(Scotland).
REC reference:	15/SS/0047
EudraCT number:	n/a
Amendment number:	AM08 (your Substantial amendment 07)
Amendment date:	31 January 2022
IRAS project ID:	172425

The above amendment was reviewed on 18 February 2022 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Completed Amendment Tool [Substantial amendment 07]	1	31 January 2022
Other [15-SS-0047 updated REC_Form_new CI 17022022]	NA	15 February 2022



Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	07 February 2022
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Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities- see details at: <u>https://www.hra.nhs.uk/planning-and-improving-research/learning/</u>

IRAS Project ID - 172425: Please quote this number on all correspondence

Yours sincerely

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Mr Robert Wyllie Chair

E-mail: ruth.fraser4@nhslothian.scot.nhs.uk

Enclosures:

List of names and professions of members who took part in the review

Copy to: Prof Simon Thomas, Newcastle Hospitals NHS Foundation Trust Dr Simon Hill, Newcastle Hospitals NHS Foundation Trust Mr Aaron Jackson, Newcastle Joint Research Office



Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 18 February 2022

Committee Members:

Name	Profession	Present	Notes
Mr Graham Ayres	Solicitor	Yes	
Dr Jill Bradshaw Senior Lecturer in Intellectual and Developmental Disability Yes		Yes	
Mr Robert Wyllie	Policy Adviser	Yes	

Also in attendance:

Name	Position (or reason for attending)
Ruth Fraser	SESRES administrative officer
Manx Neill	Scotland A/B REC Manager