

13 April 2021

Professor 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: AM06 (your Substantial amendment 5)

Amendment date: 24 March 2021

IRAS project ID: 172425

The above amendment was reviewed 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.

The Sub-Committee had no ethical concerns regarding the amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Completed Amendment Tool [172425_Substantial amendment 5_]	1	24 March 2021

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

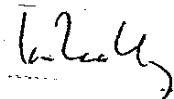
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

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

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



Dr Ian Zealley
Chair

E-mail: Manx.Neill@nhslothian.scot.nhs.uk

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

Copy to: Mr Andrew Johnston, Newcastle Joint Research Office

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Joanne Mair	Research Facilitator	Yes	
Professor Brian McKinstry	Retired GP/Director Scottish Health Research Register	Yes	
Dr Ian Zealley	Consultant In Department Of Radiology	Yes	In the Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Agnieszka Di Domenico Prada	SESRES-Administrative Assistant
Manx Neill	Scotland A/B REC Manager