

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

12 June 2018

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

Date: 12 June 2018

Enquiries to: Manx Neill  
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Dear Prof 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:** 15/SS/0047/AM03

**Amendment date:** 16 April 2018

**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.

The Sub-Committee had no objection to the use of data and samples from participants included on the advice of a person with relevant powers, even when it has not been possible to obtain the participants consent after recovery because of their lack of response to a written request, and at least two telephone attempts at contact.

**Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letters of invitation to participant [person previously included when they did not have capacity]	1	16 April 2018
Notice of Substantial Amendment (non-CTIMP)		16 April 2018
Participant information sheet (PIS) [nearest relative/guardian or welfare attorney]	4.0	16 April 2018
Research protocol or project proposal	4	16 April 2018

**Chairman Dr Ian Zealley**  
**Vice-Chairman Dr Colin Selby**

## 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.

## 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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>15/SS/0047:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Dr Anthony Pottage**  
**Alternate Chair**

E-mail: [pavlina.yaneva@nhslothian.scot.nhs.uk](mailto:pavlina.yaneva@nhslothian.scot.nhs.uk)

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

*Copy to: Mr Michael White, The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Mr Andrew Johnston, Newcastle Joint Research Office*

## Scotland A REC



### 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	Researcher	Yes	
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Yes	In the Chair
Mrs Mary Sweetland	Statistician	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Manx Neill	REC Manager
Miss Pavlina Yaneva	Ethics Administrative Officer