



Health Research Authority

North East - Newcastle & North Tyneside 2 Research Ethics Committee

Room 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
NE32 3DT

Tel: 0191 4283476

12 February 2016

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

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.

REC reference: 15/NE/0023

EudraCT number: n/a

Amendment number: Substantial Amendment 1 - 6/1/16

Amendment date: 06 January 2016

IRAS project ID: 168706

The above amendment was reviewed at the meeting of the Sub-Committee held via 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper	Email from Simon Thomas	25 January 2016
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 1 - 6/1/16	06 January 2016

Participant consent form [Participant]	Version 2	06 January 2016
Participant consent form [Consultee Declaration Form]	Version 2	06 January 2016
Participant consent form [Person previously included when they did not have capacity]	Version 2	06 January 2016
Participant information sheet (PIS) [Participant]	Version 2	06 January 2016
Participant information sheet (PIS) [Information Sheet for Consultees]	Version 2	06 January 2016
Research protocol or project proposal	Version 2	06 January 2016

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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 NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/NE/0023:	Please quote this number on all correspondence
--------------------	---

Yours sincerely

pp 

Dr Alasdair MacSween
Chair

E-mail: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net

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

Copy to: Michael White, The Newcastle upon Tyne Hospitals NHS Foundation Trust

Mr Sean Scott, The Newcastle upon Tyne Hospitals NHS Foundation Trust

North East - Newcastle & North Tyneside 2 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held via correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Sumeet Gupta	Consultant Psychiatrist	Yes	
Dr Alasdair MacSween (Chair)	Principal Lecturer in Research Governance	Yes	