



Health Research Authority

North East - Newcastle & North Tyneside 2 Research Ethics Committee

Room 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne & Wear
NE32 3DT

Tel: 0207 104 8282

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.

09 February 2017

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 3 - 12/1/17
Amendment date:	12 January 2017
IRAS project ID:	168706

The above amendment was reviewed by the Sub-Committee in correspondence.

The amendment is to gain approval for the adjustment of recruitment targets; inclusion of patients with severe opioid toxicity; changes to participant data collection sheet; sharing of linked anonymous samples between laboratories and updating the protocol;.

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.

Members requested that the participant information sheet be updated to include the novel opiates aspect of the research.

You replied that and acknowledged the way the PIS was written you thought it covered the inclusion of people with toxicity possibly related to opioid novel psychoactive substances, but looking at this again, you understand the REC's point of view. You explained that the PIS has been amended and updated the other relevant documents to refer to this latest version.

The Sub Committee was satisfied with the response given to the issue raised.

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	20 January 2017
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 3 - 12/1/17	12 January 2017
Other [Data Collection Sheet]	Version 3	12 January 2017
Participant consent form	Version 4.1	08 February 2017
Participant consent form [Consultee Declaration Form]	Version 4.1	08 February 2017
Participant consent form [Consent Form (person previously included when they did not have capacity)]	Version 4.1	08 February 2017
Participant information sheet (PIS)	Version 4.1	08 February 2017
Research protocol or project proposal	Version 4	12 January 2017

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/>

15/NE/0023:

Please quote this number on all correspondence

Yours sincerely

pp



Mr Richard Tomlin
Chair

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

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

*Copy to: Mr Michael White, Newcastle Upon Tyne Hospitals NHS Foundation Trust
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 on 08 February 2017 via
correspondence.**

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Susan P Phillips	Clinical Lead Pharmacist	Yes	
Mr Richard Tomlin (Chair)	Consultant in Research Management (Retired)	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Kerry Dunbar	REC Assistant