

North East - Newcastle & North Tyneside 2 Research Ethics Committee

North East REC Office
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Jarrow Business Centre
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Jarrow
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Tel: 0207 104 8118

24 May 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 2 - 12/5/16**

Amendment date: **12 May 2016**

IRAS project ID: **168706**

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

This amendment is to gain approval for the changes to the Protocol and subsequent changes to the participant information sheet and consultee declaration form.

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 queried what would happen if the FEWS lab found something in the sample that was sent for testing that could be identified as toxic. Members requested clarification around this point and asked how participants would be informed in these circumstances and what reassurances would be provided.

You replied that all of the recreational substances that might be identified, including the novel psychoactive substances could be classified as 'toxic'. Many could have severe and even life threatening effects under some circumstances, depending on dose taken and other factors. However, results from analysis or powders/drug product or of biological samples would not be available until several weeks after the event, when any acute toxicity would have resolved (unless the person died from the acute effects of the drugs taken). While there could be long term health effects from drug use, including chronic neurotoxicity, as yet there is no information on that to give to patients, especially if the exposure was to a novel psychoactive substance.

It was always the intention to pass on results of analysis to participants if they requested this and would be done by the investigator or an appropriately skilled clinician with delegated responsibility for that. There would be the opportunity for the participant to ask questions and receive explanations and/or reassurance as needed.

The documents were amended and submitted for review.

The Sub Committee was satisfied with the responses given to the issues 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	12 May 2016
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 2 - 12/5/16	12 May 2016
Participant consent form	Version 3.1	20 May 2016
Participant consent form [England and Wales (previously incapacity)]	Version 3.1	20 May 2016
Participant consent form [Consultee Declaration Form (England and Wales)]	Version 3.1	20 May 2016
Participant information sheet (PIS)	Version 3.1	20 May 2016
Research protocol or project proposal	Version 3	18 April 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



Mr Ian Campbell
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

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Attendance at Sub-Committee of the REC meeting on 20 May 2016 via correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Ian Campbell (Chair)	Pharmacist	Yes	
Ms Vicky Ryan	Statistician	Yes	

Also in attendance:

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