



Health Research Authority

North East - Newcastle & North Tyneside 2 Research Ethics Committee

NHS BT Blood Donor Centre
Holland Drive
Newcastle upon Tyne
Tyne and Wear
NE2 4NQ

Tel: 0207 104 8079

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.

10 February 2020

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.

REC reference: 15/NE/0023

Amendment number: Substantial Amendment 6, 06/01/2020

Amendment date: 13 January 2020

IRAS project ID: 168706

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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 6, 06/01/2020	13 January 2020
Other [Data Collection Sheet]	4, track change	06 January 2020
Participant information sheet (PIS) [Participant Information Sheet]	5, track change	06 January 2020
Research protocol or project proposal [Protocol]	7, track change	06 January 2020

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.

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/>

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

Yours sincerely
Pp



Dr Raymond Chadwick
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 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 via correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Mrs Joan Bedlington	Charity Manager	Yes
Dr Raymond Chadwick (Chair)	Postgraduate Tutor in Clinical Psychology	Yes

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Donna Bennett	Approvals Administrator