

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: 02071048103

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.

27 November 2019

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 5
Amendment date:	21 October 2019
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>
Notice of Substantial Amendment (non-CTIMP)		21 October 2019
Research protocol or project proposal	6: Tracking removed	21 October 2019
Research protocol or project proposal	6: Tracked	21 October 2019

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

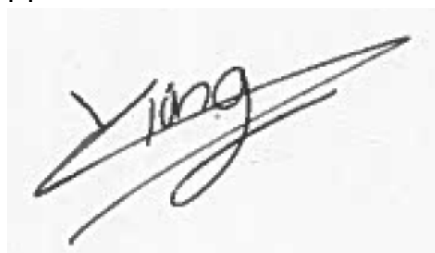
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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

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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 Liz Baker	Clinical Research Scientist	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 Yasmin King	Approvals Administrator