

North East - Newcastle & North Tyneside 2 Research Ethics Committee

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

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.

19 April 2021

Mr Sean Scott
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Level 1 Regent Point
Regent Farm Road
Gosforth
NE3 3HD

Dear Mr Scott

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 7
Amendment date:	24 March 2021
IRAS project ID:	168706

The above amendment was reviewed on 20 April 2021 by the Sub-Committee in correspondence.

Ethical opinion

The Sub-Committee did not raise any ethical issues. 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>
Completed Amendment Tool [168706_Substantial amendment 7_]	1	24 March 2021
Research protocol or project proposal [NIHR HPRU Theme 4 - NPS study (EW) RD 7312 -TRACKED]	9	24 March 2021

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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/>

IRAS Project ID - 168706:	Please quote this number on all correspondence
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Yours sincerely



Saira Adil
Approvals Administrator
P.P
Dr Raymond Chadwick
Chair

E-mail: newcastlenorthtyneside2.rec@hra.nhs.uk

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Attendance at Sub-Committee of the REC meeting on 20 April 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Owen Burbidge	CCLG Tissue Bank Manager	Yes	
Dr Raymond Chadwick	Postgraduate Tutor in Clinical Psychology	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Saira Adil	Approvals Administrator