

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 8388

11 March 2022

Dr Simon Hill Consultant Physician and Clinical Pharmacologist / Honorary Clinical Senior Lecturer Newcastle Hospitals NHS Foundation Trust Regional Drug and Therapeutics Centre 16/17 Framlington Place Newcastle NE2 4AB

Dear Dr Hill

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 09
Amendment date:	31 January 2022
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:

Document	Version	Date
Completed Amendment Tool [Substantial amendment 09]	1	31 January 2022
Other [Updated REC Form]	NA	
Other [GCP certificate]	Nov 2020	06 December 2021
Summary CV for Chief Investigator (CI) [Chief investigator CV]	1	07 February 2022

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: <u>https://www.hra.nhs.uk/planning-and-improving-research/learning/</u>

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

Yours sincerely

Jamin Harren

On Behalf Of Professor Barry Hirst Chair

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

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

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Attendance at Sub-Committee of the REC meeting on 07 March 2022

Also in attendance:

Name	Position (or reason for attending)
Professor Barry Hirst	Professor of Cellular Physiology
Dr Meiyi Pu	Consultant