

27 January 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 (Scotland).

REC reference: 15/SS/0047

EudraCT number: n/a

Amendment number: AM04

Amendment date: 13 January 2020

IRAS project ID: 172425

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.

The Sub-Committee had no ethical concerns regarding the amendment.

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) [Amendment 4 (Scotland) 6th Jan 2020 Final] | | 13 January 2020 |
| Other [IONA Data collection sheet V4 06Jan2020 tracked] | 4 | 06 January 2020 |
| Participant information sheet (PIS) [IONA-S PIS & Consent form_nearest relative AWI V5 6Jan2020] | 5 | 06 January 2020 |
| Participant information sheet (PIS) [IONA-S PIS and Consent V4 6jan2020] | 4 | 06 January 2020 |

| | | |
|--|---|-----------------|
| Research protocol or project proposal [NIHR HPRU Theme 4-5 NPS study V5 (Scotland) R&D 7312 6Jan2020] | 5 | 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

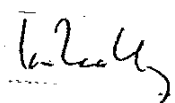
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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/>

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|--------------------|---|
| 15/SS/0047: | Please quote this number on all correspondence |
|--------------------|---|

Yours sincerely



Dr Ian Zealley
Chair

E-mail: Manx.Neill@nhslothian.scot.nhs.uk

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

Copy to: Mr Andrew Johnston, Newcastle Joint Research Office

Scotland A REC

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-----------------------|--|----------------|--------------|
| Miss Kenna Bisset | Trainee Solicitor | Yes | |
| Dr Laura Doull | Clinical Brain Sciences Project Manager | Yes | |
| Mr David Ronald Evans | Scottish Parliament- Parliamentary Assistant | Yes | |
| Dr Lindsay Ramage | Leader of Research Info Management | Yes | |
| Dr Jacqueline Stephen | Trial Statistician | Yes | |
| Mr Robert Wyllie | Scottish Government Policy Advisor | Yes | |
| Dr Ian Zealley | Consultant In Department Of Radiology | Yes | In the Chair |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|---------------------------------|---|
| Mrs Agnieszka Di Domenico Prada | SESREC Administrative Officer |
| Miss Manx Neill | Scotland A REC Manager |

Written comments received from:

| <i>Name</i> | <i>Position</i> |
|-----------------------|---|
| Mr David Ronald Evans | Scottish Parliament-Parliamentary Assistant |
| Dr Lindsay Ramage | Leader of Research Info Management |