

**Scotland A Research Ethics Committee**

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20 August 2021

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:** AM07 (Your substantial amendment 6)

**Amendment date:** 29<sup>th</sup> July 2021

**IRAS project ID:** 172425

The above amendment was reviewed on 13 August 2021 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>
Completed Amendment Tool [IONA substantial amendment 6 (Scotland) 29Jul2021 Amendment_Tool_v1_5_25Mar21]	1	29 July 2021
Other [IONA Data collection sheet V6 29Jul 2021 tracked]	6	29 July 2021
Other [IONA Data collection sheet V6 29Jul 2021 excel version]	6	29 July 2021
Research protocol or project proposal [NIHR HPRU Theme 4-NPS study V6 (Scotland) R&D 7312 29Jul2021 tracked]	6	29 July 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

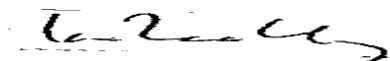
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## 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/>

<b>IRAS Project ID - 172425:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Dr Ian Zealley**  
Chair

E-mail: [ruth.fraser4@nhsllothian.scot.nhs.uk](mailto:ruth.fraser4@nhsllothian.scot.nhs.uk)

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

*Copy to: Prof Simon Thomas, Newcastle Hospitals NHS Foundation Trust  
Mr Andrew Johnston, Newcastle Joint Research Office*

**Chair-Dr Ian Zealley**  
**Vice-Chair-Dr Mary-Joan MacLeod**

**Scotland A: Adults with Incapacity only**

**Attendance at Sub-Committee of the REC meeting on 13 August 2021**

**Committee Members: ,**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	Yes	
Professor Brian McKinstry	Retired GP/Director Scottish Health Research Register	Yes	
Dr Ian Zealley	Consultant In Department Of Radiology	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Ruth Fraser	SESRES administrative officer
Manx Neill	Scotland A/B REC Manager