Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Identification of Novel Psychoactive Substances (IONA)

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

(●) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Will you be taking new samples primarily for research purposes (i.e. not surplus or existing stored samples), including any removal of organs or tissue from the deceased?	(●) Yes ( ) No
b) Will you be using surplus tissue or existing stored samples identifiable to the researcher?	(●) Yes ( ) No
c) Will you be using only surplus tissue or existing stored samples not identifiable to the researcher?	(●) Yes ( ) No
d) Will you be processing identifiable data at any stage of the research (including in the identification of participants)?	(●) Yes ( ) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

- [x] England
- [x] Scotland
- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

- [ ] IRAS Form
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?

(•) Yes ( ) No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

(•) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

(•) Yes ( ) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

◉ Yes ○ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Simon	Thomas
Work Address	Medical Toxicology Centre		
	Newcastle University		
	Newcastle		
PostCode	NE2 4HH		
Email	simon.thomas@ncl.ac.uk		
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For guidance on this section of the form refer to the guidance

Full title of study:	Identification and characterization of the clinical toxicology of novel psychoactive substances (NPS) by laboratory analysis of biological samples from recreational drug users.
Lead sponsor:	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Name of REC:	North East - Newcastle and North Tyneside 2
REC reference number:	15/NE/0023

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Date study commenced:	22nd March 2015
Protocol reference (if applicable), current version and date:	Version 6, 21st October 2019
Amendment number and date:	5, 21st October 2019

Type of amendment

(a) Amendment to information previously given in IRAS

(●) Yes ( ) No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

○ Yes ◉ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

BACKGROUND

The IONA study is collecting blood, urine and oral fluid samples from people presenting to UK hospitals with severe toxicity suspected to be related to use of novel psychoactive substances (sometimes previously called 'legal highs') or non-pharmaceutical opioids. The latter, including heroin, are included so that the involvement of unlicensed fentanyl analogues in episodes of severe toxicity can be monitored. Sample analysis is being performed to identify the substances involved and to link these with clinical features of toxicity experienced by the participant. The study currently involves 27 study sites in England and Wales and 2 sites in Scotland. Because the study can involve adults with incapacity, separate ethical approval was required in England and Wales (15/NE/0023) and Scotland (15/SS/047).

AMENDMENT REQUESTED

This is a request for a substantial study amendment to adjust the recruitment target for England and Wales and for a small extension to the end date to allow time to complete laboratory analysis.

The current ethical approval is for recruitment of 750 participants, 570 recruited in England and Wales and 180 recruited in Scotland, by 31st March 2020. Research sites in England and Wales have achieved their overall recruitment target of 570 with 6 months of the currently funded recruitment period still remaining. We would to increase their overall recruitment target by 100 (to 670) to allow them to continue recruitment until 31st March 2020. We would also like to extend the end date for the study for a further 6 months to 30th September 2020, to provide sufficient time to complete laboratory analysis of all samples collected by 31st March 2020.

The current NIHR funding of the IONA study will not continue beyond the end of March 2020, but work is being done to secure further funding from another source to allow the study to continue beyond that date, although this is not yet guaranteed. Were this funding to be secured, a further substantial protocol amendment will be requested to cover the new arrangements. The proposed additional recruitment in England and Wales to the end of March 2020 requested here would provide continuous data collection over 5 years from March 2015 to March 2020. This is important for monitoring time trends in misuse of drugs and other substances, which would otherwise be undermined by a gap in data collection between October 2019 and March 2020. In the event that further external funding is not obtained, local funds are available to cover analytical costs related to these 100 additional participants.

IONA is an observational study and there are no specific statistical comparisons planned. We are requesting additional recruitment numbers to allow further monitoring of the substances involved in severe episodes of toxicity

associated with exposure to new psychoactive substances, rather than for any specific statistical comparison.

These revised recruitment targets are reflected in the updated schedule of events (Protocol V6, 21st October 2019, pages 33-34 of the clean version).

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Protocol	6	21/10/2019

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Prof Simon Thomas on 22/10/2019 15:30.

Job Title/Post:	Consultant
Organisation:	Newcastle Hospitals NHS FT
Email:	simon.thomas@ncl.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mr Aaron Jackson on 04/11/2019 09:56.

Job Title/Post:	RM&G Manager
Organisation:	NuTH
Email:	aaron.jackson@nhs.net