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?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [ ] IRAS Form
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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		
Telephone	01912606180		
Fax	01912820288		

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
Name of lead R&D office:	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Date study commenced:	22/3/2015
Protocol reference (if applicable), current version and date:	V3, 18th April 2016
Amendment number and date:	2, 18th April 2016

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 <u>either</u> 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.

Protocol V3, 18th April 2016

(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.

Participant information sheet, V3, 18th April 2016
Participant informed consent form, V3, 18th April 2016
Consultee declaration from, V3, 18th April 2016

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.

AMENDMENT 2 (V1 – 18th April 2016)

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 called 'legal highs'). 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 11 study sites in England and Wales and 1 site 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).

This is a request for a substantive amendment to be made in the light of Home Office advice on the appropriate handling of drug product/powders donated to the study by participants, taking into account forthcoming changes to the law concerning psychoactive substances.

SUBSTANTIAL AMENDMENTS REQUESTED

Analysis of residual drug product

Occasionally patients with suspected recreational drug toxicity may have some of the product they have used in their possession when they present to hospital, such as unopened or opened packets, powders, herbal material etc. Analysis of these products is very useful as it is technically easier to identify NPS in them than in biological samples and the results of analysis inform the more challenging analysis of blood, urine or oral fluid.

Some participants are willing to donate such products to the study for analysis. Prior to this amendment, such samples were sent with the biological samples and clinical data to the HPRU laboratory in Newcastle, provided the clinician did not suspect that the product contained controlled substances.

There are, however, difficulties with this approach as investigators cannot be certain that there are no controlled substances involved and there is increasing evidence that so-called 'legal high' products do sometimes contain substances controlled under the Misuse of Drugs Act. Furthermore, psychoactive substances that have previously not been controlled will be captured by the Psychoactive Substances Act 2016. Although the HPRU laboratory in Newcastle has a license for handling controlled substances, there are legal difficulties with transfer of such samples between the participating hospital and the HPRU laboratory.

Home Office advice is that special precautions are needed for transfer of these samples. They already have a system

in place for transfer of drug product samples to laboratories in their Forensic Early Warning System (FEWS) and have agreed that this system can also be used for samples of drug product collected in the IONA study. These would be sent from the local research site to a FEWS laboratory using a courier approved by them for this purpose.

The detailed instructions for this are provided in Appendix 4 of the protocol. The drug sample would be put in an evidence bag provided for this and labelled with the participants study identification number. This allows the results of the analysis to be linked to the participant's clinical details and biological analytical sample results without the FEWS laboratory being able to identify the individual. The sample would then be transported to one of the Home Office-approved FEWS laboratories by the courier.

Donation of drug samples by participants is voluntary. The process is described in the participant information sheets and consent for donation is provided via the consent form which refers to this.

Revised documentation affected by this amendment is as follows

1. Protocol – V3 (18th April 2016)
(Text above included, p34-35; Appendix 4 added)

2. Participant Information Sheet – V3 (18th April 2016)
The following section has had text added as follows:

What will happen with any samples?

If you have a sample of the drug product you have taken, you may decide to donate this to the research study so we can find out exactly what substances are in it. This is your choice. If you do agree to donate this, the drug product sample will be sent to a laboratory in the Forensic Early Warning System (FEWS) organized by the Home Office.

(and)

All samples will only be labelled with your unique study code rather than your personal details. This means that the research teams in Newcastle and Edinburgh and the scientists in the FEWS laboratories will not be able to identify who you are.

3. Consultee declaration form (England and Wales) v3, 18Apr2016

Updated to refer to Version 3 of the participant information sheet

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*
Notice of Substantial Amendment 2	V1	18/04/2016
Protocol	V3	18/04/2016
Participant Information Sheet	V3	18/04/2016
3. Consultee declaration form (England and Wales)	V3	18/04/2016

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 25/04/2016 14:39.

Job Title/Post:	Consultant
Organisation:	Newcastle University
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 Andrew Johnston on 09/05/2016 08:17.

Job Title/Post:	RM&G Manager
Organisation:	NUTH-FT
Email:	andrew.johnston@nuth.nhs.uk