Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Identification Of Novel psychoActive substances (IONA)
IRAS project ID* (or REC reference if no IRAS project ID is available):	168706
Sponsor amendment reference number*:	Substantial amendment 8
Sponsor amendment date* (enter as DD/MM/YY):	29 July 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. 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 (note: this field will adapt to the amount of text entered)*:	(1) Extension of the study end-date to 31/07/2024; (2) Increase in participant numbers during the extension (3) Collection of additional data from participants (about usual drug therapy) (4) Additional option for digital data collection rather than collection on paper (5) Minor changes to inclusion/exclusion criteria (5) Minor administrative updates to the protocol. Note that there is a similar study taking Place in Scotland that has separate ethical approval as the study involves adults with incapacity. Similar amendments are being requested for that study.

Project type (select):	◉ Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		◉ No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	◉	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		◉ No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		◉ No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	◉ Yes		○ No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve children OR does the amendment introduce this?:	○ Yes		◉ No	
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		◉ No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☑	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☑	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Study Design

Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Further funding has been obtained from Public Health England to extend the study. Funding has been confirmed for the period August 2021-July 2022, but further funding is anticipated subject to annual review of study progress. We therefore seek approval to extend the study to 31st July 2024. This will allow inclusion of further participants and continuing analytical surveillance of the substances involved in non-medical ('recreational') drug use resulting in hospital presentations.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Participant numbers - Significant change to sample size
Further information (free text - note that this field will adapt to the amount of text entered):	The study extension and additional available funding will allow recruitment of further participants. We are seeking approval to recruit 525 participants between August 2021 and July 2022 across the UK (375 in England and Wales and 150 in Scotland) and between 525 (375 in England and Wales and 150 in Scotland) and 800 (550 in England and Wales and 250 in Scotland) participants annually in the UK over the next 2 years up to 31st July 2024. This will require increases in the rate of recruitment which will be achieved by increasing recruitment at current IONA research sites and also by increasing the numbers of research sites participating. The additional data will provide further detail of trends and geographical variations in toxicity caused by substance use over that time period. As previously, the data is analysed using descriptive statistics; no specific a priori hypotheses are being tested and as such no formal power calculations are appropriate. Study sites continue to receive the same funding per participant, which is limited to sample procesing and transfer costs.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 3	
Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Modification to data collection to include participant's usual drug therapy. See updated data collection sheet (V6, 29th July 2021)

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 4	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Data is currently collected on paper, but we are seeking approval for digital data collection using a bespoke excel spreadsheet (IONA data collection sheet V6, 29th July 2021 - excel version). Study sites can use either the digital or paper version and the data collected is identical for both.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐

Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All	○ Some

Add another change: ☑

Change 5				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study			
Further information (free text - note that this field will adapt to the amount of text entered):	The inclusion/exclusion criteria have been adjusted to (a) exclude participants known to be HIV positive as our current laboratory is unable to handle HIV positive samples (note that HIV testing is not done as part of this study) (b) clarify that previous participants can be included again if they present after further episodes of substance use. As the study is observational and involves use of urine, residuals of clinical blood samples and data collection from clinical notes, we believe that this does not present an unreasonable burden.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☑

Change 6				
Area of change (select)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Other administrative change - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	The protocol has been simplified by removing details of co-investigators and descriptions of other planned research not directy relevant to this specific project. This makes it shorter and more focussed. It also includes an updated schedule of events including the proposed updated sample sizes.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Judith Marston
Email address:*	judith.marston2@outlook.com

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies			
UK wide:	England and Wales:	Scotland:	Northern Ireland:

	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approva	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating func	HSC REC	HSC Data Guardians	Prisons	National coordinating func	Category:
Change 1:	N					(Y)				(Y)									C
Change 2:	Y					(Y)				(Y)									A
Change 3:	N					(Y)				(Y)									C
Change 4:	N					(Y)				(Y)									C
Change 5:	N					(Y)				(Y)									A
Change 6:	N					Y				(Y)									C
Overall reviews for the amendment:																			
Full review:	Y					Y				N									
Notification only:	N					N				Y									
Overall amendment type:	Substantial																		
Overall Category:	A																		

For national coordinating function office use:	
Update HARP:	This amendment may involve an update to contact details, project end date, or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.