**From:** Simon Thomas
**Sent:** 20 May 2016 17:16
**To:** NewcastleandNorthTyneside2 NRESCommittee.NorthEast- (HEALTH RESEARCH AUTHORITY)
**Cc:** Wilson, Natalie (Natalie.Wilson7@nuth.nhs.uk)
**Subject:** RE: IONA REC Ref 15-NE-0023 Amendment 2 - QUERIES on Amendment

Dear Kathryn

I am grateful to the subcommittee for looking at this amendment request.

In answer to the one question raised, all of the recreational substances we might identify, including the novel psychoactive substances can be classified as ‘toxic’. Many could have severe and even life threatening effects under some circumstances, depending on dose taken and other factors. However, results from analysis or powders/drug product (done by FEWS labs) or of biological samples (done here in Newcastle) will not be available until several weeks after the event, when any acute toxicity will have resolved (unless the person dies from the acute effects of the drugs taken).  While there could be long term health effects from drug use, including chronic neurotoxicity, as yet we have no information on that to give to patients, especially if the exposure was to a novel psychoactive substance.

Having said that, it has always been our intention to pass on results of analysis to participants if they request this. This is done by the investigator or an appropriately skilled clinician with delegated responsibility for that. There would be the opportunity for the participant to ask questions and receive explanations and/or reassurance as needed.

Looking at the information sheet, I agree with the subcommittee that this is perhaps not as clear as it might have been. I am therefore proposing some changes in the attached modified version (**Version 3.1, 20th May 2016).** The following text has been included on p5 (new text in red).

‘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. The medical team looking after you in hospital will be able to link you with the results from analysis of the blood, urine, oral fluid and/or drug product that you have provided. They can pass on the results of these analyses to you if you request this. Please be aware, however, that these results will not be available for several weeks.’

To allow the participants decision to be recorded and appropriate contact details collected, the consent forms have hads the following statements included:

If you would like to hear the results of the analysis of your samples (when these are available) please provide contact details here:

The affected forms are attached and are as follows:

**Participant informed consent form V3.1, 20th May 2016**

**Consent form (previous incapacity) V3.1, 20th May 2016**

The following has been updated to refer to the correct version of the participant information sheet

**Consultee declaration form V3.1, 20th May 2016**

I hope that with this modification the subcommittee will be able to approve the amendment, but I am happy to make further changes according to their advice.

With best wishes

Simon Thomas

**From:** NewcastleandNorthTyneside2 NRESCommittee.NorthEast- (HEALTH RESEARCH AUTHORITY) [mailto:nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net]
**Sent:** 20 May 2016 14:29
**To:** Simon Thomas
**Subject:** RE: IONA REC Ref 15-NE-0023 Amendment 2 - QUERIES on Amendment
**Importance:** High

Dear Simon,

The sub-committee have reviewed the amendment and have raised one minor query which they hoped you may be able to offer some further information on please?

Details as follows:

Members queried what would happen if the FEWS lab found something in the sample sent for testing that maybe identified as toxic – please provide clarification around this point and advise how you would inform participants in this circumstances and what reassurances would be provided. Revise the participant information sheet accordingly (annotating with a revised version number and document date).

**I would appreciate a response on this by 10am on Tuesday 24 May 2016**.

Should you have any queries, please let me know.

Best Wishes,

Kathryn

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| Kathryn Murray | Covering REC Manager**Health Research Authority**Research Ethics Committee (REC) CentreRoom 002, Jarrow Business Centre, Rolling Mill Road, Jarrow, Tyne and Wear, NE32 3DT| T: 0207 104 8085 | [www.hra.nhs.uk](http://www.hra.nhs.uk/) |
| **IMPORTANT** – [**Click here**](http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/) for the latest details of the roll-out of HRA Approval in EnglandThe HRA is keen to know your views on the service you received – our short feedback form is available [**here**](http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/) |

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