Information sheet for consultees (England and Wales)

Version 5, 16th April 2018

Identification and characterization of the clinical toxicology of novel psychoactive substances (NPS) by laboratory analysis of biological samples from recreational drug users.

Information sheet for consultees

As someone who knows _____ (person's name) well / in an independent capacity (delete as appropriate), you are being invited to consider whether he/she would be willing to participate in a research study based on your knowledge of him/her.

Please read the Information Sheet (Version 4.1, 8th February 2017) that all participants read before deciding whether or not they would like to take part in this study. We will then ask you whether or not you think the person we are asking you about would have chosen to take part in the study, if they been able to read this Information Sheet and make that decision for themselves.

Further information is provided below about the provisions for people who lack capacity to consent to participate in research for themselves and explains your role as a consultee, if you agree to take on this role.

Capacity to give consent

Usually an adult must give their own informed consent before they can be entered into a research study. Some people however, may lack the mental capacity to make such a decision. This might include some people being treated for intoxication with drugs or chemicals. For some research projects, including this one, it is important that adults lacking mental capacity can be included in the research because results obtained from them can be particularly important.

To protect both the person lacking capacity and the person providing advice about them, certain processes must be followed. Firstly, a formal assessment of mental capacity must be carried out by a doctor who is not involved in the research. If, after assessment, the person is deemed not to have the capacity to consent for themselves to being entered into the study, the researcher must appoint someone to provide advice, called a 'consultee'.

Consultees

Consultees can either be **personal** or **nominated**.

A **personal consultee** is someone unconnected with the research who knows the potential research participant in a personal capacity and is able to advise on the person's wishes or feelings. This could be a friend or family member or someone appointed by the court.

A **nominated consultee** is someone unconnected with the research, who is appointed by the research team to advise the researcher about the person's wishes or feelings in relation to the project. This could be another professional but they must not have any connection with the research study. A nominated consultee would only be appointed once the research team has taken reasonable steps to identify a personal consultee in the first instance.

The consultee's role

If you are prepared to act as a consultee, your role will be to advise the research team as to the individual's likely wishes/feelings with regard to taking part in the study. You are not being asked to consent on the individual's behalf, but rather to give advice about their wishes. However, your opinion will be respected in making a decision as to whether they take part in the study or not.

You will be given a copy of the participant information sheet and opportunity to discuss the project with one of the researchers so that you can form an opinion as to the individual's likely wishes/feelings in respect to the project. If, at the end of this process, you feel that the individual would be willing to take part in the project you will be asked to sign a form to that effect.

Please note that on return of capacity, we will make every effort to inform the individual about their participation in the research project, give them information about it and ask them to give written consent for their participation before they leave hospital. If they decide not to participate, they can tell us what that want to happen to any information collected so far. In cases where the person leaves hospital before we are able to complete this process, we will send them information by post, providing a prepaid envelope for them to return the consent documents or inform us that they do not want their information or samples used. We will then also make 2 attempts to contact them by telephone, if a number has been provided. While we are awaiting their response, or if they do not respond, we will continue to use the anonymised information about them that has already been collected

Further information

If you have any questions please ask the person who provided this information sheet to you. You may also address questions to

Study Doctor:	***Study Nurse:***
insert	**insert**

For any concerns about rights as a participant or consultee, or for any complaints, please contact:

……

Before you sign the consultee declaration form, you should ask questions about anything that you do not understand. The study staff will answer any questions before, during and after the study.

Thank you for taking the time to read this information.