PARTICIPANT INFORMATION SHEET

PROJECT TITLE: USE OF WEARABLE TRANSDERMAL ALCOHOL SENSORS FOR MONITORING ALCOHOL CONSUMPTION IN INDIVIDUALS RECEIVING TREATMENT FOR AUD WITH CONTINGENCY MANAGEMENT: A FEASIBILITY STUDY

I would like to invite you to participate in this research project which is part of my PhD. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is this research about? This study is using one of the latest transdermal alcohol sensor devices and aims to examine the use of this device with or without rewards for abstinence from drinking or low-risk drinking. You will be wearing the device for two weeks, meet with the research team regularly and complete a survey at the end of the two weeks on your experience. This device can only monitor alcohol concentration and skin temperature, there is no GPS tracking or location services. We will also be testing to see the correlation between self-reported alcohol consumption to that measured by this device.

Do I have to take part? No, you do not have to take part, it is your choice. The researcher can tell you more about the study and go through the information sheet with you, answering any questions you may have. If you agree, the researcher will ask you to sign a consent form to show you have agreed to take part. You are still free to withdraw at any time and you do not have to give a reason if you do wish to withdraw. The decision to not participate, or, to withdraw, will not affect your health care rights but you must return the device to the research team.

Why are we doing this research? We are doing this research because we want to understand the experience of someone wearing this device for two weeks, with or without rewards for abstinence from drinking or low-risk drinking. The findings of this study will help the research team gain a better understanding of these devices and their potential use within alcohol treatment.

What would taking part involve?
This study involves meeting with the researcher seven times over two weeks.

- The first meeting to talk through the study, how to wear the device and to arrange the subsequent meeting time/dates, this should take 30 minutes.
- Meetings 2, 3, 4, 5 and 6 (the meetings between the first and last) will involve device data download, this should take 5 minutes.
- The last meeting at the end of the study period to complete a survey on your experience with the device, this should take 20 minutes in total.
- You will be randomised by a computer into a group either with rewards or without, this means neither you nor me can decide which group you are allocated. This means, that if you remain abstinent or low-risk drinking throughout the study (measured by the device and our set low-risk drinking level) in the group with rewards, you can earn additional rewards.

All your usual care at your alcohol treatment service will remain the same, your key worker will be informed of your participation. The researcher can meet you at your usual alcohol service for all meetings, or a café closer to your home if more convenient for you.

An example of when our meetings would take place is in the table below, this example would be if the first meeting was on a Monday:

Week 1	Meeting	Week 2	Meeting	Week 3	Meeting
Monday	(1) Talk through the study, arrange following meetings	Monday	(4) Device data download	Monday	(7) Survey
Tuesday		Tuesday		Tuesday	
Wednesday	(2) Device data download	Wednesday	(5) Device data download	Wednesday	
Thursday		Thursday		Thursday	
Friday	(3) Device data download	Friday	(6) Device data download	Friday	
Saturday		Saturday		Saturday	
Sunday		Sunday		Sunday	

All participants will receive:

- £5 voucher at every meeting with the researcher (£35 total).
- £10 voucher for returning the device at the last meeting.
- £4 to cover travel expenses at every meeting.

Participants randomly allocated into the rewards group will be able to earn additional vouchers each day for low-risk drinking or abstinence as measured by the device.

What are the possible benefits of taking part? We cannot guarantee any specific treatment benefits. However, research does deliver wider benefits to society and future treatment options for those undergoing alcohol treatment. You may also benefit from the data gathered on your alcohol consumption over the weeks you are monitored.

What are the possible disadvantages of taking part? There are no immediate disadvantages of taking part, but if you discover that you are talking about personal matters that do cause you distress, you remain entitled to cease the discussion at any time and you are under no obligation to continue if you feel uncomfortable. Previous studies have reported that this device may be slightly uncomfortable to wear but it should adjust and become more comfortable over time. During the week the researcher will be contactable to go through any questions you have for the device.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Dr Paolo Deluca, paolo.deluca@kcl.ac.uk]. If you remain unhappy and wish to complain formally, you can do this through the SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk. In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my data be kept confidential? In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. Any information that is stored will have your identifiable details removed so that you cannot be recognised. These details will be replaced with a unique identifier code, which will be matched to your name in a separate and password protected file. Your data will be stored at KCL for 10 years. The only

individuals at KCL who will have access to your data will have are the PhD student, Eileen Brobbin, and her three supervisors (Paolo Deluca, Colin Drummond and Stephen Parkin).

All the information collected about you will be kept strictly confidential subject to legal limitations. If there are any significant concerns about your or someone else's safety, the research team may deem it necessary to share information with your care team or the relevant authorities'. This is standard practice for all research. The same would apply if you disclose details of abuse, neglect, or serious crime, we will have to report this to the appropriate authorities such as the police.

The data collected by the device is non-identifiable, is not shared with the device manufacturer, and is wiped on the device every 72 hours. At the end of the study, this data will be saved in case we need to check it. The data will be stored at KCL for 10 years.

We may take photographs of your wrist if you experience side effects from wearing the device and if you consent to this. These photographs may be included in the thesis or journal publications. No identifying features will be included in these photographs and your identity will be kept anonymous.

What will happen if I don't want to take part with the study? You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

What will happen to the results of the study? We intend to publish the results in medical and science journals and disseminate findings at conferences and online. In addition, this will also be part of my PhD thesis. We can also share the results of this study with you via your preferred method (email or post).

Who is paying for this research? NIHR ARC South London. This PhD is co-sponsored by South London and Maudsley NHS Foundation Trust and King's College London.

Who has reviewed this study? All research in the NHS is looked at by an independent group of people called Research Ethics Committees, to protect your safety, rights, wellbeing and dignity. The study has been reviewed and given a favourable opinion by the Cornwall and Plymouth Research Ethics Committee. If you have any questions or would like more information please contact Eileen Brobbin (Mobile: 07826510509, email: eileen.brobbin@kcl.ac.uk).PhD supervisor: Dr Paolo Deluca, paolo.deluca@kcl.ac.uk, Addiction Science Building, 4 Windsor Walk, Denmark Hill, London, SE5 8BB.
If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact KCL using the details below for further advice and information: PhD Supervisor: Dr Paolo Deluca, paolo.deluca@kcl.ac.uk.

Thank you for reading this information sheet and for considering taking part in this research.

For further information and advice about alcohol…
1. Talk to Frank: www.talktofrank.com
2. Speak to Drinkline: 03001231110
3. Lorraine Hewitt House (Brixton, Drug and Alcohol service): 02032281500

How your personal data will be used in compliance with General Data Protection Regulation (GDPR)
King's College London (KCL) is the lead sponsor for this study based in the United Kingdom and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. KCL will keep identifiable information about you for 10 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information by contacting the Chief Investigator: Dr Paolo Deluca (paolo.deluca@kcl.ac.uk) or the Data Protection officer (info-compliance@kcl.ac.uk) or visiting the KCL website: https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.