

ECG-X: CLINICAL STAKEHOLDER CONSULTATIONS

Participant Information Sheet (PIS)

You are being invited to take part in a research study about the interpretation of electrocardiograms and novel ways of visualising them. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ **Who will conduct the research?**

Name: Dr Lukas Hughes-Noehrer

Address: Department of Computer Science, University of Manchester, Oxford Rd,
Manchester M13 9PL

Email: lukas.noehrer@manchester.ac.uk

➤ **What is the purpose of the research?**

ECG interpretation is known to be complex, challenging both humans and machines. By taking part in our research, you will help us to inform the development of a suite of visualisation techniques for interrogating ECG data, combining principles of visual perception with clinical knowledge to create decision support tools where humans and machines share the same representation of the data.

You were asked to take part in this research project based on your profession and we solely ask you to answer and participate in the capacity of your professional role.

➤ **Am I suitable to take part?**

Should you belong to one of the clinical groups (all training levels) outlined below, you can be included in our research:

- Emergency doctors and emergency medical services (EMS) staff
- Cardiologists and electrophysiologists
- General practitioners (GP)
- Intensive and critical care doctors; anaesthetists

➤ **Will the outcomes of the research be published?**

The primary outcome of this research will be qualitative data. This data will be used to inform ECG-X's application development and will be used by the named researchers above and other researchers based at the University of Manchester and Manchester University NHS Foundation Trust. Pseudonymised data will be made available to the public to support future research.

The pseudonymised data will be included in research and teaching publications.

➤ **Disclosure and Barring Service (DBS) Check**

This research does not fall in a category requiring DBS checks.

➤ **Who has reviewed the research project?**

This project is exempt from ethical approval as it does not collect person identifying information apart from participants' names, their professional role titles and recordings of the focus groups or interviews. It further does not collect information that is considered sensitive or confidential and does not involve vulnerable or dependant groups. There is no real risk of participants disclosing illegal/unprofessional conduct and participants are solely taking part in their professional capacity (The University of Manchester Ethics Approval Tool, accessed 07/11/2023; HRA Ethics Approval Tool, accessed 07/11/2023)

➤ **Who is funding the research project?**

This project is funded by the Engineering and Physical Sciences Research Council (EPSRC) under grant EP/X02945X/1

What would my involvement be?

➤ **What would I be asked to do if I took part?**

You will be asked to take part in a focus group or interview. The research interventions follow a semi-guided format to elicit opinions about and insights of professionals using ECGs. We assume that the focus groups will take no longer than 90 minutes; interviews will be shorter and last approximately 30 minutes.

➤ **Will I be compensated for taking part?**

This study is compensated and you will receive a £50.00 (fifty GBP) Amazon voucher.

➤ **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. Should you decide not to take part, please indicate this by either informing the research team via email or should you decide – for any reason – that you do not want to take part during the research, please inform the research team about your decision. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form on the day of the research study. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been pseudonymised. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

The focus groups/interviews will be audio-recorded. This is essential to collect the data we will later use for our research. You should be comfortable with the recording process at all times, and you are free to stop the recording at any time. You have the right to withdraw from the study at any time, however, we can't remove your data once it has been anonymised.

Data Protection and Confidentiality

➤ **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

- Your full name and signature – *We will ask you to provide these as part of the process of completing the consent form which will be stored separately to all other data*
- Recordings of your voice during the focus group discussion or interview – *We use approved devices and recordings will be deleted as soon as they have been transcribed*

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- We will pseudonymise any transcribed data and the key to participants’ details and participants’ IDs will be accessed by research staff only
- Voice recordings will be destroyed after transcription
- Data will be transcribed by members of the research team who have all received the necessary data protection training
- Published data will be anonymised and the keys to IDs will be broken
- Data will be stored on a Research Data Server (also known as Isilon) and anonymised data will be deposited on the university’s preferred repository Figshare
- Data will be stored over the course of the research project and therefore deleted after 3 years. Data held to facilitate issue of vouchers will be held by Finance for 7 years for audit reasons, but will not be used or shared for any other purposes

If you can’t take part in-person, we might use **Teams**.

Your participation in this research will then be recorded in Teams and your personal data will be processed by Microsoft. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with [The University of Manchester's Research Privacy Notice](#).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

So that we can provide the Amazon voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose.

At the end of the project we will deposit a fully anonymised dataset [e.g. including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

There are several ways you can raise a complaint. You can either contact a member of the research team or you can make a formal complaint to the University of Manchester. Details for both routes are listed below.

➤ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

DR LUKAS HUGHES-NOEHRER

Email: lukas.noehrer@manchester.ac.uk

Tel.: 0161 306 2116

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

If using a hard copy version of the PIS with participants, you must ensure the full URL of the ICO's complaints procedure is listed here or a hard copy is printed and appended with the information sheet.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

Name: Dr Lukas Hughes-Noehrer

Address: Department of Computer Science, University of Manchester, Oxford Rd, Manchester M13 9PL

Email: lukas.noehrer@manchester.ac.uk