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IRAS 374406

Participant Information Sheet: Staff Participants (CUS operators and clinicians)

Evaluating the integration of a guided 3D ultrasound imaging system (CUS) operated by non-specialist staff in a community urology setting

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

In this study we would like to find out whether CUS, a handheld guided 3D ultrasound system, can be embedded into the routine workflow of a community urology clinic when operated by non-specialist staff. Alongside the patient-facing part of the study, we want to understand the experience of the staff who deliver the scans and the clinicians who receive the reports: how usable the system is, how well the training prepares operators, how the scanning fits around normal clinic activity, and what would need to change for routine use.

Why have I been invited?

We are asking you to think about joining this study because you are either a member of staff at the participating clinic who has been trained to deliver CUS scans, or a clinician at the clinic who will receive CUS reports as part of the study. We anticipate recruiting no more than 20 staff participants in total, across clinics.

Please note that delivering CUS scans is arranged between CarrierTech and your employer, and is separate from this invitation. What we are inviting you to do here, as a research participant, is to share data and views about your experience, through the usability questionnaires and an interview.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be

sent this information sheet and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Taking part, declining, or withdrawing will have no effect on your employment, your professional standing, or your relationship with your employer or with CarrierTech. You will be given 72 hours in which to think about it, although if you wish to take part sooner after reading this sheet, you may do so.

What will happen to me if I take part?

If you are thinking of taking part in the research, you will have the opportunity to discuss it with a member of the team and ask any questions that you might have. If you decide to take part, you will be asked to sign a consent form. You will be given a copy of the information and signed Informed Consent form to keep. Please note that, even if you sign the consent form and agree to participate, you can withdraw your consent at any time by contacting a member of the research team. If you withdraw your consent, no further data will be collected from you and any data relating to you will be deleted, except where analysis using your data has already taken place and cannot be undone.

If you take part, you will receive a study ID number. The study will be divided into a few parts.

1. If you are a CUS operator, you will be asked to give feedback on your confidence using CUS at a few points during the scanning period, then complete a short usability questionnaire (approximately 5 minutes) at the end of the scanning period. Routine operational data linked to your scanning (such as scan setup time, scan duration and image capture success) will also be recorded against your study number. These data will be used to describe how the system performs in the clinic overall; they will not be shared with your employer in a way that identifies you, and they will not be used to assess your individual performance.

2. Towards the end of the scanning period, we will ask to talk to (interview) you for around 20 minutes, at a time and place convenient to you. This will be conducted and recorded using only your study number. An audio recording of this will be made with your consent, although recordings will be deleted once we have transcribed the interviews. You will be asked not to divulge any personal identifiable information, and if you should do so, this will be removed from transcripts of the interviews. Questions you will be asked will relate to your experiences of the training and of delivering CUS scans (or, for clinicians, of receiving and using CUS reports), how it fitted around your normal work, and the pitfalls and potential improvements. Although quotes may be used in the final published work, it will not be possible to identify any individuals from the included quotes.

There is no follow-up after the interview.

What will I have to do if I take part?

You will not have to do anything in particular for this study, apart from what is described above.

What are the possible disadvantages and risks of taking part?

There should be no disadvantages to taking part, apart from the time spent kindly helping us. We recognise that you will be sharing views about a system developed by the study sponsor, and about your own workplace; for this reason your questionnaire answers, operational data and interview transcripts are held under your study number only, and nothing you say will be reported to your employer in a form that identifies you. If you have any concerns about any

aspect of this study, then please do not hesitate to contact a member of the study team as below. We will not ask you to do anything you are not comfortable doing.

What are the possible benefits of taking part?

There will be no specific benefits to you from taking part, but your feedback will directly shape the training, workflow and design of community scanning pathways, and will help determine whether systems like this should be offered more widely.

What if there is a problem?

If you have a concern about any part of this study, please speak to the research team, who will do their best to answer your questions. You can email the Chief Investigator, Jade Dougoud, at jade@carriertech.uk, or ask a member of the clinic team to contact the research team for you. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the clinic from which you participated in the study.

What if something goes wrong?

Carrier Technologies Ltd (CarrierTech), the sponsor of this study, has insurance in place to cover its legal liability if you are harmed as a result of taking part in this study. This includes a clinical trial liability insurance policy with Markel International Insurance Company Limited (policy number L016647), as well as professional indemnity and public liability insurance.

If you are recruited at an NHS site, the NHS indemnity arrangements will also apply to the care you receive from NHS staff.

If you are harmed during the research and this is due to someone's negligence, you may have grounds for a legal action for compensation against CarrierTech or the organisation where you took part, but you may have to pay your legal costs. The normal National Health Service complaints procedures will still be available to you.

What will happen if I don't want to carry on with the study?

Taking part is voluntary. You can withdraw from the study at any time, without giving a reason. Withdrawing will not affect your care in any way, now or in the future.

You can stop an interview at any time, or skip any question you do not want to answer.

After your interview: to withdraw, please contact the study team at the clinic where you took

part.

You can also ask any member of the clinic team to pass on your request. Because only the clinic holds the list linking your name to your study number, the clinic will deal with your request. They will tell the study sponsor, CarrierTech, using your study number only, and will confirm in writing that you have been withdrawn.

If you withdraw, we will not collect any more information from you. The data we have already collected will be deleted, unless it has already been used in the analysis and this cannot be undone. You can withdraw your data up until the end of the study, when the list linking your name to your study number is destroyed. After that, your data will be fully anonymous. We will no longer be able to find which data are yours, so they cannot be removed.

If you cannot reach the clinic, you can email the Chief Investigator, Jade Dougoud, at jade@carriertech.uk, and she will put you in touch with the right site.

What will happen to the results of the research study?

At the end of the study, all participants will be sent a summary of the data we find (of everyone together, not data that can identify individuals). We aim to publish the results in a scientific journal that anyone can read for free, and to present them at conferences and to the NHS organisations that plan local services.

Who is organising and funding the research?

This work is organised by CarrierTech Ltd, the company that developed the CUS system, and is funded by the National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) FAST programme. Because CarrierTech developed CUS, the results of this study matter commercially to the company. To keep the study fair, scans are reviewed by an independent sonographer who does not work for CarrierTech, the analysis is independently reviewed, and the results will be published whatever they show.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London – Brighton & Sussex Research Ethics Committee (REC reference: 26/PR/1161).

Contact for Further Information

Please contact Jade Dougoud: jade@carriertech.uk.

Thank you for taking part in this study!

A copy of this written information and signed Informed Consent form will be sent for you to keep.

Transparency Notice

How will we use Information about you?

How will we use information about you?
We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details
- Consent record

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Carrier Technologies Ltd is the sponsor of this study.

Carrier Technologies Ltd is responsible for looking after your information. We will share your information related to this research project with the following type of organisations:

- Healthcare center you attended for the study

We will keep all information about you safe and secure by:

- Only saving this information at the healthcare center you attended for the study
- Access to this information will be limited to the personnel necessary to amend your details or study status
- This information will be saved in a password protected computed location or a padlock protected drawer if physical forms are used

International transfers
We may share or provide access to data about you outside the UK for research related purposes to:

- allow an independent statistician to check and analyse the study results
- support future research, or the development of new tests, medical devices or treatments, by academic institutions or companies (only if you agree to this on the consent form)

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- an independent statistician working in the European Economic Area
- academic institutions and commercial companies carrying out future research or developing new tests, medical devices or treatments (only if you agree to this on the

consent form)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach
- For this study, your data stays on our secure computer systems in the UK. The statistician can only view it through a secure connection

How will we use information about you after the study ends?
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by **t**he study to be completed and the results checked, which will be no more than 6 months after the study ends. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- 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
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to jade@carriertech.uk
- By contacting our Data Protection Office Jason Carrier at jason@carriertech.uk