Participant Information Sheet

IBEX Trueview® Study - Phase 2
Protocol Reference: IBX/SP1701

We invite you to take part in a research study

- Before you decide whether to take part, 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. Discuss it with friends and relatives if you wish
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors
- Ask us if there is anything that is not clear or if you would like more information
- If you wish to participate, you must personally sign the Informed Consent Form. You will receive a copy of your signed form along with this information sheet for your records

Important things you need to know

- We want to show that our technology can provide images of acceptable diagnostic quality without the need for an anti-scatter grid in standard digital radiography exams
- This study may require you to have an additional set of X-ray exposures if your first set required the use of an anti-scatter grid
- If your original set of exposures don't require the use of an anti-scatter grid, we make use of those without the need for additional exposures
- In case additional exposures are required, you will be exposed to a level of ionising radiation that is above the level you will normally receive
- Your participation in the study will begin when you consent to participate and will end once all X-ray exposures have been collected
- You may decide to leave the study at any point until the additional exposures have been taken

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1 Why are we conducting this study?

Digital radiography is widely used as a way of obtaining images of the internal structures of the body using X-rays. A major drawback of using X-rays is that they can be scattered by thicker body parts. This scatter significantly reduces image quality and is currently dealt with by using a physical anti-scatter grid (ASG) which prevents scattered X-rays from reaching the X-ray detector/camera.

Anti-scatter grids also absorb a portion of the direct X-rays required to form a useful image and so the patient dose needs to be increased to compensate. Removing the need for an ASG would potentially allow lower dose examinations to take place.

Additionally, current digital radiography systems offer no way of extracting numerical information about the composition of the image, meaning that a lot of potentially useful diagnostic information is lost.

Proposed clinical investigation

IBEX Innovations Limited (IBEX), a local high-technology business based in Sedgefield, has developed a novel solution that offers the potential to remove the effects of scattered X-rays without the need for an ASG. The technology also enables the extraction of bone health information which will be demonstrated in Phase 2 of the study.

IBEX and South Tees Hospitals NHS Trust are planning to demonstrate the value to patients of this new technology by undertaking a study at the James Cook University Hospital.

There are two main aims of the proposed study:

Phase 1
To demonstrate that Trueview® generates a measure of bone health to the same accuracy as a dedicated DEXA system

Phase 2
To demonstrate that the Trueview® technology generates X-ray images to at least the same quality as an existing X-ray system

We are aiming to recruit about 130 patients for phase 1 and about 60 for phase 2 from the orthopaedic outpatients' clinics and rheumatology department respectively.

2 What does taking part in the study involve?

Taking part in Phase 2 of this study would involve you being asked to consent to the processing of your radiographs (X-ray photos) using the Trueview® technology. In cases where your standard set of radiographs require an ASG to be used, you will be asked to have a second identical set of radiographs taken without the ASG in place.

The additional assessment would take place immediately after your first set of radiographs and will add a small amount of time onto your visit (~5 mins).

The additional scan will only be used to assess the performance of the technology and your scheduled assessment will still be made using the standard set of exposures as per standard clinical practice.

Your participation in the study begins once you give your consent to participate when you attend for your scheduled radiography assessment. Your participation will end once all digital radiographs required have been taken. We will not contact you for any further information in relation to this study.

In addition to these X-ray procedures, information about your gender, age height, weight and race will also be recorded to help with the analysis of the results.

If there are any new findings or amendments to the study plan that will affect your participation in the study, you will be informed and issued with an updated version of this information sheet.

A study representative may be in attendance during the subsequent processing of your anonymised X-ray images but at no point will they be in attendance at any of your procedures.

3 Why have I been invited and am I eligible?

We are inviting all orthopaedic outpatients who have a scheduled appointment for a radiography assessment of their wrist, shoulder or pelvis at James Cook University Hospital.

You <u>are eligible</u> to take part in the study if:

- you are over 18 years of age attending orthopaedic outpatient's clinic and requiring plain radiographs of your wrist or shoulder or pelvis;
- you are able to comprehend and sign the Informed Consent prior to enrolment in the study

You <u>are not eligible</u> to take part in the study if:

- you are pregnant or lactating
- you are participating in another experimental intervention or drug study
- you are unwilling or unable to provide informed consent
- you are wearing a cast on assessment site that will not be removed prior to your assessment
- you have an implant or other radio-opaque foreign body in the location of the assessment

Under certain circumstances, the investigator may terminate your participation in the study if something occurs between you signing the consent form and having the procedure that would cause you to be ineligible.

4 Are there any benefits for me in taking part?

This study is designed to demonstrate the safety and efficacy of the Trueview® technology. Since the technology hasn't been used in a clinical setting before, the study is designed so that any diagnosis, assessment and follow on care you receive will be based on the standard procedures you are already scheduled to have. No clinical decisions will be made using the outputs of the Trueview® software.

As such, by taking part in the study there will be no clinical benefit to you but you will be contributing to the development and adoption of a technology that has the future potential to:

- Improve diagnostic X-ray image quality
- Streamline radiographic assessments and improve efficiency
- Provide additional diagnostic information to enable early detection of bone health conditions

5 Are there any risks for me in taking part?

The Trueview® technology works by processing X-ray images taken using standard equipment so it poses no inherent risk to you. A thorough risk analysis of the technology has been conducted and the residual risks are associated with subsequent processing of the data. Therefore, the only risk to you as a patient is that which is associated with the additional radiation exposure imposed by additional radiographs. As with all medical procedures, there is also a possibility for unanticipated risks to occur, although every effort has been taken to ensure that patient safety is of the highest importance.

If you take part in this study, you may be required to have more set of radiographs than you would have had if you did not take part. This procedure uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The total dose that you would receive as part of this study (including the standard X-rays you would normally receive) is 0.2 – 0.6 mSv. This is equivalent to a few months of average natural background radiation. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance (0.004%) of this happening to you.

Under certain circumstances, the investigator may decide that your participation in the study be terminated. This might occur when they deem the risks associated with your participation to outweigh the benefits. The most likely situations where this would occur is if you have had a large number of X-rays previously, or if the standard set of X-rays requires multiples re-exposures due to poor image quality.

6 What if something goes wrong?

The risk of participants suffering harm as a result of taking part is minimal. If you are injured or feel ill at any point during your participation in the study, please let a Research Nurse know immediately. They will introduce themselves to you when you attend for your appointment

IBEX has insurance in place to provide compensation for any negligent harm caused by participation. This insurance is provided by Nucleus Underwriting under policy number: CCZCPL17AA/AB/AI/AF-NUW01-10733.

In the unlikely event that you wish to make a claim, please contact IBEX either in writing at IBEX Innovations, Explorer 2, NETPark, William Armstrong Way, Sedgefield, TS21 3FF, or by phone on 01740 617770.

Given the very small increase in the risk of developing cancer as a result of participation in this study, there will be no provision of additional healthcare over and above the standard treatment pathways offered by the NHS for any participant of the study who goes on to be diagnosed with cancer.

If you have any concerns or complaints about anything to do with this study, then you can contact the Patient Advice and Liaison Services by email at: **stees.pals@nhs.net**

Alternatively, you can send a letter to: Patient Relations Department, The James Cook University Hospital, Marton Road, Middlesbrough, TS4 3BW

We will endeavour to reply to you promptly to address your comments or concerns.

7 What if I want to withdraw from the study?

If you consent to participate in the study, your involvement will be very fast as you will only be “in” the study until your additional X-ray scan has been conducted. If you want to withdraw from the study you may do so at any time up to the point that the additional scan is taken by letting a member of staff at the hospital know that you no longer wish to participate.

8 How will my information be kept confidential?

Data Controller

IBEX Innovations Ltd (IBEX) is the sponsor and Data Controller for this study based in the United Kingdom. We will be using information from you in order to undertake this study 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. IBEX will keep identifiable information about you for 15 years after the study has finished. You can contact IBEX by post at IBEX Innovations, Explorer 2, NETPark, William Armstrong Way, Sedgefield, TS21 3FF; or by phone on 01740 617770

Your data and your rights

The EU General Data Protection Regulation (GDPR) defines the rights of individuals with regards to their personal information and regulates the way in which organisations store and use that information. According to GDPR the right to be forgotten does not hold within participation in a study. 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, as per GDPR regulations relating to clinical studies. 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 our Data Protection Officer, Lisa March at **l.march@ibexinnovations.co.uk**

South Tees Hospitals NHS Foundation Trust will collect information from you or your medical records for this research study in accordance with our instructions. This will include your age, gender and race.

South Tees Hospitals NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to IBEX. South Tees Hospitals NHS Foundation Trust will use this information

as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the sponsor or contract research organisation and regulatory organisations may look at your medical and research records to check the accuracy of the research study. IBEX will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

South Tees Hospitals NHS Foundation Trust will keep identifiable information about you from this study 15 years after the study has finished.

If you would like to know more about your rights under the GDPR rights, please visit the Information Commissioner's Office website at **www.ico.org.uk/your-data-matters**

What will my data be used for?

The data collected about you will be used to support statistical analyses of this study.

Anonymised, aggregated data broken down by demographics such as age, race or gender may be used in the subsequent planning of future studies or in the commercialisation of the Trueview technology.

Your data may also be used to support the design or conduct of future research.

9 What will happen to the results of this study?

We will aim to publish the results of this study in relevant scientific journals and will present them at associated conferences. All patient related information will be anonymised and individual participants will not be identifiable in any report or publication.

The study is designed so that no health assessments or diagnoses will be made using the Trueview® technology and as such no health-related findings will be provided to participants.

10 Who is organising and funding the study?

This study is being organised and funded by IBEX Innovations Ltd. with support from the European Union's Horizon 2020 research and innovation programme under grant agreement number 777835.

The study has been designed in collaboration with clinicians from South Tees Hospitals NHS Foundation Trust to ensure the patient safety is at the forefront. It has been reviewed by an independent research ethics committee and has received approval to be conducted according to the study protocol.

IBEX may choose to suspend or terminate the study if:

- The device (Trueview) is found to be related to an adverse event (such as patient injury)
- A serious breach of good clinical practice, such as major deviation from the study plan
- A device is defective and cannot be immediately replaced
- An investigator withdraws from the study and cannot be immediately replaced
- An investigator is disqualified from further participation in the study

11 How can I find out more?

If you would like further information about the study, please contact any of the following:

- Research Nurse, Marc Atkinson / Bridget McVeigh, by email at **marc.atkinson1@nhs.net / b.mcveigh@nhs.net** or by telephone on **01642 855485**
- Principal Investigator, Professor Amar Rangan, by telephone on **01642 854144**
- The Research and Development Department by email at **stees.researchdevelopment@nhs.net** or by telephone on **01642 854089**