

Participant Information Sheet

Project title: Waist Circumference as an Estimator of Abdominal Wall Depth

Invitation paragraph

We would like to invite you to take part in our research project which seeks to assess whether the waist circumference can estimate the abdominal wall depth in order to guide initial entry into the abdominal cavity during laparoscopic (key-hole) or robotic surgery. The traditional Body Mass Index (BMI) will also be taken to see if it makes a better correlation than abdominal girth. The abdominal wall depth will be measured from your CT or MRI scan and your waist, weight and height measurements will be physically taken today. Before you decide whether to participate, we would like you to understand why the research is being conducted and what it would involve for you. Talk to others about the study if you wish. Please ask me questions if anything is unclear.

What is the purpose of the project?

This is important because during laparoscopic or robotic surgery, initial entry involves inserting the camera through a small hole in the belly button. There are no current methods of ascertaining how deep this hole should go so as to guide insertion of the access device that will guide the camera. We are therefore looking to see if we can prespecify the depth to which the initial access device should be bored to get to the abdominal cavity. We do not need to know your personal details such as name, date of birth or address. Only your hospital number to find your scan will be needed alongside your gender and age. The research is being used as part of a dissertation for a PhD study and will help make laparoscopic surgery safer.

Why have I been invited to participate?

You have been chosen because you are undergoing an MRI or CT scan of the abdomen +/- pelvis. About 385 will participate in the project.

Do I have to take part?

Taking part in the research is entirely voluntary.

For example:

It is up to you to decide whether you wish to participate in the project. We will describe the study and go through this information sheet with you before you participate and answer any questions you might have. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

The data is to be anonymised but you can decide by the end of today to withdraw from the study.

What will happen to me if I take part and what will I have to do?

We do not require you to do anything but to allow us to take your waist circumference, weight and height. This should take 2-3 minutes in total.

What are the possible disadvantages and risks involved in taking part in the project?

We foresee no risks in taking your physical measurements and only minor inconvenience while this is being done. We will be happy to give you your measurements should you wish.

What are the possible benefits of taking part?

The benefits for you as a participant if you are later to undergo surgery or for the wider surgical community will advance knowledge and understanding of how deep the abdominal wall is and how we can make our instruments and abdominal procedures safer.

Will my participation in this project be kept confidential?

We care about your data and so we will not take any personal details save your hospital number, age, gender and ethnicity. We will take all necessary measures to ensure your participation and the data that we gather through your participation confidential, during and after the study. Your hospital number will be pseudonymised to a code that won't identify you from your age, gender & ethnicity.

Once we have measured your abdominal wall depth, we will no longer need your hospital number and will instead use the pseudonymised code.

This data will be stored in a password restricted university laptop and the measures in place to store your data in a secure fashion will follow general data protection regulations.

It will not be possible to identify individual participants from the data linked to the pseudonymised code and only the research personnel will have access to this data.

Your personal identifiable data will not be required. The physical measurement data will be retained for 10 years and destroy it thereafter. It will be retained securely should it be required for future use.

To summarise:

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you will have your name and address removed so that you cannot be recognised. Data will be stored securely on my University of Bristol file store. Data will be destroyed after the stated period of retention.

What will happen to the results of the research project?

The results of the research will be submitted for publication and also will form part of my thesis

Who is organising and funding the research?

The University of Bristol Centre of Doctoral Training is organising the study funded by ESPRC.

Who has reviewed the study?

The project supervisor is Dr. Hermes Gadelha-Bloomfield

Further information and contact details

For participants who may want further information in relation to the study or may have questions about what is being asked to do, please contact Dr. Miti on zb20006@bristol.ac.uk.

For participants who may have any concerns related to participation in this study, please direct your query to the Research Governance Team: research-governance@bristol.ac.uk