

## **INFORMATION SHEET FOR PARTICIPANTS**

*Ethical Clearance Reference Number*



### **YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

#### **Title of project**

Stoma Patient Survey: Exploring Stoma Care and Management

#### **Invitation Paragraph**

We would like to invite you to participate in this research project which forms part of my PhD research. 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 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 the purpose of the project?**

The purpose of the project is to understand the stoma care, stoma management and the physical and psychological challenges faced by stoma patients when wearing a stoma bag on daily basis. The purpose of this questionnaire will serve a purpose to help in the design process of sealable valve device aimed to eliminate the use of stoma bags.

#### **Why have I been invited to take part?**

You are being invited to participate in this project because you are an ostomate and wearing a stoma bag.

#### **What will happen if I take part?**

If you choose to take part in the project, you will be asked to fill a questionnaire anonymously. The survey will ask questions regarding stoma management care and if any challenges are faced as a result of wearing a stoma bag. Furthermore, the survey will ask questions including personal information and medical history regarding stoma surgery.

#### **Do I have to take part?**

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. If you have chosen to take part, you will be asked to give your consent. To do this, you will be asked to indicate that you have read and understood the information provided and that you consent to your anonymous data being used for the purpose explained. If at any point during filling the survey and you decided to withdraw from the survey, you can do that by simply exiting the website. Once you have clicked submit, you will no longer be able to withdraw, and your data will be saved anonymously. Please do not include any personal information that might identify you in your responses

#### **What are the possible risks of taking part?**

It is imperative to note that this study poses no risk to its participants, as all the data gathered will be pseudonymised utilizing a unique study ID code, and the confidentiality of all participants involved will be protected. Furthermore, it is worth mentioning that some of the questions regarding stoma management and stoma care may be considered sensitive in nature. As a precaution, we have provided participants with a selection of pertinent resources and useful links to offer guidance and advice in the subject matter.

Some examples include:

<https://medlineplus.gov/ency/patientinstructions/000071.htm>  
<https://www.nhs.uk/conditions/colostomy/>

### **What are the possible benefits of taking part?**

In this study, there are no direct benefits to participants that are anticipated as a result of participation in this study. It has the potential to provide valuable insights into the comprehension of stoma care and management, as well as the predominant challenges encountered by stoma patients. In addition, this study aims to identify the primary stoma-related hurdles and based on these findings, propose an innovative device that could potentially ameliorate stoma care and eliminate the dependence on stoma bags. Hence, this research possesses considerable implications for the healthcare industry and holds the potential to augment the overall quality of life for stoma patients

### **Data handling and confidentiality**

This research will maintain complete anonymity throughout the study. This implies that neither the researchers nor any other party will have access to your identity, nor will they be able to link your responses to you, directly or indirectly. Nonetheless, your answers will be treated with utmost confidentiality, and the information you provide will not permit your identification in any research outputs or publications. Furthermore, your data will be stored securely in King's College's hard drive until February 2025. Any personal data obtained independently of the anonymous survey, as described elsewhere in this information sheet, will be processed in compliance with the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. For additional information regarding how your data will be processed under the terms of UK data protection laws, please refer to the link below:

<https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

### **How is the project being funded?**

King's College London University is providing the funding for this study, and as the sponsor, we are acting as the data controller for this project. This indicates that we are accountable for the security of your data and its usage exclusively for research purposes.

### **What will happen to the results of the project?**

The results of the project will be summarised and published in a journal paper and also will be included in a PhD thesis report. Both the journal paper and thesis will protect your confidentiality by ensuring that your identity remains undisclosed. Additionally, any data that is presented in an anonymous manner will not be shared with third parties to maintain the anonymity of the participants.

### **Who should I contact for further information?**

If you have any questions or require more information about this project, please contact me using the following contact details:

Ms Maleeha Al-Hamadani  
[Maleeha.al-hamadani@kcl.ac.uk](mailto:Maleeha.al-hamadani@kcl.ac.uk)

### **What if I have further questions, or if something goes wrong?**

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 King's College London using the details below for further advice and information:

Supervisor 1: Dr. Carlo Seneci  
[Carlo.seneci@kcl.ac.uk](mailto:Carlo.seneci@kcl.ac.uk)

Supervisor 2: Professor Prashant Jha  
[Prashant.jha@kcl.ac.uk](mailto:Prashant.jha@kcl.ac.uk)

Clinical supervisor 1: Mr Abrie Botha  
[Abrie.botha@kcl.ac.uk](mailto:Abrie.botha@kcl.ac.uk)

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