SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION

Protocol Title:
Natural Orifice Specimen Extraction in Colorectal Surgery

Principal Investigator:
Dr Isaac Seow-En
Consultant
Department of Colorectal Surgery
Singapore General Hospital
CDLD number: 6321 3857
PI contact number: 96423931

PURPOSE OF THE RESEARCH STUDY

Natural Orifice Specimen Extraction (NOSE) involves the removal of the surgical specimen from a natural body orifice. NOSE via the anus or vagina is an established technique in colorectal surgery regionally and internationally, but has rarely been performed or reported for laparoscopic colorectal surgery in Singapore. The purpose of this study is to demonstrate the efficacy and usefulness of NOSE in the local setting. Currently, the conventional method for laparoscopic colorectal specimen extraction is through a bigger cut on the abdominal wall. Research on the NOSE method is required to demonstrate the utility of this procedure on improving the recovery process for patients such that greater numbers of patients can benefit from this technique with NOSE potentially established as a new standard of specimen extraction for selected patients.

You were selected as a possible participant in this study because you have already undergone NOSE surgery. This study targets to recruit approximately 20 participants per year from Singapore General Hospital over three years.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to take part in this study, you will be asked to consent for your biographic information, operative data, and post-operative data to be analysed with a view for

presentation at scientific meetings or publication in medical journals. In addition, photography or videography which you have already consented for a routine component of surgical consent may be analysed and published in scientific journals. All attempts will be made to anonymise these data (e.g. no individual names or facial images), although a slight chance of breach of confidentiality is present. Your follow-up care will be identical to a patient with your condition who did not undergo NOSE as well.

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

Although NOSE is already an established technique in colorectal surgery, collecting your data for research analysis is not part of routine medical care. However, your participation will help us confirm the advantages of this technique in the local setting.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

There is a small risk of breach of confidentiality from reporting of your anonymised data. All attempts will be made to minimise this risk of this possibility.

Personal privacy and confidentiality:
This study uses health information that may affect your privacy. To protect your confidentiality, only a unique code number will be used to identify data we collected from you.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

POTENTIAL BENEFITS

If you participate in this study, we may be able to prove that the NOSE technique can benefit patients in terms of the following: less pain, less wound complications, quicker recovery, reduced hospital length of stay, and better cosmetic appearance
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ALTERNATIVE PROCEDURES/ TREATMENTS IF YOU DO NOT PARTICIPATE IN THE STUDY

If you choose not to take part in this study, your data will not be collected for research purposes. Your follow-up care will remain the same.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

There is no cost to you for participating in this research study.

The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. “Incidental findings” are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, your future data will not be analysed, but any of your data that has been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time if the study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of

personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential. Your study records and medical records, to the extent required by the applicable laws and regulations, will not be made publicly available. Only the study team will have access to the personal data being collected from you. In the event of any publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singapore General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above.

All data collected in this study are the property of Singapore General Hospital. The data will be used for the purpose of this research study only, unless you give permission for your data to be made available for future use in other research studies. For this purpose, consent for future research will be sought from you.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact:

Principal Investigator

Dr Isaac Seow-En
Consultant
Department of Colorectal Surgery, Singapore General Hospital
CDLD number: 6321 3857
PI contact number: 96423931

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board

CONSENT FORM FOR RESEARCH STUDY

Protocol Title:
Natural Orifice Specimen Extraction in Colorectal Surgery

Principal Investigator:
Dr Isaac Seow-En, Department of Colorectal Surgery, Singapore General Hospital

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

[redacted]

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: [redacted]

Name of witness Date of signing

[redacted]

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

[redacted]

Name of Investigator/ Person obtaining consent | Signature | Date

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

This is an optional component that is separate from the research study. You may still participate in the research study if you say "No" to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep your data for future research. The data will be kept in Singapore General Hospital. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store your data. Researchers will use your data for research long into the future.

This is what will be done with your stored data:

- We may use the data to answer additional research questions in other research studies. This is outside the scope of the research study but still related to colorectal Surgery
- We may share the data with other researchers and with researchers outside of Singapore.
- *The stored data will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your identifiable information.*
- *When we share your data with other researchers, it will be in a coded manner. They will not be able to identify you from the coded data.*
- *If you decide at a later time that you do not want your data to be used for future research, you can contact the Principal Investigator or study team at any time. All your stored data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information is already included in analyses or used in publications. .*

CONSENT FORM FOR FUTURE RESEARCH

This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

☐ I do not agree to have my data stored for future use in other research studies.

☐ I agree to have my data stored for future use in other research studies.

[redacted]

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant)'s data obtained from the research study to be stored for future use in other research studies in the interest of medical progress as described in and on terms set out in the Information & Consent Form for Future Research.

I understand that his/her participation is voluntary and I can withdraw his/her participation at any time, without giving reasons.

The nature of this optional component has been explained clearly to me and I fully understand them.

I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

[redacted]

Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data for future use in other research studies)has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: [redacted]
Name of witness Date of signing

[redacted]
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written

information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data for future use in other research studies) fully explained to him/her and clearly understands the purpose and the nature of the participant's participation in the study.

Name of Investigator/ Person obtaining consent	Signature	Date

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