INFORMED CONSENT FORM

1. Standing database Information:
TTSH Colorectal Standing Database

Custodian & Contact Details:
Dr Tan Ming Ngan Aloysius, Consultant (6357 7807); General Surgery, Tan Tock Seng Hospital
TTSH 24h main line (6357 1000) <aloysius_mn_tan@ttsh.com.sg>

2. Purpose of the standing database
You are invited to be part of our standing database because you have been diagnosed with a colorectal disease that requires treatment in Tan Tock Seng Hospital. This standing database allows us to perform clinical audits and future research to improve treatment and care of patients with colorectal diseases. It is important to us that you take time to read through and understand the information provided in this sheet. The standing database will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this standing database, and if you wish to take part in the standing database, you must sign this informed consent form. You will be given a copy of this consent form to take home with you if you wish.

3. What procedures will be followed in this standing database
No additional procedures will be involved or required. This standing database is to seek your consent to store and use the health information acquired during the course of your treatment for clinical audits and future research. This information is obtained as part of routine treatment.

If you agree to be part of this standing database, information about your medical condition will be collected. This will include clinical data obtained from your medical records, as well as downloaded images of your scans. The data collected will include basic demographic information, disease characteristics, operative findings and post-operative follow-up data. Your data will be used for clinical audits on outcomes of patients who underwent treatment for colorectal diseases in our department. These data may be used for future research studies that can provide better understanding of your disease and improve treatment outcomes. We will ensure that the data has been reviewed and approved by the Domain Specific Review Board (DSRB) before releasing your data and images in a de-identified manner. The DSRB is an ethics committee that reviews research studies and ensures that research participants' safety, welfare and interest are safeguarded.

All data and images obtained from this standing database may be used in collaboration with other research or public hospital institutes (both local and overseas). Only anonymized (de-identified) data and images will be transferred to all collaborators whether within or outside of Singapore. All collaborations and data transfer will be carried out with full knowledge of the custodian, with appropriate ethics (DSRB) approval and in accordance with the terms and conditions laid out in the Research Collaborative Agreement.

4. Your Responsibilities in This Standing Database
If you agree to be part of this standing database, you should allow data and images to be collected from your clinical records.

5. What Is Not Standard Care or is Experimental in This Standing Database
The collection of data for this standing database is not part of standard care. However, there is no experimental procedure if you agree to participate in this standing database. The care that you will be receiving is in accordance to the standard of practice in our institution.

6. Possible Risks and Side Effects
There is a potential risk of breach of confidentiality. However, we will take all measures to ensure that your data is kept securely. Your data will be stored in a secured electronic database that is encrypted and password protected. All information will be treated confidentially and your data will be de-identified when used for any audit, analysis or research. The data collected and kept shall comply at

all times with the Personal Data Protection Act requirements. All the data will be anonymized if analytic works are performed.

7. Possible Benefits from Participating in the Standing Database
There is no immediate benefit from participating in this standing database. However, your participation in this standing database will help other patients with colorectal diseases in the future. You will allow us to better understand these conditions and develop new ways of improving treatments and outcomes.

8. Alternatives to Participation
If you choose not to participate in this standing database, you will continue to receive standard care for your condition.

9. Costs & Payments if Participating in the Standing Database
If you take part in this standing database, there will be no cost involved for participation. You will also not receive any reimbursement.

10. Voluntary Participation
Your participation in this standing database is entirely voluntary. You reserve the right to withdraw your consent for the collection of your clinical data for this database. Your decision not to take part in this standing database or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you wish to stop taking part in this standing database, you should inform the custodian or any member of the standing database team.

However, the data that have been collected and used in research studies and clinical audits until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the research studies and clinical audits. In the event of any new information becoming available that may be relevant to your willingness to continue in this standing database, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Custodian or his/her representative.

11. Compensation for Injury
Since we are only collecting data from your medical records as part of the routine treatment process, we do not expect any research-related injuries to occur to you. However, you will not waive any of your legal rights or release the parties involved in this standing database from liability for negligence by signing this consent form.

12. Confidentiality of Standing Database and Medical Records
All information collected for the purposes of this standing database will be kept confidential. Only those directly involved in the standing database will have access to your records. The data and images collected from you are de-identified and given a code. It will not be possible to link the data or images back to you with only this code. Only the custodian of the database and delegated personnel will maintain the link between these codes and your identifiers. All other persons will only have access to the codes and will not be able to re-identify the coded data and images and will not be able to trace these back to you.

Information collected for this standing database will be kept strictly confidential. Your records, to the extent of the applicable laws and regulations, will NOT be made publicly available.

However, NHG Domain-Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check standing database procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing such access (i) collection, access to, use and storage of your “Personal Data, and (ii) disclosure to authorized service providers and relevant third parties. Re-identification of clinical data will be done when ordered so by the court, where required to in connection with the Human Biomedical Research Act, or when the Director of Medical Services deems that it is in the public interest.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organization has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Your Personal Data will not be used for future research, as the information we gather will be de-identified before analysis.

By participating in this standing database, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at http://www.ttsh.com.sg/patient-guide/page.aspx?id=4468

Data collected and entered into the database are the property of Tan Tock Seng Hospital. In the event of any publication regarding this standing database, your identity will remain confidential.

Any information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymized data will be transferred to potential collaborators, whether within or outside of Singapore. These collaborations may be part of future studies. All collaborations, whether within or outside of Singapore, will be carried out in accordance to the terms in the Research Collaborative Agreement.

13. Who To Contact if You Have Questions

If you have questions about this standing database, you may contact the Custodian, (Dr Tan Ming Ngan Aloysius, Consultant. Contact number 6357 7807. Contact email (aloysius_mn_tan@ttsh.com.sg)

The standing database has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this standing database, you may contact the Custodian or the NHG Domain Specific Review Board Secretariat.

14. Consent to be Contacted for Future Research

You are being asked for permission to be contacted in the future for participation in research studies that you may be suitable for. If you agree to be contacted, your information and contact details will be entered and stored in a secured database in Tan Tock Seng Hospital. Your information and contact details will not be released to any parties outside Tan Tock Seng Hospital without your permission. When investigators from Tan Tock Seng Hospital identify you to be suitable for a particular research study, the investigators or authorized personnel from Tan Tock Seng Hospital will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this standing database. Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting the Custodian, (Dr Tan Ming Ngan Aloysius, Consultant. Contact number 6357 7807. Contact email (aloysius_mn_tan@ttsh.com.sg)

CONSENT FORM

Standing Database Title:
TTSH Colorectal Standing Database

Custodian & Contact Details:
Dr Tan Ming Ngan Aloysius, Consultant (6357 7807); General Surgery, Tan Tock Seng Hospital
TTSH 24h main line (6357 1000) <aloysius_mn_tan@ttsh.com.sg>

I voluntarily consent to take part in this standing database. I have fully discussed and understood the purpose and procedures of this standing database. This standing database has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the standing database, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

By participating in this standing database, I confirm that I have read, understood and consent to the (Tan Tock Seng Hospital) Personal Data Protection Notification. I also consent to the use of my Personal Data for the purposes of engaging in related research arising in the future.

Please check only <u>ONE</u> option:
❑ I agree to have my data and images stored and used in future research studies, without any restriction on the kind of research done
❑ I agree to have my data and images stored and used for colorectal only related future research studies.

_____	_____	_____
Name of Participant	Signature	Date

Translator Information
The standing database has been explained to the participant / legally acceptable representative in _____ *<language>* by _____

Witness Statement
I, the undersigned, certify that:

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

_____	_____	_____
Name of Witness	Signature	Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the standing database team.

Custodian Statement
I, the undersigned, certify that I explained the standing database to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the standing database.

_____	_____	_____
Name of Custodian / Authorised Database Team Member	Signature	Date