SUMMARY OF UPDATES TO THE NHG DSRB INFORMED CONSENT FORM TEMPLATE *(01 Aug 2025)*

The latest version of the NHG DSRB Informed Consent Form Template (Version 14.1, dated 01 Aug 2025) has been updated to:

- *Align with the SingHealth CIRB Informed Consent Form Template. This alignment will streamline the IRB submission process for this frequently used document in cross-cluster studies,*
- *Make it clear that a participant's data from another institution that is captured in Next Generation Electronic Medical Records (NGEMR) may be viewed and used if relevant to the study,*
- *Replace the URL of the website where the participant can find more information about participating in clinical research and the DSRB to one that connects directly to the NHG Office of Human Research Protection Programme (OHRPP) website, and*
- *Make other administrative and formatting changes.*

Please refer to the table below for more details.

Page on ICF Template	Section of ICF Template	Section Title	Change From	Change To	Explanation
Page 1	Nil	TEMPLATE FOR PARTICIPANT INFORMATION SHEET AND CONSENT FORM	Nil.	**TEMPLATE FOR PARTICIPANT INFORMATION SHEET AND CONSENT FORM** *Please remove this text box when finalizing the document **In this template:** • [Square brackets in blue text] indicate instructions to researchers only and should not be included in the consent form. • (Brackets in yellow highlight) indicate where specific information is to be inserted. • Yellow-highlighted text without brackets indicates words or phrases that should be looked at carefully whether to retain, modify or delete it as relevant to your study. • Text formatting*: - Headings : Arial, font size 11, Bold, All caps - Sub-headings : Arial, font size 11, Bold - Text (Description) : Arial, font size 11 - Line spacing : 1.0 *Where necessary, use bigger font size for research involving patients with visual impairment. • Write in simple language, at Primary 6 reading level or lower. • Avoid medical/ scientific/ technical language; or if they must be used, to include in brackets simple definitions or explanations for such terms. • Remove text in red, text in blue, yellow highlight. • Change *text in italics* to standard lettering. • Delete this "TEMPLATE FOR PARTICIPANT INFORMATION SHEET AND CONSENT FORM" text box when finalizing the document.	Adapted from SingHealth CIRB template to provide clearer guidance
Page 2	1	Study Information	Nil	**If Investigators intend to recruit participants aged 12 to 20 years old (with sufficient understanding and intelligence), where their agreement regarding participation in the research study will be documented**	Adapted from SingHealth CIRB template to provide clarity for studies involving minors

				using this consent document, along with consent from their legal representative, please add the following paragraph] If you are a parent or legal guardian giving consent for a child to participate in the study, please note that the word "you" refers to your child.	
Page 2-3	3	What procedures will be followed in this study	Nil	**[If study involve double blinding. please add the following statement] No one (including you and the study doctor) will know which group you are in. If it becomes necessary for your care, your study doctor will be able to find out whether you are (taking the placebo or the study drug).**	Adapted from SingHealth CIRB template to provide clarity for studies that employ double blinding
Page 3	3	What procedures will be followed in this study	In total, (insert amount in teaspoons) of blood will be taken as part of this study. When your participation in the study ends, you will no longer have access to (the study medication/device), unless special additional arrangements are made by the Principal Investigator.	~~In total, (insert amount in teaspoons) of blood will be taken as part of this study.~~ When your participation in the study ends, you will no longer have access to (the study medication/device), unless special additional arrangements are made by the Principal Investigator. **Biological materials:** **The following samples ("biological materials") will be obtained:** **((Describe in lay language and simple terms with the types of samples that will be collected, and details of sample collection, the specific research purpose for which the biological materials is intended to be used, as necessary).** **Example:** **We will take blood ("biological materials") from your arm using a**	Adapted from SingHealth CIRB template to provide clearer details about the biological materials in a separate paragraph for studies involving collection of biological materials

				syringe and needle, every 3 months. Each time, we will take about 2.5ml (half a teaspoon) of blood. In total, we will take about 10ml (2 teaspoons) over a period of one year. The blood sample will be tested for HbA1c (a test to measure the average blood sugar level over the previous 3 months), in Singapore and for research purpose.	
Page 3	3	What procedures will be followed in this study	Nil.	**[If Investigators intend to use any of the following study procedures, please add the applicable section]** **Medical history:** **We will collect information (data) from your medical records. The information will include your past medical history, diagnosis, treatments, and medications (describe whatever else data that will be collected for the disease or condition being studied and state the period of data extraction from medical records (e.g. x month before surgery to y months after surgery).)**	Adapted from SingHealth CIRB template for studies involving collection of data from medical records
Page 3	3	What procedures will be followed in this study	Nil.	**Questionnaire:** **We will ask you to complete questionnaires about (describe the type of questions that will be asked (e.g. your quality of life, your daily activities, your mood and how you have been feeling) and state the duration required to complete the questionnaire).**	Adapted from SingHealth CIRB template for studies involving questionnaires

Pages 3-4	3	What procedures will be followed in this study	Nil.	**Videography:** **This study involves video recording of (describe the study procedures that would be recorded), which is optional. The purpose is to (describe why there is a need for video recording.) Consent for the optional videography will be sought from you.** **Example:** **We will use an observational tool, called PICCOLO to access and monitor the quality of parent-child interactions when the child is 24 months and 32 months. This PICCOLO assessment will be video recorded and then transcribed to provide additional documentation to support the data collected in this research study, and to provide positive feedback to the parents, plan individualized family interventions, and measure program effectiveness.**	Adapted from SingHealth CIRB template for studies involving video recording
Page 4	3	What procedures will be followed in this study	Nil.	**Photography:** **This study involves photo taking of (describe the body part or study procedures that would be captured) which is optional. The purpose is to (describe why there is a need for photo taking.) Consent for the optional photography will be sought from you** **Example:** **We will take photographs of your front and back trunk, legs and arms and/or any target skin lesions/ eczema areas, which may include your face and private body parts.**	Adapted from SingHealth CIRB template for studies involving photo taking

				This is to provide additional documentation to support the data collected in this research study. You will need to undress prior to the photographs being taken. All accessories such as watches and necklaces should be removed. You may leave undergarments on. Any photos obtained and used in a report published as a result of this study will not identify you by name, and to the extent possible, the photos will be presented so that you are not recognizable (if a photograph bearing your face is required, a black "bar" will be placed over the eyes, and if applicable, other identifying features such as piercings, scars, tattoos). Your confidentiality will be protected to the best of our ability. However, absolute confidentiality cannot be guaranteed.	
Page 4	3	What procedures will be followed in this study	Nil.	**[For research studies that require linkages of data with other sources (including, but not limited to healthcare billing information, government administrative data and/or research data such as health and health-related data, social data, education data, birth and death data, economic and housing data, and data from disease registries and databases, whether by itself or with the assistance of a data intermediary), researchers should explain the rationale for such data linkages in the DSRB application and describe the details in the section]**	Adapted from SingHealth CIRB template for studies that require linkages of data with other sources

				Data about you from other resources: **We will use data that identifies you like your name and national registration identity card (NRIC), to access and add data from other sources that is specific to you. This will give researchers more data about factors that might affect your health. For example, we may combine or link the data that we collect about you in this study with data from other sources. This includes but is not limited to healthcare billing information, government administrative data and/or research data such as health and health-related data, social data, education data, birth and death data, economic and housing data, and data from disease registries and databases, whether by itself or with the assistance of a data intermediary.**	
Page 4	3	What procedures will be followed in this study	Nil.	**[If the study is supported by NMRC funding and/or where investigators are required by funding agency or publishers to deposit research data into research or scientific database, researchers should describe the details in the section. Please refer to the sample language below. You may delete or modify the information according to your study design]** **Data deposition into scientific database:** **We will deposit data collected in this study, including the data we collect**	Adapted from SingHealth CIRB template for NMRC-funded or other funded studies whereby it is mandatory for data to be deposited into research or scientific databases for future research

				about you to public and/or controlled-accessed scientific databases. It will not include your name or other data that directly identifies you. This will enable other researchers, whether locally or overseas, to use the data to investigate other important research questions.	
Pages 4-5	4	What Happens to the Data and/or Samples Collected for the Research	(If Investigators intend to use the blood or tissue samples only for the purposes of the current research, please add the following paragraph.) Any blood or tissue samples obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding (insert intended duration of storage), and will be destroyed after completion of the study. The blood or tissue samples (will/will not) be used for restricted human biomedical research involving human-animal combinations. (If Investigators intend to use individually-identifiable health information only for the purpose of the current research, please add the following sentence.) Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research.	**4. What Happens to the Data and/or Samples Collected for the Research** **Example # 1:** (If Investigators intend to use the blood or tissue samples only for the purposes of the current research, please add the following paragraph.) Any blood or tissue samples obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding (insert intended duration of storage), and will be destroyed after completion of the study. The blood or tissue samples (will/will not) be used for restricted human biomedical research involving human-animal combinations. **Example # 2:** (If Investigators intend to use individually-identifiable health information only for the purpose of the current research, please add the following sentence.) Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research. **Example # 3:** (If Investigators intend to keep the leftover blood or tissue	The information was separated from "What procedures will be followed in this study" into a new section "What Happens to the Data and/or Samples Collected for the Research" for better readability.

			(If Investigators intend to keep the leftover blood or tissue samples and/or individually-identifiable/de-identified information for future research in any way beyond the completion of the study, then the following information must be disclosed here, and the participant or his/her legally acceptable representative must explicitly agree to this storage and future use in the signed Consent Form: (a) Specific purpose for which the blood or tissue samples and/or individually-identifiable/de-identified information will be used, if this information is available; but if not available, the purpose may be stated as for general research; (b) Whether the blood or tissue samples (will/will not) be used for future restricted human biomedical research involving human-animal combinations; (c) Period of storage; and Provisions to ensure privacy and confidentiality; including whether the blood or tissue samples will be used in an individually-identifiable form.)	samples and/or individually-identifiable/de-identified information for future research in any way beyond the completion of the study, then the following information must be disclosed here, and the participant or his/her legally acceptable representative must explicitly agree to this storage and future use in the signed Consent Form) (a) Specific purpose for which the blood or tissue samples and/or individually-identifiable/de-identified information will be used, if this information is available; but if not available, the purpose may be stated as for general research; (b) Whether the blood or tissue samples (will/will not) be used for future restricted human biomedical research involving human-animal combinations; (c) Period of storage; and provisions to ensure privacy and confidentiality; including whether the blood or tissue samples will be used in an individually-identifiable form.)	
Page 5	4	What Happens to the Data and/or Samples Collected for the Research	(If Investigators intend to transfer biological samples and/or data out of Singapore, please include either of the statements where relevant): Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be	**Example # 5:** (If Investigators intend to transfer biological samples and/or data out of Singapore, please include either of the statements where relevant) Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only	The information was moved from "Confidentiality of Study and Medical Records" section to this new section for better readability

			stored in Singapore. Only anonymised biological samples and/or data will be transferred out of Singapore to (Insert Name of overseas collaborator/company). OR Your biological samples and/or information containing your "Personal Data" will be transferred out of Singapore to (Insert Name of overseas collaborator/company) for the purposes described in this Informed Consent Form. (Name of institution transferring the samples and/or data) will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your 'Personal Data" to be transferred remains in its possession or under its control. (If biological samples and/or data will not be transferred out of Singapore, please include): Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.	anonymised biological samples and/or data will be transferred out of Singapore to (Insert Name of overseas collaborator/company). OR Your biological samples and/or information containing your "Personal Data" will be transferred out of Singapore to (Insert Name of overseas collaborator/company) for the purposes described in this Informed Consent Form. (Name of institution transferring the samples and/or data) will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your 'Personal Data" to be transferred remains in its possession or under its control. **<u>Example # 6:</u>** (If biological samples and/or data will not be transferred out of Singapore, please include) Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.	
Pages 5-6	5	Incidental Findings	(If the study expressly provides for re-identification in the case of an incidental finding, please indicate this and inform the participant that he/she has a choice whether he/she would wish to be re-identified and notified. The study should also list	**5. Incidental Findings** **Example # 1:** (If the study expressly provides for re-identification in the case of an incidental finding, please indicate this and inform the participant that he/she has a choice whether he/she	The information was moved from "Confidentiality of Study and Medical Records" section to this new section for better readability

			the types of anticipated incidental findings (if applicable) that may be discovered in the course of the study. Please refer to the sample language below. You may delete or modify the information according to your study design.)	would wish to be re-identified and notified. The study should also list the types of anticipated incidental findings (if applicable) that may be discovered in the course of the study. Please refer to the sample language below. You may delete or modify the information according to your study design.)	
Page 6	5	Incidental Findings	During the course of the study, there is a possibility that we might unintentionally come to know of new information about your/your child's health condition from (insert reasons e.g. the imaging scans, the genetic testing etc.) that is/are conducted as part of the study. These are called "incidental findings". "Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may affect your/your child's current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (insert list of anticipated incidental findings, if applicable). You will be asked to indicate whether you wish to be re-identified	During the course of the study, there is a possibility that we might unintentionally come to know of new information about your/your child's health condition from (insert reasons e.g. the imaging scans, the genetic testing etc.) that is/are conducted as part of the study. These are called "incidental findings". "Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may affect your/your child's current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (insert list of anticipated incidental findings, if applicable). You will be asked to indicate whether you wish to be re-identified and notified in the case of a clinically significant	Adapted from SingHealth CIRB template to add a paragraph regarding exceptional situations to re-identify and notify participants even though they may have indicated earlier not to do so

			and notified in the case of a clinically significant incidental finding that is related to you/your child. If you agree to be re-identified and notified, your study doctor/a qualified healthcare professional will explain the incidental finding to you/your child and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek advice to confirm this incidental finding. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.	incidental finding that is related to you/your child. If you agree to be re-identified and notified, your study doctor/a qualified healthcare professional will explain the incidental finding to you/your child and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek advice to confirm this incidental finding. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. **If you do not wish to be re-identified and notified, your decision will be respected. However, in exceptional situations such as discovery of life-threatening incidental findings with available treatment options, you will be contacted to confirm your decision whether to learn more about the incidental findings. In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), you will be contacted and informed of the incidental findings.**	
Page 6	5	Incidental Findings	Nil	**<u>Example # 2:</u> (If research anticipates Incidental Findings, but provide NO**	Adapted from SingHealth CIRB template for studies involving incidental findings

				provision for re-identification and notification, please include the following sample language below.) **"Incidental findings" are findings that have potential health or reproductive importance to a participant like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may cause you to feel anxious and may affect your current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (insert lists of anticipated incidental findings, if applicable).** **It is possible that incidental findings may be detected or suspected in the course of conducting the study. As this is a research and there is no intention to perform medical diagnosis, the medical significance of the incidental finding may not be clear. Hence, there is no notification for incidental findings.**	
Page 7	7	What Is Not Standard Care or is Experimental in This Study	5. What Is Not Standard Care or is Experimental in This Study The study is being conducted because (the intervention or device) is not yet proven to be a standard (investigation, treatment) in subjects with (condition under investigation in this study). We hope that your participation will help us to determine whether (investigation or	~~5~~**7. What Is Not Standard Care or is Experimental in This Study** The study is being conducted because (the intervention or device) is not yet proven to be a standard (investigation, treatment) in participants with (condition under investigation in this study). We hope that your participation will help us to determine whether (investigation or	Adapted from SingHealth CIRB template for studies that use a prototype

			treatment) is equal or superior to existing (investigation or treatment). Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. (Modify as relevant for your study.) Although (Investigation or Treatment) may be part of standard medical care, in this study this/these procedure(s) are only being performed for the purposes of the research, and are not part of your routine care.	treatment) is equal or superior to existing (investigation or treatment). **In this study, the (state name of the device) used is a prototype. A prototype is a first or preliminary version of a device from which other forms are developed.** Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. (Modify as relevant for your study.) Although (Investigation or Treatment) may be part of standard medical care, in this study this/these procedure(s) are only being performed for the purposes of the research, and are not part of your routine care.	
Pages 7-8	8	Possible Risks and Side Effects	Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs In addition, as you cannot (take any other medication) to treat your (insert condition here) while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will (explain rescue/crossover/alternative therapy).	**In addition, as you cannot (take any other medication) to treat your (insert condition here) while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will (explain rescue/crossover/alternative therapy).** **Collection of blood:** Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs. ~~In addition, as you cannot (take any other medication) to treat your (insert~~	Adapted from SingHealth CIRB template for studies involving collection of blood; the information is moved to a new sub-section for better readability

				~~condition here) while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will (explain rescue/crossover/alternative therapy).~~ **[Include if relevant for your study] If possible, the research blood sample(s) will be collected at the same time you have blood drawn for clinical care or through an existing catheter already inserted into a vein.**	
Page 8	8	Possible Risks and Side Effects	Nil	**Collection of urine, stool, saliva, cheek cell samples:** **Collection of urine, stool, saliva, cheek cell may cause inconveniences and momentary discomfort. [Include only if the study involves cheek swabbing] A cheek swab could cause irritation in the cheek where the swab was taken**	Adapted from SingHealth CIRB template for studies involving collection of urine, stool, saliva, cheek
Page 8	8	Possible Risks and Side Effects	Nil	**Questionnaires/ surveys/ interviews: [Delete or modify as necessary]** **Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study**	Adapted from SingHealth CIRB template for studies questionnaires/surveys/interviews
Page 8	8	Possible Risks and Side Effects	Nil	**Personal privacy and confidentiality: [If data and/or biological materials will be de-identified (coded) for use, please include the following sample language below. Otherwise, modify as relevant for your study] This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data and/or**	Adapted from SingHealth CIRB template for studies involving data and/or biological materials collection and use

				biological material that 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.**	
Pages 8-9	11	Alternatives to Participation	Nil	**[If there are NO alternatives are available for this research, please add the following statement. Delete or modify as necessary] There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.**	Adapted from SingHealth CIRB consent form template for studies which do not have any alternatives to the research procedures
Page 9	13	Voluntary Participation	(Please indicate if there are any circumstances under which the participant or his/her legally acceptable representative will be contacted for further consent, e.g. the development of minors to make decisions.)	**[Please indicate if there are any circumstances under which the participant or his/her legally acceptable representative will be contacted for further consent, e.g. the development of minors to make decisions] In the event of changes to the development of your capacity to make decisions (i.e. when you reach the age of 21 years old), you will be contacted for further consent.**	Adapted from SingHealth CIRB template for studies involving minors
Page 10	14	Withdrawal From Study	If you withdraw from the study, you will be required to (insert	If you withdraw from the study, **or the study drug/ medication is stopped**	Adapted from SingHealth CIRB template to provide additional guidance on

			consequences of subject withdrawal and procedures for orderly termination).	**for any reason**, you will be required to (insert consequences of participant withdrawal and procedures for orderly termination). **• (Add anticipated consequences, if any, of discontinuing the study drug or device).** **• (Clearly state the protocol-specific termination procedures).** **• (Obligation for participant to return all study-related supplies, including unused study drug).**	information required regarding withdrawal and discontinuation
Page 10	14	Withdrawal From Study	Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study. (PI should also include any other foreseeable events which might lead to the PI or the Sponsoring company terminating the study before completion.)	Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time **for one or more of the following reasons (Delete and modify if necessary):** **• Failure to follow the instructions of the Principal Investigator and/or study staff.** **• The Principal Investigator decides that continuing your participation could be harmful to your health or safety.** **• Pregnancy** **• You require treatment not allowed in the study.** **• The study is cancelled.** ~~if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study. (PI should also include any other foreseeable events which might lead to the PI or the Sponsoring company~~	Adapted from SingHealth CIRB consent form template to describe the reasons for withdrawal and discontinuation

				~~terminating the study before completion.)~~	
Page 11	16	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. This includes medical conditions, medications, investigations and treatment history.	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. This includes **name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number,** medical conditions, medications, investigations and treatment history **as well as socio-economic data**.	Added socio-economic data, as well as the other examples adapted from SingHealth CIRB template
Page 11	16	Confidentiality of Study and Medical Records	Information and "Personal Data" collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. However, the Sponsoring company (Name of company, if relevant), Regulatory Agencies (HSA, FDA, if relevant) and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you (or your legally acceptable representative, if relevant) are authorising (i) the collection, access to, use and storage of your	Information and "Personal Data" collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. **To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. Your personal data may be disclosed to third parties *(Insert examples of third parties which data may be shared with e.g. external funding agencies and/or research collaborators, etc)* for the purpose of *(Insert circumstances where data would be***	Added information regarding access and use of data from NGEMR, as well as the data protection measures adapted from SingHealth CIRB template

			"Personal Data", and (ii) the disclosure to authorised service providers and relevant third parties.	***shared in this study e.g. seeking funding and/or research purposes for this research project, etc)*. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.** However, the Sponsoring company (Name of company, if relevant), Regulatory Agencies (HSA, FDA, if relevant) and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to **all** your original medical records **regardless of where and whom you seek care from,** to check study procedures and data, without making any of your information public. **These may include data from other hospitals where you may have had medical consultations and/or procedures being carried out and the data is captured under the Next Generation Electronic Medical Records (NGEMR). Such data on NGEMR may be viewed and used if relevant to the study.** ~~By signing the Informed Consent Form attached, you (or your legally acceptable representative, if relevant) are authorising (i) the collection, access to, use and storage of your "Personal Data", and (ii) the disclosure to authorised service providers and relevant third parties.~~ **By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal**	

				Data by *(name of institution)*, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will *(name of institution)* and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.	
Page 11	16	Confidentiality of Study and Medical Records	Data collected and entered into the Case Report Forms are the property of (Institution or Company). In the event of any publication regarding this study, your identity will remain confidential. Research arising in the future, based on your "Personal Data", will be subject to review by the relevant institutional review board.	~~Data collected and entered into the Case Report Forms are the property of (Institution or Company). In the event of any publication regarding this study, your identity will remain confidential.~~**[Include if there is NO intention to keep the data for future research. Otherwise, delete.] All data collected in this study are the property of *(name of institution / sponsor)*. The data will be used for the purpose of this research study only.** **[Include if there is intention to keep the data for future research. Otherwise, delete.] All data collected in this study are the property of *(name of institution / sponsor)*. 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. Research arising in the future, based on your "Personal Data", will be subject to**	Adapted from SingHealth CIRB template to split into 2 options for studies which either has the intent to store the data for future research or not

				review by the relevant institutional review board.	
Page 12	18	Who Has Reviewed The Study	The study 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 research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.	**18. Who Has Reviewed The Study** The study 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 participant, 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 **ethics.gri.nhg.com.sg**. If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.	The information about contacting DSRB was moved from “Who To Contact if You Have Questions” section to this new section for better readability, and the URL of the website has been replaced with the one that connects directly to the NHG OHRPP website
Page 13	Nil	Consent Form	Nil	**Please use this statement, if relevant]** **I understand that my individually identifiable information (Personal Data) and data collected about me may be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative data and/or research data such as health, and health-related data, social data, education data, birth and death data, economic**	Adapted from SingHealth CIRB template for studies that may require linkages with data from other sources

				and housing data, data from disease registries and database, whether by itself or with the assistance of a data intermediary.	
Page 13	Nil	Consent Form	Nil	**[Please use this statement, if relevant]** **I understand that the de-identified data collected about me in this study may be deposited in open-access or access-controlled scientific database for potential use by other researchers, whether locally or overseas, to answer other important research questions, to advance medical research.**	Adapted from SingHealth CIRB template for NMRC-funded or other funded studies whereby it is mandatory for data to be deposited into research or scientific databases for future research
Page 13	Nil	Consent Form	Nil	**[Please include the additional consent section below if videography is optional]** **Consent for Videography** **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.** □ **Yes, I agree to the videography.** □ **No, I do not agree to the videography.**	Adapted from SingHealth CIRB template for consent to the optional components
Pages 13-14	Nil	Consent Form	Nil	**[Please include the additional consent section below if photography is optional]** **Consent for Photography**	Adapted from SingHealth CIRB template for consent to the optional components

				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.** ☐ **Yes, I agree to the photography.** ☐ **No, I do not agree to the photography.**	
Page 15	Nil	Consent Form	<Consent should be taken from the subject, unless consent from Legally Acceptable Representative has been specifically approved for the study by DSRB. Please insert the provision for the Legally Acceptable Representative's Name, Signature and Date if applicable.>	**[**<Consent should be taken from the participant, unless consent from Legally Acceptable Representative has been specifically approved for the study by DSRB. Please insert the provision for the Legally Acceptable Representative's Name, Signature and Date if applicable~~>~~**]** _____ _____ _____ **Name of participant's Parent/legal guardian/ Legal representative** **Signature** **Date**	Adapted from SingHealth CIRB template to include parent/LAR signatory information
Page 19	Nil	Consent Form	The Parties (Investigator, Participant / Legally Authorised Representative & Witness) may execute this Informed Consent Form requiring a party's signature by using electronic signature process (e.g. by DocuSign, E-signature by Adobe Singe etc) and agree that such signatures obtained or transmitted through electronic means, including	The Parties (Investigator, Participant / Legally Authorised Representative & Witness) may execute this Informed Consent Form requiring a party's signature by using ~~electronic signature process (e.g. by DocuSign, E-signature by Adobe Singe etc) and~~ **industry standard electronic signature software and delivered electronically by emailed portable document**	Modified the electronic signature clause to align with template from NHG Legal

			the abovementioned signature process, shall be binding and effective for all purposes as if the signatures were executed in-person.	**format ("PDF") document (or other mutually agreeable document format) and such electronic version shall be treated as an original. The Parties also** agree that such signatures obtained or transmitted through electronic means, ~~including the abovementioned signature process,~~ shall be binding and effective for all purposes as if the signatures were executed in-person.	

Reference: DSRB Templates for Study Documentation (https://ethics.gri.nhg.com.sg/dsrbtemplates/) > Informed Consent Form Template (English) > 207-001: Informed Consent Form Template