Summary of Changes to the CIRB Participant Information Sheet and Consent Form Template (version 12.4 to 13) – 23 Feb 2023

<table>
<tr><th>No.</th><th>Section</th><th>Change From</th><th>Change To</th><th>Explanation</th></tr>
<tr>
<td>1.</td>
<td>Cover Page - Instructions to Researchers</td>
<td>
TEMPLATE FOR
PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Please remove this text box when finalizing the document

<u>GUIDELINES:</u>
Important: This Participant Information Sheet & Consent Form ("Informed Consent Document (ICD)") template has been updated with the following:

(a) Change in Security Marking label
The default label (on document header) is Restricted, Sensitive (Normal).

Researchers should update the label to Restricted, Sensitive (High) according to nature of their research studies, where applicable.

For more information on Data Classification and Security Markings for Classified Materials, click here (intranet).

(b) Change of CIRB hotline number
With effect from 1 October 2022, the CIRB hotline number will be changed to 8126 3660. The current number 6323 7515 will be discontinued.

Researchers should update their ICD with the new CIRB hotline number under the "WHO HAS REVIEWED THE STUDY" section, the soonest possible and latest before 1 October 2023. Existing enrolled participants with ongoing follow-up visits should also be informed of the change in CIRB hotline number.

<u>Table 1:</u> Implementation for the change of CIRB hotline number and ICD revision
<table>
<tr><th></th><th>What action is required from the Researchers?</th></tr>
<tr><td>New research studies</td><td>IRB application (In draft)
➢ Use this ICD template with the new CIRB hotline number.
IRB application (Pending IRB review)
➢ Update the ICD with the new CIRB hotline number.</td></tr>
<tr><td>Ongoing research studies</td><td>Amendment (change of CIRB hotline number only)
➢ Revise the ICD with the new CIRB hotline number.
➢ Include a note-to-file in Investigator Site File, to document the revision of ICD with the new CIRB hotline number and implementation date. Change of version number of ICD is not required if this is the only revision.
➢ Submit the revised ICD in the next study amendment, for IRB review and approval.
(Note: Immediate submission for IRB review will not be required.)
Amendment (change of CIRB hotline number + other amendments)
➢ Revise the ICD with the new CIRB hotline number.
➢ Submit the revised ICD together with other amendments, for IRB review and approval.</td></tr>
</table>
</td>
<td>
TEMPLATE FOR
PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Please remove this text box when finalizing the document

<u>GUIDELINES:</u>
With effect from 1 March 2023, all new IRB applications (for research studies, which involves obtaining informed consent from the research participants), are required to use this ICD template.

For ongoing research studies, where the ICDs are already in compliance with the applicable consent requirements; as stipulated in the Human Biomedical Research Act (HBRA), Health Product Act (HPA), and Medicine Act (MA), the researchers can continue to use the ICDs without further modification.

Important: This Participant Information Sheet & Consent Form ("Informed Consent Document (ICD)") template has been updated with the following:

(a) Single ICD for multiple SingHealth sites study
For research studies involving multiple SingHealth study sites, researchers should only prepare a single "generic" ICD for submission to IRB and recruitment purpose.

Under STUDY INFORMATION section, researchers should list all participating SingHealth study sites and the respective contact details. During informed consent process, the informed consent takers should indicate in the relevant checkbox, the study site, where the research participants are recruited into the study.

Throughout the consent document, the word "SingHealth" refers to the SingHealth study site(s), where the research participants are recruited. Repetition of Site-PI's information and contact details at various sections within the ICD have also been removed. This streamlines the work processes and minimises error in customising site-specific information.

(b) Updates to guidance notes and examples of consent language

<u>(i) Videography/ Photography</u>
The ICD (Videography/ Photography) template is no longer available for use.

For research studies that involve videography of the research procedures and/or photography of the research participants, whether essential to the research study or optional component, researchers should incorporate the details in the main ICD, under STUDY PROCEDURES section. If it is an optional component, researcher should include consent options under the CONSENT FORM page.
</td>
<td><u>Important</u>

- Describe changes to the ICD template and the implementation.</td>
</tr>
</table>

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No.	Section	Change From	Change To	Explanation
		Table 2: Communication to Participants on the change of CIRB hotline number **What should the Researchers do?** Participants who have ongoing follow-up procedures/ visits ➢ Inform participants of the change in CIRB hotline number. Document the communication on study file. ➢ Re-consent from the participants is not required. Participants who have completed all study procedures; with no further follow-up visits ➢ No need to inform participants on the change in CIRB hotline number. ➢ Re-consent from the participants is not required. **(c) Updates to guidance notes and examples of consent language** With effect from 1 October 2022, all new IRB applications (for research studies, which involves obtaining informed consent from the research participants), are required to use this ICD template. For ongoing research studies, which the ICDs are already in compliance with the applicable consent requirements; as stipulated in the Human Biomedical Research Act (HBRA), Health Product Act (HPA), and Medicine Act (MA), the researchers can continue to use the ICDs without further modification.	(ii) Linkages of research data with other sources 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 CIRB application and describe the details in the ICD. (iii) Deposition of research data into databases For research studies that involve deposition of research data into research or scientific database/ repository (whether a requirement from the funding agency or publishers), researchers should describe the details in the ICD. (iv) Destruction of samples following withdrawal from research When a participant withdraws from a research study, researchers should destroy any remaining biological materials that have been collected for the study if they are individually-identifiable and (i) have not been used for research; OR (ii) have been used for research but it is practicable to discontinue further use of the samples for the research. (v) Liability exclusion on data breach National Clinical Trial Insurance has liability exclusion on data breach. Disclaimer against data breach has been included under CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section. (vi) INFORMATION & CONSENT FORM FOR FUTURE RESEARCH Examples of language have been rephrased to avoid limiting researchers' ability to share data with the wider research community. Researchers should describe the possible or intended future use of the data and leftover biological materials (e.g. for research purpose (including but not limited to data linkages with other sources, data deposition into repository, return of medically actionable incidental findings from future research), for non-research purpose (such as teaching, quality control, validation testing, etc.), and protection of confidentiality that also allows the data sharing and/or transfer of the leftover biological materials.	

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No.	Section	Change From	Change To	Explanation
2.	**STUDY INFORMATION**	**STUDY INFORMATION** **Protocol Title:** (Full protocol title as used in the CIRB Application) **Principal Investigator:** (PI's Name) (PI's Department) (PI's Institution Name)	**STUDY INFORMATION** **Protocol Title:** (Full protocol title as used in the CIRB Application) This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study. [Include for study involving single SingHealth institution as recruiting site. Otherwise, delete.] **(PI's Institution Name)** Principal Investigator: (PI's Name) (PI's Department) Tel: (Insert PI's Contact Number) Institution Mainline: (Insert number) 24-hour contact: (Insert number) [Include for study involving multiple SingHealth institutions as recruiting sites. Otherwise, delete.] (Note to PI: Remove any unused placeholder for study sites before submitting the ICD to IRB for review. Informed consent taker is to indicate in the relevant checkbox the study site, where the research participant is recruited.) ☐ **(PI's Institution Name)** Principal Investigator: (PI's Name) (PI's Department) Tel: (Insert PI's Contact Number) Institution Mainline: (Insert number) 24-hour contact: (Insert number) ☐ **(Site PI's Institution Name)** Principal Investigator: (Site-PI's Name) (Site-PI's Department) Tel: (Insert Site-PI's Contact Number) Institution Mainline: (Insert number) 24-hour contact: (Insert number) ☐ **(Site PI's Institution Name)** Principal Investigator: (Site-PI's Name) (Site-PI's Department) Tel: (Insert Site-PI's Contact Number) Institution Mainline: (Insert number) 24-hour contact: (Insert number) ☐ **(Site PI's Institution Name)** Principal Investigator: (Site-PI's Name) (Site-PI's Department) Tel: (Insert Site-PI's Contact Number) Institution Mainline: (Insert number) 24-hour contact: (Insert number) [For more than minimal risks studies, 24-hour contact of the PI or study coordinator should be included.]	**Major change** - Allow the use of single ICD for study involving multiple SingHealth study sites. - Consolidate site's contact details, so researchers no longer need to update multiple sections of the ICD.
3.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	**Videography:** This study involves video recording of (describe the study procedures that would be recorded), [Include if videography is optional. Otherwise, delete] *which is optional*. The purpose is to (describe why there is a need for video recording.) [Include if videography is an optional component. Otherwise, delete] *Consent for the optional videography will be sought from you.* **Example:**	**Major change** - Added example statement for research procedures that requires video recording. NOTE: This replaced the need for separate ICD for videography.

No.	Section	Change From	Change To	Explanation
			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.	
4.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	**Photography:** This study involves photo taking of (describe the body part or study procedures that would be captured, [Include if photography is optional. Otherwise, delete] *which is optional*. The purpose is to (describe why there is a need for photo taking.) [Include if photography is an optional component. Otherwise, delete] *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. 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	**Major change** - Added example statement for research procedures that requires photo taking. NOTE: This replaced the need for separate ICD for photography.

No.	Section	Change From	Change To	Explanation
			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.	
5.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	**Biological materials:** The following samples ("biological materials") will be obtained: (expand with the types of samples that will be collected, and details of sample collection, as necessary). (Describe in lay language and simple terms, the following details: a) The specific research purpose for which the biological materials is intended to be used; and b) Whether the biological materials will be used for any purpose other than research and if so, the specific purpose of which the biological materials will be used; and c) Whether the biological materials will be exported or removed from Singapore to a place outside of Singapore; and d) Whether the biological materials will be used in restricted human biomedical research involving human-animal combination.	**Biological materials:** The following samples ("biological materials") will be obtained: (expand with the types of samples that will be collected, and details of sample collection, whether the removal of samples is solely for research purpose, OR in excess of samples primarily removed for a therapeutic or diagnostic purpose, OR leftover from samples primarily removed for therapeutic or diagnostic purpose, as necessary). (Describe in lay language and simple terms, the following details: a) The specific research purpose for which the biological materials is intended to be used; and b) Whether the biological materials will be used for any purpose other than research and if so, the specific purpose of which the biological materials will be used; and c) Whether the biological materials will be exported or removed from Singapore to a place outside of Singapore; and	**Minor change** - Added instruction notes to include information whether the removal of samples is solely for research, in excess of clinical samples or leftover from clinical samples.

No.	Section	Change From	Change To	Explanation
			d) Whether the biological materials will be used in restricted human biomedical research involving human-animal combination.	
6.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	**Data about you from other resources:** [Include for study requiring access to data from other sources for data linkages. Modify as relevant for your study. Otherwise, delete.] (Note to PI: The rationale for the need for data linkages should be explained in CIRB application.) *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.*	**Administrative change** - Added example statement for research that requires linkages of data about the participants from other sources.

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No.	Section	Change From	Change To	Explanation
7.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	**Data deposition into scientific database:** [Include for study supported by NMRC funding and/or where investigators are required by funding agency or publishers to deposit research data into research or scientific database. Modify as relevant for your study. Otherwise, delete. (Note to PI: Do not use this if research participants will be given a choice regarding data deposition. Instead, use "Information & Consent Form for Future Research".) *We will deposit data collected in this study, including the data we collect 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.*	**Administrative change** - Added example statement for research that requires mandatory deposition of research data into databases for other future use.
8.	**WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY**	[Delete or modify as relevant for your study.] *Although (intervention or investigation or treatment) may be part of standard medical care, in this study this / these procedure(s) are being performed for the purposes of the research, and are not part of your routine care.*	[Delete or modify as relevant for your study.] *In this study, (intervention or investigation or treatment or procedures) are being performed for the purposes of the research, and are not part of your routine care.*	**Administrative change** - Simplified the language for clarity.
9.	**POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES**	**Personal privacy and confidentiality:** [Include only if data and/or biological materials will be de-identified (coded) for use. Otherwise, modify as relevant for your study.] *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*	**Collection of blood:** Taking blood may cause momentary discomfort, pain, bleeding, bruising or swelling at the site of the needle stick. Rarely, taking blood may cause fainting or infection. [Delete or modify as relevant for your study.] *If possible, the research blood sample(s) will be collected at the same time you have blood drawn for*	**Administrative change** - Reorganized such that research procedures that are invasive and interventional are described first.

No.	Section	Change From	Change To	Explanation
		and/or 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.* **Questionnaires/ surveys/ interviews:** [Delete or modify as relevant for your study.] *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.* **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.* **Collection of blood:** Taking blood may cause momentary discomfort, pain, bleeding, bruising or swelling	*clinical care or through an existing catheter already inserted into a vein.* **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.* **Questionnaires/ surveys/ interviews:** [Delete or modify as relevant for your study.] *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.* **Personal privacy and confidentiality:** [Include only if data and/or biological materials will be de-identified (coded) for use. 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 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*	

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No.	Section	Change From	Change To	Explanation
		at the site of the needle stick. Rarely, taking blood may cause fainting or infection. [Delete or modify as 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.*	*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.*	
10.	**POTENTIAL BENEFITS**	Nil	(Note to PI: For H.S.A regulated clinical trials involving children who lack mental capacity to give consent to being a participant, or the children lack sufficient understanding and intelligence to give such consent, it must be shown that there is a reasonable prospect that participation in the clinical trial will directly benefit the children, or there is some direct benefits for the group of children participants involved in the trial. Refer to SHS-RSH-CIRB-225 Research Involving Children on Docupedia (intranet only).)	**Administrative change** - Added reminder to researchers regarding regulatory requirement on consent language.
11.	**WHAT HAPPENS TO THE SAMPLES COLLECTED FOR THE RESEARCH**	The biological materials collected for this research study will be deemed to be donated to (name of institution) as a gift. By agreeing to this, you give up your rights to the biological materials. If the use of your biological materials and/or your data results in intellectual property rights and commercial benefits, you will not receive any financial benefits or proprietary interest.	The biological materials collected for this research study will be deemed to be donated to SingHealth as a gift. By agreeing to this, you give up your rights to the biological materials. If the use of your biological materials and/or your data results in intellectual property rights and commercial benefits, you will not receive any financial benefits or proprietary interest.	**Major change** - Use “SingHealth” referring to the recruiting study site(s), regardless of single or multiple SingHealth sites(s).

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12.	**WITHDRAWAL FROM STUDY**	[Include for research that involves collection of human biological materials. Otherwise, delete.] *The biological materials that have been collected for the study will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised and/or have not been used.*	[Include for research that involves collection of human biological materials. Otherwise, delete.] *Any remaining biological materials that have been collected for the study will be destroyed following the withdrawal of your consent if they are individually-identifiable and (i) have not been used for research; OR (ii) have been used for research but it is practicable to discontinue further use of the samples for the research.*	**Minor change** - Rephrased the language for clarity.
13.	**WITHDRAWAL FROM STUDY**	However, 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.	However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.	**Administrative change** - Rephrased the language for clarity.
14.	**CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS**	**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	**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 and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the	**Major change** - Added statement for mandatory deposition of research data into databases for future use. - Added disclaimer against data breach. - Use "SingHealth" referring to the recruiting study site(s), regardless of single or multiple SingHealth sites(s).

No.	Section	Change From	Change To	Explanation
		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. [Include for research recruiting patient participants. Otherwise, delete.] *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.* [Include for research recruiting non-patient participants. Otherwise, delete.] *However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your 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 (Insert Name of Institution), and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. Any information containing your Personal Data that is collected for the purposes of this	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. 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 monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) 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 SingHealth, 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 SingHealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.	

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		research will be stored in Singapore. To protect your identity, your Personal Data will be labelled with a unique code number. 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 number to your Personal Data. This will be kept in a safe place with restricted access. [Include if Investigators intend to transfer data out of Singapore as part of this research study. Otherwise, delete.] *To (state purpose of data transfer), your coded data will be transferred out of Singapore.* [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 (Insert Name of Institution or Sponsor Company). 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 (Insert Name of Institution or Sponsor Company). 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.*	[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 (SingHealth or Sponsor Company). 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 (SingHealth or Sponsor Company). 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.	

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		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.		
15.	**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** **(PI's Name)** **(PI's Department, Institution)** **Contact Number: (Insert PI's phone number)** [For more than minimal risks studies, include 24-hour contact of the PI or study coordinator.] **(Insert PI's Institution) Mainline: (Insert number)** If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.	If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document. If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.	**Administrative change** - Removed the Principal Investigators' information in this section so that researchers do not need to update multiple sections of the ICD in the event of information change
16.	**CONSENT FORM FOR RESEARCH STUDY**	**Protocol Title:** (Full protocol title as used in the CIRB Application) **Principal Investigator:** (PI's Name) (PI's Department, Institution Name)	**Protocol Title:** (Full protocol title as used in the CIRB Application) **Declaration by Research Participant** (i) I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks	**Administrative change** - Removed the Principal Investigators' information in this section so that researchers do not need to update multiple sections of the

No.	Section	Change From	Change To	Explanation
		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.	and benefits of the study have been explained clearly to me and I fully understand them. (ii) 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. (iii) 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 and housing data, data from disease registries and database, whether by itself or with the assistance of a data intermediary. (iv) 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. (v) I understand that my participation is voluntary and that I am free to withdraw at any	ICD in the event of information change - Added clauses regarding data linkages and data deposition.

No.	Section	Change From	Change To	Explanation
			time, without giving any reasons and without my medical care being affected. (vi) By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.	
17.	**CONSENT FORM FOR RESEARCH STUDY**	Nil	[Include if the videography is optional. Otherwise, delete.] **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.	**Administrative change** - Added consent options for videography.
18.	**CONSENT FORM FOR RESEARCH STUDY**	Nil	[Include if the photography is optional. Otherwise, delete.] **Consent for Photography** 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.	**Administrative change** - Added consent options for photography.

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19.	**CONSENT FORM FOR RESEARCH STUDY**	**Consent to be Re-identified and Notified in the case of an Incidental Finding** There may be potential incidental findings arising from this research. Please indicate whether you consent to re-identification and notification about the incidental finding: ☐ Yes, I wish to be re-identified and notified in the case of an incidental finding from this research. I can be reached by: *Phone/ Email:* ☐ In the event that I cannot be reached, please contact the following person nominated by me: [Optional] *Name/ Phone/ Email:* ☐ No, I do not wish to be re-identified and notified in the case of an incidental finding from this research. However, I understand that in exceptional or rare situations, I will be contacted as described in the Participant Information Sheet: - In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my decision whether to learn more about the incidental findings.	[Include if there is provision for re-identification and notification. Otherwise, delete.] **Consent to be Re-identified and Notified in the case of an Incidental Finding** There may be potential incidental findings arising from this research. Please indicate whether you consent to re-identification and notification about the incidental finding: ☐ Yes, I wish to be re-identified and notified in the case of an incidental finding from this research. I can be reached by: *Phone/ Email:* ☐ In the event that I cannot be reached, please contact the following person nominated by me: [Optional] *Name/ Phone/ Email:* ☐ No, I do not wish to be re-identified and notified in the case of an incidental finding from this research. However, I understand that in exceptional or rare situations, I will be contacted as described in the Participant Information Sheet: - In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my	**Administrative change** - Added instruction note to delete the consent for incidental finding, if not applicable.

No.	Section	Change From	Change To	Explanation
		- In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), I will be contacted and informed of the incidental findings.	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), I will be contacted and informed of the incidental findings.	
20.	**Future Research - Example # 1: (Data only)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	[Include if data will be stored for a specific duration for future research. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data for (state intended storage duration) for future research. The data will be kept in (state institution) for use by researchers.* [Include if data will be stored for an indefinite period of time. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data for future research. The data will be kept in (state institution). 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.*	In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) for Future Research. 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 the data. Researchers will use the data for research long into the future.	**Major change** - Rephrased the language to be less restrictive.

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21.	**Future Research - Example # 1: (Data only)**
	INFORMATION & CONSENT FORM FOR FUTURE RESEARCH
		This is what will be done with your stored data:
		• We may use the data to answer additional research questions in other research studies (state the specific research purpose, if available). This is outside the scope of the research study but still related to (state the specific disease of condition).
		• We may share the data with other researchers at (state institutions, etc.) and with researchers outside of Singapore (state collaborators, country, etc.)
			This is what will be done with the data:
			• We may use the data to answer additional research questions in other research studies which are outside the scope of the research study ("Future Research"). We may also share the data with other researchers within and/or outside of Singapore, for use in Future Research.
			• [Modify as relevant for your study. Otherwise, delete.] We may deposit the data into a research data repository for long-term use by the wider research community, for use in Future Research. Researchers share information with each other by depositing data into research databases. These databases store information from many other research studies. Researchers can then study the combined information to learn even more about human health and diseases, to advance medical research.
			  • We may deposit the data into one or more open-access (public scientific database) and/or controlled-access research databases. Anyone on the Internet can access publicly accessible database. Only researchers (including private companies involved in publicly-funded research) who apply and are granted approval can access controlled-access databases.
			  • Where required, researchers may request that the research data be combined or linked with data from
				Major change
				
				- Rephrased the language to be less restrictive.
				
				- Added example statement for deposition of data into databases, and linkages with data from other sources, in view that data sharing is increasingly common and encouraged in the research community nowadays.
				
				- Added example statement regarding return of medically actionable incidental findings from future research.
				
				- Added example statement regarding use of data for purposes other than research.

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			other sources, including but not limited to healthcare billing information, government administrative and/or research data such as health, and health-related data social data, education data, birth and death data, economic and housing data, data from disease registries and databases, whether by itself or with the assistance of a data intermediary. This will enrich their data analysis and provide valuable information for policy and research into health and wellbeing of the population (public interest). The data intermediary will use strict privacy preserving policies, protocols and procedures to ensure security of the data and confidentiality of the individuals the records relate to. • You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.	

No.	Section	Change From	Change To	Explanation
			• We may also use the data for purposes other than research such as teaching, or training future researchers, development of health policy, or (to expand as necessary).	
22.	**Future Research - Example # 1: (Data only)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	[Include if stored data will be coded. Otherwise, delete.] • *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.* [Include if stored data will be stripped of identifiers. Otherwise, delete.] • *The stored data will be anonymized with the removal of all information that directly identifies you so that no one can identify which data came from you.*	This is what will be done to protect confidentiality of the data: • Any information that could identify you will be removed (de-identified) before this de-identified data is used and/or shared with other researchers and/or deposited into research data repository. • The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low. • If you decide at a later time that you do not want the data to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information has already been deposited into the research data	**Major change** - Rephrased the language to cater for scenarios including deposition of data into databases, and linkages with data from other sources.

No.	Section	Change From	Change To	Explanation
		• *This means that even if you decide at a later time that you do not want your data to be used for future research, we will not be able to remove your data and discontinue from further use.*	repository or included in analyses or used in publications.	
23.	**Future Research - Example # 1: (Data only)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	[Include if applicable. Otherwise, delete.] *The use of your data in future research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.*	The use of your data in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.	**Administrative change** - Removed instruction note.
24.	**Future Research - Example # 1: (Data only)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	**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.	**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, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data for such Future Research. Research arising in the future,	**Administrative change** - Rephrased the language for clarity. - Added consent options for return of medically actionable incidental findings from future research.

No.	Section	Change From	Change To	Explanation
			will be subject to review by the relevant institutional review board, where applicable. **Disclosure of incidental findings arising from Future Research** ☐ I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options). ☐ I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings), I may be contacted to confirm my decision whether to learn more about the incidental findings.	
25.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	[Include if data and leftover biological materials will be stored for a specific duration. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data and leftover biological materials (state the type of human biological materials that will be kept for future research) for (state intended storage duration) for future research. The data and biological materials will be kept in (state institution) for use by researchers.* [Include if data and leftover biological materials will be stored for an indefinite period of time. Otherwise delete.] *In this Consent Form for*	In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) and leftover biological materials (state the type of human biological materials that will be kept for future research) for Future Research. 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 the data and biological materials. Researchers will use the data and biological materials for research long into the future.	**Major change** - Rephrased the language to be less restrictive.

No.	Section	Change From	Change To	Explanation
		Future Research, we seek your permission to keep your data and leftover biological materials (state the type of human biological materials that will be kept for future research) for future research. The data and biological materials will be kept in (state institution). 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 and biological materials. Researchers will use your data and biological materials for research long into the future.		
26.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	This is what will be done with your stored data and leftover biological materials: • We may use the data and biological materials to answer additional research questions in other research studies (state the specific research purpose/ tests, if available). This is outside the scope of the research study but still related (state the specific disease of condition). • *[Delete if not applicable.] We may use the biological materials for (state if human biological materials will be used for any purpose other than research e.g. quality control, validation testing, etc.)* • We may share the data and biological materials with other researchers at (state institutions, etc.) and with researchers outside of Singapore (state collaborators, country, etc.)	This is what will be done with the data and leftover biological materials: • We may use the data and biological materials to answer additional research questions in other research studies, which are outside the scope of the research study ("Future Research"). (Note to PI: For study recruiting (a) an adult who lacks mental capacity; OR (b) a minor who lacks mental capacity; OR (c) a minor who lacks sufficient understanding and intelligence to give consent, thereby requiring consent from their legal representative; AND the removal of tissue is solely for research purpose; OR in excess of tissue primarily removed for a therapeutics or diagnostic purpose, the scope of future research should be defined.) • We may also share the data and biological materials with other researchers within and/or outside of	**Major change** - Rephrased the language to be less restrictive. - Added example statement for deposition of data into databases, and linkages with data from other sources, in view that data sharing is increasingly common and encouraged in the research community nowadays. - Added example statement regarding return of medically actionable incidental

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			Singapore, for use in Future Research. The biological materials will not be used in research involving human-animal combinations, which is restricted by Singapore law.
			• [Modify as relevant for your study. Otherwise, delete.] We may deposit the data into research data repository for long-term use by the wider research community, for use in Future Research. Researchers share information with each other by depositing data into research databases. These databases store information from many other research studies. Researchers can then study the combined information to learn even more about human health and diseases, to advance medical research.
			  • We may deposit the data into one or more open-access (public scientific database) and/or controlled-access research databases. Anyone on the Internet can access publicly accessible database. Only researchers (including private companies involved in publicly-funded research) who apply and are granted approval can access controlled-access databases.
			  • Where required, researchers may request that the research data be combined or linked with data from other sources, including but not limited to healthcare billing information, government
				findings from future research.
				
				- Added example statement regarding use of data and samples for purposes other than research.

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			administrative and/or research data such as health, and health-related data, social data, education data, birth and death data, economic and housing data, data from disease registries and databases, whether by itself of with the assistance of a data intermediary. This will enrich their data analysis and provide valuable information for policy and research into health and wellbeing of the population (public interest). The data intermediary will use strict privacy preserving policies, protocols and procedures to ensure security of the data and confidentiality of the individuals the records relate to. • You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you. • We may also use the data and biological materials for purposes other than research such as teaching, or training future researchers, development of	

No.	Section	Change From	Change To	Explanation
			health policy, quality control, validation testing, or (*to expand as necessary*).	
27.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	*[Include if stored data and leftover biological materials will be coded. Otherwise, delete.]* • *The stored data and biological materials 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 and biological materials with other researchers, it will be in coded manner. They will not be able to identify you from the coded data and biological materials.* • *You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.* • *If you decide at a later time that you do not want your data and biological materials to be used for future research, you can contact the Principal Investigator or study team at any time. All your stored data and biological materials that have not been used or shared with other researchers will be removed from the storage facility and/or destroyed, unless this information is already included in analyses or used in publications.*	This is what will be done to protect confidentiality of the data and biological materials: • Any information that could identify you will be removed (de-identified) before this de-identified data and biological materials are used and/or shared with other researchers and/or deposited into research data repository. • The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low. • If you decide at a later time that you do not want the data and biological materials to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the stored data and biological materials that have not been used or shared with other researchers will be removed from the storage facility and/or destroyed, unless this information is	**Major change** - Rephrased the language to cater for scenarios including deposition of data into databases, and linkages with data from other sources.

No.	Section	Change From	Change To	Explanation
		[Include if stored data and leftover biological materials will be stripped of identifiers. Otherwise, delete.] • *The stored data and biological materials will be anonymized with the removal of all information that directly identifies you so that no one can identify which data and biological materials came from you.* • *Since the data and biological materials have been made anonymous, any results, obtained cannot be traced back to the original source, and no results or incidental findings will be reported.* • *This means that if you decide at a later time that you do not want your data and biological materials to be used for future research, we will not be able to remove your data and biological materials from the storage facility.*	already deposited into the research data repository or included in analyses or used in publications.	
28.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	The leftover biological materials will be deemed to be donated to (name of institution) as a gift. By agreeing to this, you give up your rights to the leftover biological materials. The use of your data and leftover biological materials in future research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.	The leftover biological materials will be deemed to be donated to SingHealth as a gift. By agreeing to this, you give up your rights to the leftover biological materials. The use of your data and leftover biological materials in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.	**Major change** - Use “SingHealth” referring to the recruiting study site(s), regardless of single or multiple SingHealth sites(s).

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29.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	Nil	If you have questions or wish to provide feedback on the purposes for which the leftover biological materials will be used, you may contact the Principal Investigator.	**Administrative change** - Added example statement for clarity.
30.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	**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 and leftover biological materials stored for future use in other research studies. ☐ I agree to have my data and leftover biological materials stored for future use in other research studies.	**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 and leftover biological materials stored for future use in other research studies. ☐ I agree to have my data and leftover biological materials stored for future use in other research studies, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data biological materials for such Future Research. Research arising in the	**Administrative change** - Rephrased language for clarity. - Added consent options for return of medically actionable incidental findings from future research.

No.	Section	Change From	Change To	Explanation
		[Delete if leftover biological materials will NOT be transferred out of Singapore for future research.] ☐ *I agree for my leftover biological materials to be transferred out of Singapore.* ☐ *I do not agree for my leftover biological materials to be transferred out of Singapore.* *[Delete if leftover biological materials will be stripped of identifiers.]* ☐ *I wish to be re-identified and notified of any incidental finding arising from future research studies using my leftover biological materials.* ☐ *I do not wish to be re-identified and notified of any incidental finding arising from future research studies using my leftover biological materials. However, I understand that in exceptional or rare situations, I will be contacted:* - *In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my 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*	future, will be subject to review by the relevant institutional review board, where applicable. **Disclosure of incidental findings arising from Future Research** ☐ I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options). ☐ I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings), I may be contacted to confirm my decision whether to learn more about the incidental findings.	

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		Disease Act), I will be contacted and informed of the incidental findings.		