Summary of Changes to the CIRB Participant Information Sheet and Consent Form Template (version 13 to 14) – 25 Jul 2024

No.	Section	Change From	Change To	Explanation
1.	**Cover Page - Instructions to Researchers**	**TEMPLATE FOR** **PARTICIPANT INFORMATION SHEET AND CONSENT FORM** Please remove this text box when finalizing the document **GUIDELINES:** 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** (i) Videography/ Photography 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.	**TEMPLATE FOR** **PARTICIPANT INFORMATION SHEET AND CONSENT FORM** Please remove this text box when finalizing the document **GUIDELINES:** With effect from 01 August 2024, all new IRB applications (for research studies, which involves obtaining informed consent from the research participants), are required to use this Participation Information Sheet and Consent Form ("Informed Consent Document ("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 current approved ICDs without further modification. **Latest Update: Major change has been made to this template to provide guidance and examples of consent language to fulfil consent element specified under section 12(2)(c) of the HBRA. Other minor changes are described in a separate document - Summary of Changes: Participant Information Sheet & Consent Form (version 13 to 14).** **Section 12(2)(c) of the HBRA that states** *"the proposed areas of research approved by the institutional review board in a case where it has waived the requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose under section 37(3)"* **where section 37 *Restrictions on activities relating to human tissue* of the HBRA states** *37.–(2) No person may remove any human tissue from any of the following persons unless the removal of the tissue was primarily for a therapeutic or diagnostic purpose:* *(a) an adult who lacks mental capacity;* *(b) a minor who lacks mental capacity;* *(c) a minor who lacks sufficient understanding and intelligence to give consent.* *37.–(3) Despite subsection (2), an institutional review board may waive the requirement that the tissue be removed, from any person referred to in that subsection, primarily for a therapeutic or diagnostic purpose if the board is satisfied that –* *(a) the removal of the tissue involves no more than minimal risk to that person; and* *(b) there are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue from the class of persons to which that person belongs to.* **Human tissue** means any human biological material but excludes human biological material specified in the HBRA First Schedule.	**Important** - Included guidance notes and examples of consent language to fulfil consent element specified under section 12(2)(c) of the HBRA. - Described management for informed consent and human tissue that has obtained without the explicit consent element section 12(2)(c).

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<table>
<tr><th>No.</th><th>Section</th><th>Change From</th><th>Change To</th><th>Explanation</th></tr>
<tr>
<td></td>
<td></td>
<td>
<u>(ii) Linkages of research data with other sources</u>
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.

<u>(iii) Deposition of research data into databases</u>
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.

<u>(iv) Destruction of samples following withdrawal from research</u>
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.

<u>(v) Liability exclusion on data breach</u>
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.

<u>(vi) INFORMATION & CONSENT FORM FOR FUTURE RESEARCH</u>
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.
</td>
<td>
Table 1: Management & Implementation Plan for The Affected Studies
<table>
<tr><td>Affected research study</td><td colspan="2">• Ongoing, approved HBR study involving removal of <u>human tissue</u>

• Ongoing, approved CT study involving collection, storage, supply or use of leftover <u>human tissue</u> for purposes outside of the regulated clinical trial (e.g. for biobanking or future research) – Such activities should comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act (HBRA)</td></tr>
<tr><td>The research is recruiting</td><td>• Adult who lacks mental capacity

• Minor who lacks mental capacity. Example:
- Minor who has cognitive difficulties/ disabilities

• Minor who lacks sufficient understanding and intelligence to give consent. Example:
- Minor aged 0 to 5 years
- Minor aged 6 to 11 years
- Minor aged 12 to 20 years who do not have sufficient understanding and intelligence to enable the minor to understand what is proposed in the research</td><td>• Adult with mental capacity to personally give consent

• Minor who has sufficient understanding and intelligence to understand what is proposed in the research to give consent. Example:
- Minor aged 12 to 20 years</td></tr>
<tr><td>What action is required from the Researchers?
- ECOS</td><td colspan="2">➢ Update Section N2 (Cognitively Impaired Persons) or Section L3 (Children) of ECOS Amendment Form, where applicable, to provide information regarding any removal of human tissue <u>not</u> primarily for therapeutic or diagnostic purpose.</td></tr>
</table>
Continue on next page
</td>
<td></td>
</tr>
</table>

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No.	Section	Change From	Change To	Explanation
			<table><tr><td>**Affected research study**</td><td>• Ongoing, approved HBR study involving removal of human tissue • Ongoing, approved CT study involving collection, storage, supply or use of leftover human tissue for purposes outside of the regulated clinical trial (e.g. for biobanking or future research) – Such activities should comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act (HBRA)</td></tr><tr><td>**What action is required from the Researchers? ICD**</td><td>➢ Revise ICD to provide information regarding the consent element section 12(2)(c)[1]. See STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY > Biological materials: section, for examples of the consent language. ➢ **The ICD must be updated by 31 Dec 2024.** ➢ Include a note-to-file in Investigator Site File, to document the missing consent element section 12(2) in ICD(s) that had been used to recruit research participants and the management plan. See item (a) and (b) below.</td></tr><tr><td>**(a) Existing research participants with no further removal of Human Tissue**</td><td>➢ Researchers can continue to use human tissue that has already been collected for purposes outlined in the signed ICD. ➢ Re-consent is not required.</td></tr><tr><td>**(b) Existing research participants with further removal of Human Tissue**</td><td>➢ Researchers can continue to use human tissue that has already been collected for purposes outlined in the signed ICD. ➢ **The ICD must be updated by 31 Dec 2024.** ➢ Re-consent is required prior to subsequent removal of human tissue.</td></tr><tr><td>**(c) New research participants**</td><td>➢ Researchers should recruit new participants using revised ICD with the required consent elements, including Section 12(2)(c)[1].</td></tr></table> Continue on next page	

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No.	Section	Change From	Change To	Explanation
			[1]**Important Notes:** See STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY > Biological materials: section, for examples of the consent language. For HBR studies involving collection of human tissue; or CT studies involving collection, storage, supply or use of leftover human tissue for purposes outside of the regulated clinical trial (e.g. for biobanking or future research), there should be a statement in the ICD to address the HBRA consent element section 12(2)(c) to describe: • whether human tissue will be obtained from any of the vulnerable classes of persons (a) an adult who lacks mental capacity; (b) a minor who lacks mental capacity; (c) a minor who lacks sufficient understanding and intelligence to give consent. AND • whether the IRB has waived the requirement that the removal of human tissue is primarily for a therapeutic or diagnostic purpose under section 37(3) of the HBRA. A negative statement must be included even if the HBRA consent element section 12(2)(c) is not relevant, such as the following scenarios: • Scenario # 1: The study involves collection of human tissue from adults with mental capacity to personally give consent. • Scenario # 2: The study involves collection of human tissue from minors who have sufficient understanding and intelligence to enable the minors to understand what is proposed in the research to give consent. • Scenario # 3: The study involves collection of leftover human tissue from therapeutic or diagnostic procedures obtained from the vulnerable class of persons (i.e. adults and minor who lacks mental capacity or minors who lacks sufficient understanding and intelligence to give consent).	
2.	**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**	Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document.	Please read the information provided here carefully. If you agree to participate, please sign the consent form. You will be given a copy of this document.	**Administrative change** - Reposition the word “carefully”.

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No.	Section	Change From	Change To	Explanation
3.	**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**	[Include for study recruiting participants aged 12 to 20 years old (with sufficient understanding and intelligence), where their agreement regarding participation in the research study will be documented using this consent document, along with consent from their legal representative. Otherwise, delete.] *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.*	[Include for study recruiting participants aged 12 to 20 years old (with sufficient understanding and intelligence), where their agreement regarding participation in the research study will be documented using this consent document, along with consent from their legal representative. Otherwise, delete.] *If you are a parent or legal guardian giving consent for a child to participate in the study, please note that the word "you", "my" and "I" refer to the child you are consenting for.*	**Administrative change** - Updated to include "my" and "I" that is stated under Declaration by Research Participants on Consent Form.
4.	**STUDY INFORMATION**	**Protocol Title:** (Full protocol title as used in the CIRB Application)	**Study Title:** (Full study title as used in the ECOS Application)	**Administrative change** - Updated to ECOS terminology.
5.	**STUDY INFORMATION**	Tel: (Insert PI's Contact Number)	Tel: (Insert PI's Office Number)	**Administrative change** - Updated for clarity.
6.	**STUDY INFORMATION**	24-hour contact: (Insert number)	[For more than minimal risks studies, 24-hour contact of the PI or study coordinator should be included.] 24-hour contact: (Insert Number)	**Administrative change** - Updated to clarify that 24-hour contact should not be the same as the institution mainline.
7.	**PURPOSE OF THE RESEARCH STUDY**	The purpose of this study is to (explain in lay language why the research is being done, ensuring it is consistent with the Aims described in your CIRB application form). You were selected as a possible participant in this study because (briefly explain why participant is being approached about	The purpose of this research study is to (explain in lay language why the research is being done, ensuring it is consistent with the Specific Aims described in your ECOS Application). You were selected as a possible participant in this research study because (briefly explain why participant is being approached about	**Administrative change** - Updated "study" to "research study". - Updated to ECOS terminology.

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		participation, without the need to list all the inclusion criteria). This study targets to recruit (insert number of participants) participants from (state PI's institution). [Include for multi-site study. Otherwise, delete.] *About (insert total number of participants) participants are expected to take part in this study at multiple hospitals and medical facilities in (state countries of those study sites).*	participation, without the need to list all the inclusion criteria). This research study targets to recruit (insert number of participants) participants from (state PI's institution). [Include for multi-site study. Otherwise, delete.] *About (insert total number of participants) participants are expected to take part in this research study at multiple hospitals and medical facilities in (state countries of those study sites).*	
8.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	**Biological materials:** The following samples ("biological materials") will be obtained:	**Biological materials:** We will collect the following samples ("biological materials"):	**Minor change** - Updated "study" to "research study".
9.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	[Include this NEGATIVE statement for HBRA section 12(2)(c) applicable to study involving Scenario # 1 or # 2 or # 3. Otherwise, delete.] The Institutional Review Board waiver under Section 37(3) of the Human Biomedical Research Act 2015 ("HBRA") for the removal of human biological materials is not required. This is because we will collect samples from the following individuals: • [Scenario # 1: Include for study involving collection of biological materials from adults with mental capacity to personally give consent. Otherwise, delete.] Adults with mental capacity to personally give consent for this research study.	**Major change** - Included examples of consent language to fulfil consent element specified under section 12(2)(c) of the HBRA. This is an example of negative statement. <u>Note:</u> This is mandatory for studies involving the collection, storage, supply or use of human tissue.

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			• [Scenario # 2: Include for study involving collection of biological materials from minors aged 12 to 20 years, who have sufficient understanding and intelligence to understand what is proposed in the research. Otherwise, delete.] Minors (children) who have sufficient understanding and intelligence to understand what is proposed in the research, whereupon consent will be obtained from both the minors and their legal representative. • [Scenario # 3: Include for study involving collection of leftover biological materials from vulnerable groups (i.e. adults or minors lacking mental capacity or minors lacking sufficient understanding and intelligence to give consent). Otherwise, delete.] Adults who lack mental capacity / minors who have cognitive difficulties/ disabilities / minors who do not have sufficient understanding to personally give consent for this research study, whereupon consent will be obtained from their legal representative. These are leftover samples that have been primarily removed for a therapeutic or diagnostic purpose as part of medical care, and that are no longer required for any clinical purposes.	

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10.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	Nil	[Include this statement for HBRA section 12(2)(c) applicable for study involving collection of fresh biological materials solely for research purposes or extra biological materials (in excess of the biological materials primarily removed for a therapeutic or diagnostic purpose) from vulnerable groups (i.e. adults or minors lacking mental capacity or minors lacking sufficient understanding and intelligence to give consent). Otherwise, delete.] We will also collect research samples from the following individuals who are unable to personally give consent for this research study, whereupon consent will be obtained from their legal representative. The SingHealth Centralised Institutional Review Board has waived the requirement that the removal of the samples be primarily for a therapeutic or diagnostic purpose under Section 37(3) of the Human Biomedical Research Act 2015 ("HBRA"). [Include for study involving collection of biological materials in excess of biological materials primarily removed for a therapeutic or diagnostic purpose. Otherwise, delete.] These research samples are in addition to the samples required for clinical care purposes. The research samples will be obtained at the same time when samples are removed as part of medical care. • Adults who lack mental capacity • Minors who have cognitive difficulties/ disabilities • Minors who do not have sufficient understanding	**Major change** - Included examples of consent language to fulfil consent element specified under section 12(2)(c) of the HBRA. Note: This is mandatory for studies involving the collection, storage, supply or use of human tissue.

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11.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	**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.*	Nil	**Administrative change** - Shifted to CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section.
12.	**STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY**	**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	Nil	**Administrative change** - Shifted to CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section.

No.	Section	Change From	Change To	Explanation
		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.*		
13.	**WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY**	[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.*	[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 medical care.*	**Minor change** - Updated "routine care" to "medical care".
14.	**POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES**	**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 clinical care or through an existing catheter already inserted into a vein.*	**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 medical care or through an existing catheter already inserted into a vein.*	**Minor change** - Updated "clinical care" to "medical care".
15.	**ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY**	[Include for research, where alternatives procedures/ treatments are available. Otherwise, delete.] *If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be (investigation / treatment / procedure). You may discuss the*	[Include for research, where alternatives procedures/ treatments are available. Otherwise, delete.] *If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be (investigation / treatment / procedure).*	**Minor change** - Updated to include examples of consent language (for potential benefits and risks of alternatives) to fulfil consent element

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		possible risks and benefits of the alternatives with your doctor.	[Modify as relevant for your study. Otherwise, delete.] *This procedure has the following potential benefits: (Insert list of possible benefits of the "standard" alternative) and the following potential risks: (Insert list of possible risks from the "standard" alternative).* *You may discuss the possible risks and benefits of the alternatives with your doctor or the Principal Investigator to make an informed decision whether to take part in this study.*	specified under section 12(1)(d) of the HBRA.
16.	**COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY**	[Include if participants will receive payment or reimbursement. Otherwise, delete.] *You will be reimbursed for your time, inconvenience and transportation costs as follows:* • *If you complete the study, you will receive (insert payment amount).* • *If you do not complete the study for any reason, you will receive (insert payment amount) for each visit you complete.*	[Modify as relevant for your study, if participants will receive payment or reimbursement for single-visit study. Otherwise, delete.] *You will be reimbursed (insert payment amount), for transport, time, and inconvenience.* [Modify as relevant for your study, if participants will receive payment or reimbursement for multiple-visits study. Please state that payment and that reimbursement will be pro-rated. Otherwise, delete.] *You will be reimbursed for transport, time, and inconvenience. You will receive (insert pro-rated payment amount) for each visit you have completed.*	**Minor change** - Updated to include examples of consent language for single-visit study and multiple-visit study. - Payments to research participants should be pro-rated and not wholly contingent on completion of the study by the research participants.
17.	**WITHDRAWAL FROM STUDY**	You are free to withdraw your consent and discontinue your participation in the study at any time, without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.	You are free to withdraw your consent and discontinue your participation in the study at any time, without giving any reasons and without your medical care being affected. If you decide	**Minor change** - Added "without giving any reasons", consistent with declaration statement

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			to stop taking part in this study, you should tell the Principal Investigator.	on CONSENT FORM FOR RESEARCH STUDY section.
18.	**CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS**	Nil	**Data about you from other resources:** [Include for study requiring access to data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY 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 Section E3 or Section G7 of ECOS 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** - Shifted from STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY section. - Updated guidance note to describe the applicable scenarios for data linkages.
19.	**CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS**	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	**Administrative change** - Shifted from STUDY PROCEDURES & YOUR RESPONSIBILITIES

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			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.*	IN THIS STUDY section.
20.	**CONSENT FORM FOR RESEARCH STUDY**	**Protocol Title:** (Full protocol title as used in the CIRB Application)	**Study Title:** (Full study title as used in the ECOS Application)	**Administrative change** - Updated to ECOS terminology.
21.	**CONSENT FORM FOR RESEARCH STUDY**	**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 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 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.	**Declaration by Research Participant** • 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. • [Include only if you have added **Data about you from other resources:** under CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section. Otherwise, delete.] 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. • [Include only if you have added **Data deposition into scientific database:** under CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section. Otherwise, delete.] 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. • I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons. • By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.	**Administrative change** - Changed from numbered list to bulleted list. - Added instructions to researchers to include or delete the example of declaration statement, whichever applicable. - Removed "and without my medical care being affected" to minimize edits.

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22.	**Future Research - Example # 1: (Data only)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	• 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 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.	• [Include for scenarios that allow data linkages with data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY. Modify if required. Otherwise, delete.] 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 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.	**Administrative change** - Updated guidance note to describe the applicable scenarios for data linkages.

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Summary of Changes to the CIRB Participant Information Sheet and Consent Form Template (version 13 to 14) – 25 Jul 2024

No.	Section	Change From	Change To	Explanation
23.	**Future Research - Example # 2: (Data and Leftover Biological Materials)** **INFORMATION & CONSENT FORM FOR FUTURE RESEARCH**	• 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 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.	• [Include for scenarios that allow data linkages with data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY. Modify if required. Otherwise, delete.] 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 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.	**Administrative change** - Updated guidance note to describe the applicable scenarios for data linkages.