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| **CIRB Application Form** |
| (This document is for reference only.) |

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# Instructions

1. Please include the study site(s) and the information of the Principal Investigator and Site-Principal Investigator(S) in Section B2(a).
2. The list of investigators including Principal Investigator and Site-Principal Investigator(s) should be listed in Annex 1 (Study Team Form).
3. If any of the investigators listed in Annex 1 have conflict of interest, please complete Annex 2 (Conflict of Interest Declaration Form). One Annex 2 per investigator.
4. Not all sections are required to be filled up, please refer to the instructions highlighted in yellow.
5. If attachment(s) will be submitted, please type the name of the document(s) in the attachment table of the applicable sections.

Example:

 **J13. Please attach the Informed Consent Document(s).**

|  |
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| **J13. Attachment** |
| 1. Participant Information Sheet and Consent Form v1 dated 1 Apr 2024 for patients2. Participant Information Sheet and Consent Form v1 dated 1 Apr 2024 for healthcare workers |

1. Submissions to CIRB:
2. Completed Application Form
3. Annex 1: Study Team Form
4. Signed Annex 2: Conflict of Interest Declaration Form (if applicable)
5. Study documents (e.g. Recruitment materials, Informed Consent Document, Study Protocol, Investigator’s Brochure, Data Collection Form etc.)
6. Signed Principal Investigator Declaration Form
7. Signed Department Representative Endorsement Form
8. Signed Institution Representative Endorsement Form
9. The IRB may request for clarifications/ amendments/ additional information/ documents after reviewing the submissions.

# Application Form

Below listed all the Sections and questions of the IRB Application Form. Please fill up the Sections relevant to your study. Only questions with “#” indicated are optional.

## Section A: Study Title

***Please complete this Section.***

**A1. Please enter the Study Title for this Study.**

Click or tap here to enter text.

## Section B: Submission Board, Study Site, Study Investigator and Conflict of Interest

***Please complete this Section.***

**Note: Please list down the Principal Investigator, Site-Principal Investigator(s) and Co-Investigator(s) in Annex 1. If any of the investigators have conflict of interest, please complete Annex 2 (one Annex 2 per investigator).**

**B1. Submission IRB and Board**

**B1. (a) The reviewing IRB would be: SingHealth CIRB**

**B1. (b) Please select the board.** Choose an item.

**B1. (c) Please select the specialty.** Choose an item.

**B1. (d) Has the study been submitted to another IRB?**





**B1. (d) (i) Please state the name of the IRB. (If “Yes” is selected in B1. (d))**

Click or tap here to enter text.

**B1. (e)** **Has the application been previously rejected by any IRB?**





**Please state which IRB had rejected the study and provide reason(s) for the rejection.**

**(If “Yes” is selected in B1. (e))**

**B1. (e) (i) Name of the IRB: (If “Yes” is selected in B1. (e))**

Click or tap here to enter text.

**B1. (e) (ii) Reason(s): (If “Yes” is selected in B1. (e))**

Click or tap here to enter text.

**B2. Study Site and Study Investigator**

**B2. (a) Please select the study sites and investigator:**

| **Study Site** | **Location#** | **PI/ Site-PI’s Name** | **Department of PI/ Site-PI** | **Institution of PI/ Site-PI** |
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**B2. (b) Study Sites (For Information Only) #**

Note: Other local/ overseas site (The sites listed here is for the IRB’s information only. IRB’s approval will not include any of the sites. The sites should apply for their own IRB approval if required.)

Click or tap here to enter text.

## Section C: Study Funding Information

***Please complete this Section.***

**C1. Please provide information regarding the study’s funding source or sponsor information.**





**C1. (b) (i) Name of Grant Agency: (If “Grant” is selected in C1)**

Click or tap here to enter text.

**C1. (b) (ii) Grant Holder: # (If “Grant” is selected n C1)**

Click or tap here to enter text.

**C1. (b) (iii) Grant Amount Applied for: (If “Grant” is selected in C1)**

Click or tap here to enter text.

**C1. (b) (iv) Has the grant been approved? (If “Grant” is selected in C1)**





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| **C1. (b) (iv) Attachment (If “yes” is selected in C1.(b) (iv))** |
| Click or tap here to enter text. |

**C1. (b) (v) Is the study’s initiation dependent on grant approval? (If “Grant” is selected in C1)**





**C1. (b) (v) (I) Please state alternate funding: (If “No” is selected in C1. (b) (v))**

Click or tap here to enter text.

**C1. (b) (vi) Grant Reference Number # (If “Grant” is selected in C1)**

Click or tap here to enter text.



**C1. (c) (i) Name of Sponsor Company (If “Pharmaceutical/ Industry Sponsored” is selected in C1)**

Click or tap here to enter text.

**C1. (c) (ii) Is the sponsor offering any incentive connected with research participant recruitment or completion of research study (e.g. finder’s fee, recruitment bonuses etc.) that will be paid to the research staff?  (If “Pharmaceutical/ Industry Sponsored” is selected in C1)**





**C1. (c) (ii) (I) Please elaborate: (if “yes” is selected in C1. (c) (ii))**

Click or tap here to enter text.

**C1. (c) (iii) Will the sponsor be providing monitoring?** **(if “Pharmaceutical/ Industry Sponsored” is selected in C1)**





**C1. (c) (iv) Would the sponsor be responsible for the payment and compensation of injury or illness to research participants arising from participation in the study? (if “Pharmaceutical/ Industry Sponsored” is selected in C1)**





**C1. (c) (iv) (I) Please elaborate: (if “No” is selected in C1. (c) (iv))**

Click or tap here to enter text.

**C2. Will the funding/sponsor cover all research-related costs e.g., drugs, devices, procedures, tests and visits?**







**C2. (a) Please explain. (if “no” is selected in C2)**

Click or tap here to enter text.

## Section D: Study Type and Nature

***Please complete this Section.***

**D1. Form Type: Please select the appropriate form for submission.**

 

 

**D1. (a) Please select the exemption application categories. (If “Exemption Application Form” is selected in D1)**

[ ]  Category S1 – Research in Established or Commonly Accepted Educational Settings

[ ]  Category S2 – Research that Only Involves Educational Tests, Surveys, Interviews, or Observation of Public Behaviour

[ ]  Category S3 – Research Involving Benign Behavioural Interventions

[ ]  Category S4 – Secondary Research Using Biospecimens or Private Information

**D1. (a) (i) Category S4: Please select: (If “Category S4” is selected in D1. (a))**





[ ]  Category S5 – Taste and Food Quality Evaluation and Consumer Acceptance Studies

**D2. Study Classification: Please determine which set of regulations would govern the study (or any part of the study).**



**D2. (a) Please indicate the Phase of the Trial. (If “Clinical Trial” is selected in D2)**

 Click or tap here to enter text.



**D2. (b) Select the checkbox(es) that apply. (If “Human Biomedical Research” is selected in D2)**

NOTE:

(1) When options from D2. (b) (i) is selected, selections from D2. (b) (ii) and D2. (b) (iii) are NOT required unless applicable.

(2) When options from D2. (b) (i) is not selected, selections from D2. (b) (ii) and D2. (b) (iii) are mandatory.

**D2. (b) (i) Any research that involves (if applicable):**

[ ]  a. human gametes or human embryos.

[ ]  b. cytoplasmic hybrid embryos.

[ ]  c. the introduction of any human-animal combination embryo into an animal or human.

[ ]  d. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo).

[ ]  e. any entity created as a result of any process referred to in (c) or (d).

**D2. (b) (ii) My human biomedical research is intended to study:**

[ ]  a. the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body.

[ ]  b. the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques.

[ ]  c. the performance or endurance of human individuals.

**D2. (b) (iii) Where the research involves:**

[ ]  a. subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual.

[ ]  b. the use of any individually-identifiable human biological material.

[ ]  c. the use of any individually-identifiable health information.



**D2. (c) Select the checkbox(es) that apply. My restricted human biomedical research involves:**

**(If “Restricted Human Biomedical Research” is selected in D2)**

Category A

[ ]  a. human eggs or human embryos (includes derivation of new human embryonic stem cell lines from donate human embryos).

Category B

Research involving any of the following human-animal combination embryos:

[ ]  a. cytoplasmic hybrid embryos.

[ ]  b. human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells).

[ ]  c. human-animal combination embryos created in-vitro by using human gametes and animal gametes.

[ ]  d. human-animal combination embryos created in-vitro by using one human pronucleus and one animal pronucleus.

Note: Research involving the development of human-animal combination embryos referred to in (a) or (c) beyond 14 days or the appearance of primitive streak, whichever is earlier, is prohibited.

Category C

[ ]  a. the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo.

[ ]  b. the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction.

[ ]  c. the use of any entity created as a result of (a) and (b) above.

Category D

[ ]  a. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal.

[ ]  b. the use of any entity created as a result of (a) above.



**D2. (d) Please justify why the study is not regulated by Health Products Act/ Medicines Act (HSA) or Human Biomedical Research Act (MOH).  (If “others” is selected in D2)**

Click or tap here to enter text.

**D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).**

[ ]  Questionnaire/ Survey/ Interview/ Focus Group Discussion

[ ]  Medical Records Review

[ ]  Human Biological Material

[ ]  Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

[ ]  Use of Software or Mobile Applications

[ ]  Medical Device (including Telehealth Medical Device. Please refer to [HSA website](https://www.hsa.gov.sg/medical-devices/registration/is-it-a-medical-device) to determine if your product is considered Medical Device in Singapore.)

[ ]  Surgical / Radiotherapy Procedure

[ ]  Interventions/ Invasive Procedures

[ ]  None of the above

**D4. Would the study involve recruitment?**





**D4. (a) Would the study involve recruitment of any of the following as research participants?  (If “Yes” is selected in D4)**

[ ]  Not applicable, the study does not involve vulnerable research participants

[ ]  Pregnant Women, Foetuses & Neonates

[ ]  Children

[ ]  Prisoners

[ ]  Cognitive Impaired Person

[ ]  Other Vulnerable Population

**D4. (a) (i) Please specify the population: (If “Others vulnerable population” is selected in D4. (a))**

Click or tap here to enter text.

**D4. (a) (ii) Why does your research need to involve this group of vulnerable research participants? (If “Others vulnerable population” is selected in D4. (a))**

Click or tap here to enter text.

**D4. (a) (iii) What are the additional safeguards that will be provided to protect the rights and welfare of this group of vulnerable research participants? (If “Others vulnerable population” is selected in D4. (a))**

Click or tap here to enter text.

**D5. Please select the applicable type(s) of consent for the study.**

[ ]  Consent will be obtained

[ ]  Waiver of documentation of consent (Verbal or Implied Consent) - This option is mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion

[ ]  Waiver of consent during emergency situation

[ ]  Waiver of consent

[ ]  Not applicable as study involves De-identified Data

[ ]  Consent obtained from research participants previously

**D5. (a) Please state the source. For approved study, please state the protocol title, IRB reference number and name of approving IRB. Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document. (If “Consent was obtained from research participants previously” is selected in D5)**

Click or tap here to enter text.

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| **D5. (a) Attachment (If “Consent was obtained from research participants previously” is selected in D5)** |
| Click or tap here to enter text. |

**D5. (i) Please state which population(s) are involved for the above combination selected. (If more than 2 checkbox options are selected in D5)**

Click or tap here to enter text.

## Section E: Research Methodology (Exemption Application)

***Please complete this Section if "Exemption Application Form” is selected in D1.***

**E1. What are the specific aims of this study?**

Click or tap here to enter text.

**E2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.**

Click or tap here to enter text.

**E3. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research.**

Note:

* + - * 1. If study involves research participant’s visit, please describe the frequency and procedures involved. For studies with multiple visits, please attach the study schedule.
				2. If this study involves medical records review, please state the source of data and specify the period of data that will be extracted for review.

Click or tap here to enter text.

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| **E.3 Attachment** |
| Click or tap here to enter text. |

**E4. Please provide details on sample size and power calculation. If applicable, please provide the means by which data will be analysed and interpreted.**

Click or tap here to enter text.

**E4. (a) If this is part of an international study, please also state the approximate total number of worldwide research participants targeted for enrolment into this study. #**

**Number of worldwide research participants:**  Click or tap here to enter text.

**E5. Please state the target number of research participants to be enrolled for each study site. If the exact numbers are not available, please give an approximate number range for Enrolment Target.**

Note:

1. For the distribution of Males, Females and Children to be enrolled into the study, please use the Enrolment Target Minimum number to provide an approximate distribution ratio.
2. Please note that enrolling research participants beyond the Enrolment Target Maximum without the IRB’s approval would constitute a non-compliance. If you intend to enrol beyond the Enrolment Target Maximum, please submit a study amendment to increase the enrolment target for approval.
3. Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.

Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min.

| **Study Site** | **Enrolment Target Min** | **Enrolment Target Max** | **Adults (Male)** | **Adults (Female)** | **Children***(Persons less than 21 years and not married)* |
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**E6. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.**

Click or tap here to enter text.

**E7. What are the potential risks to research participants?**

[ ]  Economic risk

[ ]  Physical risk

[ ]  Psychological risk

[ ]  Social risk

[ ]  Legal risk

Click or tap here to enter text.

**E8. What are the potential benefits (direct as well as indirect) to research participants? Indirect benefits may refer to the medical knowledge gained in the future, from the research.**

Click or tap here to enter text.

**E9. What is the estimated duration required to conduct this study?**

**No. of years** Click or tap here to enter text.

**No. of months** Click or tap here to enter text.

**E10. Does this study have a study protocol?**





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| **E.10 Attachment (If “Yes” is selected in E10)** |
| Click or tap here to enter text. |

## Section F: Exemption Review Criteria

***Please complete this Section if "Exemption Application Form” is selected in D1.***

**F1. Please describe and state the source of your research participants/samples/data.**

Click or tap here to enter text.

**F2. Criteria to qualify for Exemption from IRB review.**

**F2. (a) The research involves no more than minimal risks to the research participants:**





**F2. (a) (i) Please justify: (If “No” is selected in F2. (a))**

Click or tap here to enter text.

**F2. (b) The selection of research participants is equitable:**





**F2. (b) (i) Please justify: (If “No” is selected in F2. (b))**

Click or tap here to enter text.

**F2. (c) Recording of identifiable information:**





**F2. (c) (i) Please justify and state the provisions: (If “Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data” is selected in F2. (c))**

Click or tap here to enter text.

**F2. (d) Privacy interests of the research participants:**





**F2. (d) (i) Please justify and state the provisions: (If “There are interactions with research participants and adequate provisions to maintain the privacy interests of the research participants” is selected in F2. (d))**

Click or tap here to enter text.

**F3. Please select the applicable type(s) of consent for the study.**

[ ]  Consent will be obtained

[ ]  Waiver of documentation of consent (Verbal or Implied Consent) - This option is mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion

[ ]  Waiver of consent

[ ]  Not applicable as study involves De-identified Data

[ ]  Consent obtained from research participants previously.

**F3. (a) Please state the source. For approved study, please state the protocol title, IRB reference number and name of approving IRB. Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document. (If “Consent was obtained from research participants previously” is selected in F3)**

 Click or tap here to enter text.

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| **F3. (a) Attachment (if “Consent was obtained from research participants previously” is selected in F3)** |
| Click or tap here to enter text. |

**F3. (i) Please state which population(s) are involved for the above combination selected. (If more than 2 checkbox options are selected in F3)**

Click or tap here to enter text.

**F4. Please select the option(s) for re-identification in the case of incidental findings. More than 1 option can be selected if there are different plans for re-identification for different population of participants. (If “Consent will be obtained” is selected in F3)**

[ ]  (a) Yes, research participants will be re-identified and notified.

**F4. (a) Please describe the management of incidental findings. (If “Yes, research participants will be re-identified and notified” is selected in F4)**

Click or tap here to enter text.

[ ]  (b) No, research participants will not be re-identified and notified.

**F4. (b) Please describe the rationale why research participants will not be re-identified and notified. (If “No, research participants will not be re-identified and notified” is selected in F4)**

Click or tap here to enter text.

[ ]  (c) There will not be any incidental findings arising from this study.

**F4. (c) Please elaborate why there will not be any incidental findings arising from this study. (If “There will not be any incidental findings arising in this study” is selected in F4)**

Click or tap here to enter text.

## Section G: Research Methodology

***Please complete this Section if “Application Form” is selected in D1.***

**G1. What are the specific aims of this study?**

Click or tap here to enter text.

**G2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.**

Click or tap here to enter text.

**G3. Please state concisely the importance of the research described in this application by relating the specific aims to the long term objectives.**

Click or tap here to enter text.

**G4. Please briefly describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gap(s) that the proposed study is intended to fill.**

Click or tap here to enter text.

**G5. Please provide a list of relevant references and attach at least two relevant publications that support the conduct of the study. #**

Click or tap here to enter text.

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| **G5. Attachment** |
| Click or tap here to enter text. |

**G6. Please provide an account of the Principal Investigator’s preliminary studies and progress reports (if any) pertinent to this application.**

Click or tap here to enter text.

**G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research.**

Note:

1. If the study involves research participant’s visit, please describe the procedures involved.
2. If this study involves medical records review, please state the source of data and specify the period of data that will be extracted for review.

Click or tap here to enter text.

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| **G7. Attachment** |
| Click or tap here to enter text. |

**G8. Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant’s standard care.**

Click or tap here to enter text.

**G9. Please state how long will each research participants will be expected to be directly involved (from screening procedures till completion of follow-up tests or examinations) in the study?**

Note: If the study involves research participant’s visit, please describe the frequency. For studies with multiple visits, please attach the study schedule.

Click or tap here to enter text.

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| **G9. Attachment** |
| Click or tap here to enter text. |

**G10. Please select the option(s) for re-identification in the case of incidental findings. More than 1 option can be selected if there are different plans for re-identification for different population of research participants.**

[ ]  (a) Yes, research participants will be re-identified and notified.

**G10. (a) Please describe the management of incidental findings. (If “Yes, research participants will be re-identified and notified” is selected in G10)**

Click or tap here to enter text.

[ ]  (b) No, research participants will not be re-identified and notified.

**G10. (b) Please describe the rationale why research participants will not be re-identified and notified. (If “No, research participants will not be re-identified and notified” is selected in G10)**

Click or tap here to enter text.

[ ]  (c) There will not be any incidental findings arising from this study.

**G10. (c) Please elaborate why there will not be any incidental findings arising from this study.  (If “There will not be any incidental findings arising in this study” is selected in G10)**

Click or tap here to enter text.

**G11. Please provide details on sample size and power calculation. If applicable, please provide the means by which data will be analysed and interpreted.**

Click or tap here to enter text.

**G11. (a) If this is part of an international study, please also state the approximate total number of worldwide research participants targeted for enrolment into this study. #**

**Number of worldwide research participants:** Click or tap here to enter text.

**G12. Please state the target number of research participants to be enrolled for each study site. If the exact numbers are not available, please give an approximate number range for Enrolment Target.**

Note:

1. For the distribution of Males, Females and Children to be enrolled into the study, please use the Enrolment Target Minimum number to provide an approximate distribution ratio.
2. Please note that enrolling research participants beyond the Enrolment Target Maximum without the IRB’s approval would constitute a non-compliance. If you intend to recruit beyond the Enrolment Target Maximum, please submit a study amendment to increase the enrolment target for approval.
3. Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.

Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min.

| **Study Site** | **Enrolment Target Min** | **Enrolment Target Max** | **Adults (Male)** | **Adults (Female)** | **Children***(Persons less than 21 years and not married)* |
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**G13. Please list the inclusion criteria. The age group of the research participants must be specified. If you have more than 1 research participant group, please list the inclusion criteria for each group (if applicable).**

Click or tap here to enter text.

**G14. Please list the exclusion criteria. If pregnant women will be excluded from the study, please state clearly. If you have more than 1 research participant group, please list the exclusion criteria for each group (if applicable).**

Click or tap here to enter text.

**G15. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.**

Click or tap here to enter text.

**G16. What are the potential risks to research participants?**

[ ]  Economic risk

[ ]  Physical risk

[ ]  Psychological risk

[ ]  Social risk

[ ]  Legal risk

Click or tap here to enter text.

**G17. What are the potential benefits (direct as well as indirect) to research participants? Indirect benefits may refer to the medical knowledge gained in the future, from the research.**

Click or tap here to enter text.

**G18. What is the estimated duration required to conduct this study?**

**No. of years** Click or tap here to enter text.

**No. of months** Click or tap here to enter text.

**G19. Does this study have a study protocol?**





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| **G.19 Attachment (If “Yes” is selected in G19)** |
| Click or tap here to enter text. |

## Section H: Research Details- Clinical Trials (Drug)

***Please complete this Section if "Clinical Trial” is selected in D2.***

**H1. Is this a US FDA IND study or data is intended to be reported to FDA in support of an IND Application?**





**H2. Please provide information on the study drug that will be used, and describe how you plan to manage the receipt, handling, storage, utilization, and disposal of the study drug.**

Click or tap here to enter text.

**H3. Describe standard/alternative treatments used at your institution for this condition.**

Click or tap here to enter text.

**H4. Is this a placebo-controlled trial?**





**H4. (a) Explain what 'standard of care' therapy is available for this condition. (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (b) Discuss the ethical implications of using placebo instead of 'standard of care' therapy in this situation. (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (c) Address the issues of safety and efficacy of other available therapies. (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (d) What is the total duration the research participant would be on the placebo arm of the study? (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (e) What is the greatest potential harm that the research participant might be exposed to as a result of not receiving effective therapy? (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (f) What are the procedures in place to safeguard research participant receiving placebo? (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H4. (g) Do you have any other comments supporting the use of a placebo in your study? (If “Yes” is selected in H4)**

Click or tap here to enter text.

**H5. Please attach the Investigator’s Brochure, product catalogue(s), local product information sheet/leaflet(s), as applicable.**

|  |
| --- |
| **H5. Attachment** |
| Click or tap here to enter text. |

## Section I: Research Details- Use of Medical Device

***Please complete this Section if “Medical Device” is chosen in D3****.*

**I1. Please state the name of the medical device(s) that will be tested or studied in this research (including product name and brand/ manufacturer).**

Click or tap here to enter text.

**I1. (a) Is the medical device used as a prototype (including modified devices) under in this study?**





**I1. (b) Is the medical device locally registered?**



**I1. (b) (i) Please indicate: (If “Registered as General Medical Device” is selected) in I1. (b))**











**I1. (b) (ii) Please indicate: (If “Registered as an In-Vitro Diagnostic (IVD) Medical Device” is selected in I1. (b))**











**I1. (b) (iii) Please elaborate why the medical device is not registered. (If “Unregistered” is selected in I1. (b))**

Click or tap here to enter text.

**I1. (c) Will you be submitting or have submitted the Clinical Research Material Notification (CRM-N) to HSA for the medical device?**





**I1. (c) (i) Please elaborate. (If “No” is selected in I1. (c))**

Click or tap here to enter text.

**I1. (d) Is this a US FDA IDE study or data is intended to be reported to FDA in support of an IDE Application?**





**I1. (e) Please determine the risk level of the medical device to research participants:**





**I1. (e) (i) Please select where appropriate. (If “This is a significant risk medical device” is selected in I1. (e))**

[ ]  This medical device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a research participants.

[ ]  This medical device is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a research participants.

[ ]  This medical device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a research participants.

[ ]  This medical device presents a potential for serious risk to the health, safety, or welfare of a research participants.

**I1. (f) Please provide information on the medical device/prototype. (If this is a “prototype” as selected in (i))**

* How the device achieves its goal?
* Safety/ effectiveness data to date in human trials, if available.
* Safety/ effectiveness data to date in preclinical data, if applicable.
* Instruction on the proper use of the device.
* Summary of device’s adverse effects and potential risks (including adverse effects due to misuse of the device).
* How device operator will be trained in proper administration/ use of device?

Note: For investigational medical device that requires electrical connection (e.g. plug-in to wall outlet) within SingHealth Institutions, the device should be commissioned by Biomedical Engineering (BME). Please indicate if the device had been commissioned or the study team will be doing so.

Click or tap here to enter text.

**I1. (g) Please describe on the storage, inventory, and control of the medical device?**

Click or tap here to enter text.

**I1. (h) Who will be responsible for administering the medical device?**

[ ]  Trained study team member

[ ]  Research participants

[ ]  Others

**I1. (h) (i) Please specify. (If “Others, please specify” is selected in I1. (h))**

Click or tap here to enter text.

**I1. (i) Please describe how the unused or returned medical device will be managed at the completion of this research study.**

Click or tap here to enter text.

**I1. (j) Please attach the supporting documents for the medical device (e.g., device brochure, product catalogue(s), product information sheet/leaflet(s), directions/instructions for use, insert, labelling (if appropriate and/or applicable), safety data, image/photograph/diagram of device(s), etc.)**

|  |
| --- |
| **I1. (j) Attachment** |
| Click or tap here to enter text. |

## Section J: Recruitment Details and Consent Process

***1. Please complete J1 to J4 if “Yes is selected in D4.***

***2. Please complete J5 to J13 if “Consent will be obtained” is selected in D5 or F3.***

***3. Please complete J9 if “Consent will be obtained” is selected in D5 or F3 and “Human Biomedical Research” or “Restricted Human Biomedical Research” is selected at D2.***

**J1. How will potential research participants be identified? Please tick all the applicable boxes.**

[ ]  (a) Referral by attending healthcare professional

[ ]  (b) Research participants related to the study team (e.g., doctor-patient, employee-employer, head subordinate, student-teacher)

**J1. (b) Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence. (If “Research participants related to the study” is selected in J1.**

Click or tap here to enter text.

[ ]  (c) Databases

**J1. (c) Please elaborate. (If “Databases” is selected in J1.)**

Click or tap here to enter text.

[ ]  (d) Other methods of research participant identification

**J1. (d) Please elaborate on your method(s) of research participant identification (e.g. advertisement, word of mouth etc.). (If “Other methods of research participant identification” is selected in J1.)**

Click or tap here to enter text.

**J2. Please describe the advertising/ recruitment strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster/brochure/advertisement in newspaper/radio, etc.) to be used to recruit research participants.**

Click or tap here to enter text.

|  |
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| **J2. Attachment** |
| Click or tap here to enter text. |

**J3. Are there any recruitment restrictions based on the gender of the research participants (e.g. only males will be included in this study) or race of the research participants (e.g. only Chinese research participants will be included in this study)?**





**J3. (a) Please select where appropriate. (If “Yes” is selected in J3)**

[ ]  (i) Gender

**J3. (a) (i) Gender: Please elaborate. (If “Gender” is selected in J3. (a))**

Click or tap here to enter text.

[ ]  (ii) Race

**J3. (a) (ii) Race: Please elaborate. (If “Race” is selected in J3. (a))**

Click or tap here to enter text.

**J4. Who will make the first contact with research participants and how will the research participants be contacted?**

Click or tap here to enter text.

**J5. Please select the mode of obtaining consent:**

[ ]  Consent will be obtained in-person (face-to-face consent)

**J6. Describe the face-to-face consent process. (if “consent will be obtained in-person” is selected in J5)**

* Where will the consent process take place with the potential research participant/legal representative (including the time provided for him/her to consider his/her participation in the study)?
* Where will consent be taken (e.g., room, ward, outpatient clinic, etc.)?
* How will privacy, freedom from intrusion and comfort be ensured?

Click or tap here to enter text.

[ ]  Consent will be obtained remotely (remote consent)

**J5. (a) Please explain why consent must be obtained remotely. (If “consent will be obtained remotely” is selected in J5)**

Click or tap here to enter text.

**J5. (b) Please elaborate when face to face consent and remote consent would be used. (If both options are checked in J5)**

Click or tap here to enter text.

**J7. Describe the remote consent process. (If “consent will be obtained remotely” is selected in J5)**

* Please state the institution-approved platform that would be used.
* Please state if any data would be collected via the platform. If yes, please state what data would be collected, where it would be stored, who would have access to the data and how research data confidentiality will be protected.
* How will consent be obtained (e.g., How identity of research participants will be verified, whether consent will be documented using an e-signature or wet-ink signature will be documented on a hardcopy Informed Consent Form which will be sent back to the study team via mail or email)
* If a witness/ impartial witness is required, how will he/ she join the session and how the study team will ensure that he/ she stays throughout?

Click or tap here to enter text.

**J8. Who will take consent from potential research participants/legally acceptable representatives (e.g., PI, Co-Investigators etc.)?**

Click or tap here to enter text.

**J9. Will a witness be present during the consent process? For studies that are under the purview of the HBRA, consent must be obtained in the presence of a witness, unless the requirements for exemption are met.**





**J9. (a) Please explain. (If “No” is selected in J9)**

Click or tap here to enter text.

**J10. Will research participants receive any monetary payments (e.g. transportation allowances) or gifts for their participation in the study?**





**J10. (a) Please elaborate. (If “Yes” is selected in J10)**

Click or tap here to enter text.

**J11. Will the study enrol non-English speaking research participants?**





**J11. (a) What are the possible languages that will be understood by the prospective research participant or the legal representative? (If “Yes” is selected in J11)**

[ ]  Chinese

[ ]  Malay

[ ]  Tamil

[ ]  Others

**J11. (a) (i) Please specify.** (**If “Others” is selected in J11. (a))**

Click or tap here to enter text.

**J11. (b) How will the non-English consent be documented? (If “Yes” is selected in J11)**

[ ]  Informed Consent Form (Full) translated to the language understood by the prospective research participant or legal representative.

Note: Submission of translated consent form and certificate of translation is not required. These documents should be filed in the investigator/study file.

[ ]  Informed Consent Form (English) with DSRB Short Consent Form Template (Translated).

[ ]  Informed Consent Form (English) with other Short Consent Form (Translated).

[ ]  Verbally translated using Informed Consent Form (English) in the presence of impartial witness.

**J11. (b) (i) Please state which population(s) are involved for the above combination selected. (If more than one options are selected in Section J11. (b))**

Click or tap here to enter text.

**J12. Do you have any additional comments regarding the Informed Consent process?**





 **J12. (a) Please elaborate. (If “Yes.” is selected in J12)**

Click or tap here to enter text.

**J13. Please attach the Informed Consent Document(s).**

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| **J13. Attachment** |
| Click or tap here to enter text. |

## Section K: Research Participants- Pregnant Women, Foetuses, & Neonates

***Please complete this Section if “Pregnant Women, Foetuses, & Neonates” is selected in D4. However, this Section need not be completed if only “medical records review “is selected in D3.***

**K1. Please indicate if your research involves:**

[ ]  Pregnant Women and Foetuses.

[ ]  Neonates of Uncertain Viability and/or Nonviable Neonates.

**Note: If the study involves Viable Neonates, please select “Children” under Section D4.**

**K2. Describe if preclinical studies, including studies on pregnant animals, and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and foetus.**

Click or tap here to enter text.

**K3. Describe how the risks to the foetus will be minimized.**

Click or tap here to enter text.

**K4. Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants**.

Click or tap here to enter text.

**K5. Special Informed Consent Requirements (Check all that apply).**

[ ]  Consent will be obtained from the pregnant women.

[ ]  Consent will also be obtained from the father because the research holds out the prospect of direct benefit solely to the foetus.

[ ]  The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the foetus or neonate.

**K5. (a) Consent will be obtained from the pregnant women because: (If “Consent will be obtained from the pregnant women” is selected in K5)**

[ ]  Research holds out the prospect of direct benefits to the pregnant women.

[ ]  Research holds out the prospect of direct benefits to both the pregnant women and the

foetus.

[ ]  Risk to the foetus is not greater than minimal and the purpose of the research is the

development of important biomedical knowledge that cannot be obtained by any other means.

**K6. Assurances by Principal Investigator.**

* + There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.
	+ Individuals engaged in the research will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
	+ Individuals engaged in the research will not have any part in determining the viability of a neonate.

[ ]  I agree with the above statements.

## Section L: Research Participants- Children

***1. Please complete this Section if “Children” is selected in D4.***

***2. Please complete L6 if only “medical records review” is selected in D3 and “Children” is selected in D4.***

**L1. Describe if studies have been conducted on animals and adults first, and data is available to assess risks to children participating in the research.**

Click or tap here to enter text.

**L2. Please justify the need to involve children and if the research question can be answered through alternative means (e.g., involving adults only)?**

Click or tap here to enter text.

**L3. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from children who lacks sufficient understanding and intelligence to give consent?**

Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)





**L3. (a) Please state the type of human tissues. (If “Yes” is selected in L3)**

Click or tap here to enter text.

**L3. (b) The removal of the tissue involves no more than minimal risk to children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion. (If “Yes” is selected in L3)**

Click or tap here to enter text.

**L3. (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue from children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion. (If “Yes” is selected in L3)**

Click or tap here to enter text.

**L4. Describe how the relation of potential benefits to risks is at least as favourable as that presented by alternative approaches.**

Click or tap here to enter text.

**L5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.**

Click or tap here to enter text.

**L6. What are the provisions for obtaining the child's assent and their legal representative’s consent?**



**L6. (a) Please select where appropriate: (If “Assent will be obtained from all children above 6 years old and consent will be obtained from their legal representative” is selected in L6)**

[ ]  Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form.

[ ]  Child's agreement regarding participation in the study will be documented using Participant Information Sheet and Consent Form.

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| **L6. (a) Attachment (If “Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form” is selected in L6 (a))** |
| Click or tap here to enter text. |



**L6. (b) Please justify. (If “Assent will not be obtained from the children. Consent will be obtained from their legal representative “is selected in L6)**

Click or tap here to enter text.



**L6. (c) (i) Please justify. (If “Only assent will be obtained. Consent will not be obtained from their legal representative “is selected in L6)**

Click or tap here to enter text.

**L6. (c) (ii) Please select where appropriate: (If “Only assent will be obtained. Consent will not be obtained from their legal representative “is selected in L6)**

[ ]  Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form.

[ ]  Child's agreement regarding participation in the study will be documented using Participant Information Sheet and Consent Form.

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| **L6. (c) (ii) Attachment (If “Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form” is selected in L6. (c)(ii))** |
| Click or tap here to enter text. |



**L6. (d) Please justify. (If “Neither the child’s assent nor consent of their legal representative will be obtained“ is selected in L6)**

Click or tap here to enter text.

## Section M: Research Participants- Prisoners

***Please complete this Section if “Prisoners” is selected in D4. However, this Section need not be completed if only “medical records review” is selected in D3.***

**M1. How does the research purpose justify enrolling prisoners?**

Click or tap here to enter text.

**M2. Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which research participants will be recruited?**

Click or tap here to enter text.

**M3. Are potential research related risks to prisoners comparable to risks that would be accepted by non-prisoner volunteers?**

Click or tap here to enter text.

**M4. Describe the systems in place to ensure research participant and data confidentiality.**

Click or tap here to enter text.

**M5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants?**

Click or tap here to enter text.

## Section N: Research Participants- Cognitively Impaired Persons

***Please complete this Section if “Cognitively Impaired Persons” is selected in D4. However, this Section need not be completed if only “medical records review” is selected in D3.***

**N1. Please explain why the research cannot be carried out without the involvement of cognitively impaired persons (i.e., justifications for the involvement of cognitively impaired persons).**

Click or tap here to enter text.

**N2. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from (1) an adult who lacks mental capacity; OR (2) children who lacks mental capacity?**

Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)





**N2. (a) Please state the type of human tissues. (If “Yes” is selected in N2)**

Click or tap here to enter text.

**N2. (b) The removal of the tissue involves no more than minimal risk to this group of participants. Please justify how your study meets this criterion. (If “Yes” is selected in N2)**

Click or tap here to enter text.

**N2 (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue to this group of participants. Please justify how your study meets this criterion. (If “Yes” is selected in N2)**

Click or tap here to enter text.

**N3. Are adequate procedures for evaluating the mental status of prospective research participants employed to determine if they can provide consent?**



**N3. (a) Please elaborate. (If “yes” is selected in N3)**

Click or tap here to enter text.



**N3. (b) Please explain why adequate procedures are not being employed? (if “No” is selected)**

Click or tap here to enter text.

**N4. Will legal representatives (LRs) be approached to give consent on behalf of the individuals judged incapable of providing consent?**





**N4. (a) Please elaborate. (If “No” is selected in N4)**

Click or tap here to enter text.

**N5. Will a separate Consent Form be used for cognitively impaired persons?**



|  |
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| **N5. (a) Attachment (If “(a) Yes, please submit the consent form” is selected in N5)** |
| Click or tap here to enter text. |



**N5. (b) Please elaborate. (if “(b) No” is selected in N5)**

Click or tap here to enter text.

**N6. If a research participant is incapable of giving valid consent, will his/her objection to participation be overridden?**





**N6. (a) Please elaborate. (If “Yes” is selected in N6)**

Click or tap here to enter text.

**N7. Will the research participant's physician or other health care provider be consulted before any individual is invited to participate in the research?**





**N7. (a) Please elaborate. (If “No” is selected in N7)**

Click or tap here to enter text.

**N8. Is there a possibility that the request to study participation, may provoke anxiety, stress or any other serious negative response?**





**N8. (a) Please elaborate. (If “yes” is selected in N8)**

Click or tap here to enter text.

**N9. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.**

Click or tap here to enter text.

## Section O: Consent Process- Waiver of Documentation of Informed Consent (Verbal or Implied Consent)

***Please complete this Section if “Waiver of documentation of informed consent (Verbal or Implied Consent)” is selected in D5 or F3.***

**O1. Documentation of consent will only be waived if certain conditions are fulfilled. Please select the appropriate category.**



**O1. (a) (i) The only record linking the research participant and the research would be the consent document. (If “(a) Category A” is selected in O1)**

Click or tap here to enter text.

**O1. (a) (ii) The principal risk would be potential harm resulting from a breach of confidentiality. (If “(a) Category A” is selected in O1)**

Click or tap here to enter text.

**O1. (a) (iii) The research is not subjected to FDA regulations. (If “(a) Category A” is selected in O1)**





**O1. (a) (iv) Each research participant will be asked whether the research participant wants documentation linking the research participant with the research, and the research participants’ wishes will govern. (If “(a) Category A” is selected in O1)**







**O1. (b) (i) The research presents no more than minimal risk of harm to research participants. (If “(b) Category B” is selected in O1)**

Click or tap here to enter text.

**O1. (b) (ii) The research involves no procedures for which written consent is normally required. (If “(b) Category B” is selected in O1)**

Click or tap here to enter text.

**O2. Will information sheet be provided?**





|  |
| --- |
| **O2. Attachment (If “Yes, please submit the information sheet” is selected in O2)** |
| Click or tap here to enter text. |

## Section P: Consent Process- Waiver of Informed Consent during Emergency Situation (Clinical Trial)

***Please complete this Section if "Clinical Trial” is selected in D2 and “Waiver of informed consent during emergency situation” is selected in D5.***

**Note: For the conduct of clinical trials in emergency situation, please be reminded to submit to the Health Sciences Authority written certifications by the PI and 2 independent specialists as stipulated in Section 8(3) of the Health Products/ Medicines (Clinical Trials) Regulations.**

**P1. Please justify why this study meets the following as a clinical trial in an emergency situation.**

**P1. (a) The trial needs to be conducted on potential participants who are facing a life-threatening situation to determine the safety or efficacy of an investigational product.**

Click or tap here to enter text.

**P1. (b) Available treatments or procedures are unproven or unsatisfactory.**

Click or tap here to enter text.

**P1. (c) There is a reasonable prospect that participation in the trial will directly benefit the potential participants because:**

* 1. **the potential participants are facing a life-threatening situation that necessitates intervention**
	2. **the appropriate non-clinical and clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the proposed use of the therapeutic product to provide a direct benefit to the potential participants; and**
	3. **the risks associated with the trial are reasonable in relation to what is known about:**
		1. **the medical condition of the potential participants**
		2. **the risks and benefits of standard therapy, if any; and**
		3. **the risks and benefits of the proposed used of the therapeutic product.**

Click or tap here to enter text.

**P1. (d) The trial participants are unable to consent to being trial participants in the trial as a result of their medical condition.**

Click or tap here to enter text.

**P1. (e) It is not feasible to obtained consent from the legal representatives of the potential trial participants within the window period.**

Click or tap here to enter text.

**P1. (f) There *is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the trial.***

Click or tap here to enter text.

**P2. Please explain what the window period is in relation to the amount of time to be devoted to seeking informed consent.**

Click or tap here to enter text.

**P3. If the prospective trial participant is unable to consent, please describe the procedures to obtain informed consent from the prospective trial participant’s legal representative or inform the prospective trial participant’s family member of their participation at the earliest feasible opportunity.**

Click or tap here to enter text.

**P4. If consent cannot be obtained from the prospective trial participant or participant's legal representative, and no family member has objected to the trial participant's trial participation, provision is made for an Investigator (who is a specialist) and 1 independent specialist to certify, prior to the enrolment of the trial participant that:**

1. **The prospective trial participant is facing a life-threatening situation which necessitates intervention;**
2. **The prospective trial participant is unable to consent as a result of his/her medical condition;**
3. **It is not feasible to obtain consent from the legal representative of the prospective trial participant within the window period; and**
4. **Neither the prospective trial participant nor the legal representative of the prospective trial participant nor any member of the prospective trial participant's family has informed the Principal Investigator of any objection to the prospective trial participant being a trial participant in the clinical trial.**

[ ]  Yes, the trial will be conducted in compliance with the above pre-enrolment certification.

**P5. After enrollment of a trial participant in a clinical trial in emergency situation, if the trial participant is unable to consent, describe the procedures for obtaining the trial participant’s legal representative informed consent at the earliest feasible opportunity. If informed consent cannot be obtained from the trial participant or his/ her legal representative, describe the procedures to contact his/ her family member about his/ her trial participation at the earliest feasible opportunity.**

Click or tap here to enter text.

**P6. If anytime during the clinical trial in an emergency situation, the trial participant regains capacity to give consent, a full explanation of the clinical trial will be explained to the trial participant to seek the trial participant’s consent to continue participation in the clinical trial.**

[ ]  Yes, informed consent will be sought from the trial participant when he/she regains capacity, at the earliest feasible opportunity.

**P7. Please submit the supporting documents relevant to this section. #**

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| **P7. Attachment** |
| Click or tap here to enter text. |

## Section Q: Consent Process- Waiver of Informed Consent during Emergency Situation (HBR)

***Please complete this Section if "Human Biomedical Research” or “Restricted Human Biomedical Research” is selected in D2 and “Waiver of informed consent during emergency situation” is selected in D5.***

**Please justify that the study meets the following criteria for emergency research.**

**Q1. The research participants are facing a life-threatening situation.**

Click or tap here to enter text.

**Q2. There is no professionally accepted standard of treatment, or the available treatment are unproven or are unsatisfactory.**

Click or tap here to enter text.

**Q3. The collection of valid scientific evidence is necessary to determine the safety and effectiveness of a particular intervention or treatment.**

Click or tap here to enter text.

**Q4. Participation in the proposed research holds out the prospect of direct benefit to the research participants.**

Click or tap here to enter text.

**Q5. Obtaining appropriate consent is not feasible because:**

1. **The research participant will not have capacity within the time available to give their appropriate consent as a result of their medical condition or situation; and,**
2. **The research participant’s legal representative is not available.**

Click or tap here to enter text.

**Q6. After enrolment of a participant in a study in emergency situation, if the participant is unable to consent, describe the procedures for obtaining the participant’s legal representative informed consent at the earliest feasible opportunity.**

Click or tap here to enter text.

**Q7. The research participant is to be informed as soon as is practicable after he or she regains capacity of his or her participation in the research and given an opportunity to withdraw from further participation in the research.**

[ ]  Yes, consent for continued participation will be sought from the research participant when he/she regains capacity.

**Q8. Provision is made for a specialist in the specialty relating to the research and who is not involved in the research as a researcher to certify, prior to the enrolment of the research participant that Sections Q1 to Q5 above have been complied with.**





**Q8. (a) please describe the process of certification that Q1 to Q5 have been complied with.  (If “No.” is selected in Q8)**

Click or tap here to enter text.

**Q9. Please submit the supporting documents relevant to this section. #**

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| **Q9. Attachment** |
| Click or tap here to enter text. |

## Section R: Consent Process- Waiver of Consent (Non-HBR)

***Please complete this Section if "Clinical Trial” or “Others” is selected in D2 and “Waiver of informed consent” is selected in D5 or F3.***

**Please justify how your study meets the following criteria for Non-HBR Study.**

**R1. The study poses no more than minimal risk to research participants.**

Click or tap here to enter text.

**R2. Waiver of informed consent will not adversely affect the rights and welfare of research participants.**

Click or tap here to enter text.

**R3. The study cannot be practically conducted without the waiver of informed consent.**

Click or tap here to enter text.

**R4. Whenever appropriate, will the research participants be provided with additional pertinent information after participation?**





**R4. (a) Please explain. (if “Yes.” is selected)**

Click or tap here to enter text.

**R5. Do you have any additional comments supporting the waiver of informed consent?**





**R5. (a) Please explain.****(if “Yes.” is selected)**

Click or tap here to enter text.

## Section S: Consent Process- Waiver of Consent (HBR)

***Please complete this Section if "Human Biomedical Research” or “Restricted Human Biomedical Research” is selected in D2 and “Waiver of informed consent” is selected in D5 or F3.***

**S1. Please select the type of waiver required.**

[ ]  Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3 (individually identifiable health information or human biological material obtained or compiled before, on and/ or after 1 Nov 2017)

[ ]  Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4 (individually identifiable health information obtained or compiled before 1 Nov 2017)

[ ]  Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5 (individually identifiable human biological material obtained or compiled before 1 Nov 2017)

**Please justify how your study meets the following criteria:**

**S1. (a) The use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor. (if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3”, “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4“or “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5“is selected in S1)**

Click or tap here to enter text.

**S1. (b) The waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor. (if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3”, “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4“or “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5“is selected in S1)**

Click or tap here to enter text.

**S1. (c) The research cannot reasonably be carried out without the use of the human biological material or health information in an individually‑identifiable form. (if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3”, “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4“or “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5“is selected in S1)**

Click or tap here to enter text.

**S1. (d) The process of obtaining consent from the person, to which the individually‑identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements. (if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3” or “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4“is selected in S1)**

Click or tap here to enter text.

**S1. (e) Reasonable effort has been made to re‑contact the person to which the individually‑identifiable human biological material relates for the purpose of obtaining his or her consent. (if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5” is selected in S1)**

Click or tap here to enter text.

**S1. (f) The human biomedical research or health information research would reasonably be considered to contribute to the greater public good. Please select the applicable checkbox(es). if “Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3.” is selected** **in S1)**

[ ]  (i) Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large.

**S1 (f) (i) Please explain: (if “Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large” is selected in S1. (f))**

Click or tap here to enter text.

[ ]  (ii) Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a sub-community.

**S1 (f) (ii) Please explain: (if “Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a sub-community” is selected in S1. (f))**

Click or tap here to enter text.

[ ]  (iii) Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields,

**S1 (f) (iii) Please explain: (if “Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields.” Is selected in S1. (f))**

Click or tap here to enter text.

## Section T: Research Data Confidentiality

***Please complete this Section if "Application Form” is selected in D1.***

**T1. Please select the mode of identification for the research data at the point of collection of research data.**









**T1. (a) Please elaborate. (if “Other methods” is selected in T1)**

Click or tap here to enter text.

**T2. Please state how the research data will be protected to ensure confidentiality and security.**

[ ]  Hardcopy data will be stored in designated locked location (e.g., cabinet(s), room(s), etc) that

 are accessible to authorized study personnel only.

[ ]  Electronic data will be stored in institution approved secure, and encrypted storage medium,

 such as databases, encrypted portable media (e.g., USB drives, CD/DVD, hard disks), and/or

 institution approved online storage platforms. The electronic data will not contain research

 participant identifiers. Identification code linking electronic data and research participants will

 be stored separately.

**T3. Describe who will have access to the research data, and how the access will be controlled and monitored?**

Click or tap here to enter text.

**T4. How will the research data be managed upon study completion?**





**T4. (a) Would the research data be stored in an identifiable format? (if “The research data will be used for future research” is selected in T4)**

Click or tap here to enter text.

**T4. (b) Please state where the research data would be stored. (if “The research data will be used for future research” is selected in T4)**

Click or tap here to enter text.

## Section U: Research Data - Recording of study procedures on audiotape, film/video, or other electronic medium.

***Please complete if “Recording of study procedures on audiotape, film/video, or other electronic medium” is selected in D3.***

**U1. Please describe the contents of the recording (e.g. audio-recoding of interview/ focus group discussion, images of facial feature, etc).**

Click or tap here to enter text.

**U2. What is the medium (audio tape/ video etc) used for recording?**

Click or tap here to enter text.

**U3. Explain how the recorded information will be used in the study.**

Click or tap here to enter text.

**U4. For how long and where will the recording medium be stored? Who will have access, how will access be controlled and monitored?**

Click or tap here to enter text.

**U5. How will the recording medium be disposed?**

Click or tap here to enter text.

## Section V: Research Data - Use of software or mobile applications

***Please complete this Section if “Use of software or mobile applications” is selected in D3.***

**V1. Please select the type of software(s) applicable and the name of software (including third party and mobile applications) Please also attach the supporting documents (if any).**

[ ]  (a) Telehealth Medical Device

**V1. (a) Name of Telehealth Medical Device: (If “(a) Telehealth Medical Device” is selected in V1)**

Click or tap here to enter text.

|  |
| --- |
| **V1. (a) Attachment (If “(a) Telehealth Medical Device” is selected in V1)** |
| Click or tap here to enter text. |

[ ]  (b) Telehealth Wellness Device

**V1. (b) Name of Telehealth Wellness Device: (If “(b) Telehealth Wellness Device” is selected in V1)**

Click or tap here to enter text.

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| **V1. (b) Attachment (If “(b) Telehealth Wellness Device” is selected in V1)** |
| Click or tap here to enter text. |

[ ]  (c) Others

**V1. (c) Name of software: (If “(c) Others” is selected in V1)**

Click or tap here to enter text.

|  |
| --- |
| **V1. (c) Attachment (If “(c) Others” is selected in V1)** |
| Click or tap here to enter text. |

**V2. Please describe the following:**

* + - * + What data would be collected via the telehealth device?
				+ Where the data would be stored?
				+ Who have access to the data?
				+ How would the research data confidentiality be protected?

Click or tap here to enter text.

**V3. Assurances by Principal Investigator.**

* + The use of usage of the software or a mobile application and storage of data will be in compliance with institution policy.

[ ]  I agree with the above statement.

## Section W: Biological Materials Usage & Storage

***Please complete this Section if "Human Biological Material” is selected in D3.***

**W1. Please select where applicable:**

[ ]  (a) Human biological materials will be obtained prospectively

**W1. (a) (i) Type of human biological material****: (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Click or tap here to enter text.

**W1. (a) (ii) How they will be collected? (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Click or tap here to enter text.

**W1. (a) (iii) Amount to be collected and frequency of collection: (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Click or tap here to enter text.

**W1. (a) (iv) Total amount required for the research study: (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Click or tap here to enter text.

**W1. (a) (v) How human biological material would be identified? (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Choose an item.

**For “Other Methods”, please elaborate.**

Click or tap here to enter text.

 **W1. (a) (vi) Where will human biological material be stored during the study? (If “(a) Human biological materials will be obtained prospectively” is selected in W1)**

Choose an item.

[ ]  (b) Existing human biological materials will be used

**W1. (b) (i) Type of human biological material:** **(If “(b) Existing human biological materials will be used” is selected in W1)**

Click or tap here to enter text.

 **W1. (b) (ii) Source*:* (If “(b) Existing human biological materials will be used” is selected in W1)**

Click or tap here to enter text.

 **W1. (b) (iii) How human biological material would be identified?(If “(b) Existing human biological materials will be used” is selected in W1)**

Choose an item.

**For “Other Methods”, please elaborate.**

Click or tap here to enter text.

 **W1. (b) (iv) Where will human biological material be stored during the study? (If “(b) Existing human biological materials will be used” is selected in W1)**

Choose an item.

**W1. (b) (v) Supporting document. (If “(b) Existing human biological materials will be used” is selected in W1)**





|  |
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| **W1. (b) (v) Attachment (If “Yes, please attach supporting documents(s)” is selected in W1. (b) (v))**  |
| Click or tap here to enter text. |

**W2. What tests will be performed on these human biological materials?**

Click or tap here to enter text.

**W3. Will results from the tests be communicated to the research participants? If not, please explain.**

Click or tap here to enter text.

**W4. Will any cell lines be created from the human biological materials?**





**W4. (a) How will the cell lines be identified? (if “Yes” is selected at W4)**





**W4. (a) (ii) Who will maintain the codes linking the cell lines and its donor? (if “The cell lines are coded” is selected in W4. (a))**

Click or tap here to enter text.



**W4. (a) (iii) Please explain. (if “By other methods” is selected in W4. (a))**

Click or tap here to enter text.

**W5. How will the biological materials be managed upon study completion?**





**W5. (a) Please indicate the duration and purpose of the storage. (if “The biological materials will be stored is selected in W5)**

Click or tap here to enter text.

***W5. (b) Please indicate the location of storage. (if “The biological materials will be stored is selected)***

[ ]  (i) Tissue Bank under oversight or custodian of SingHealth/NHG

**W5. (b) (i) Name of the tissue bank. (if “Tissue Bank under oversight or custodian of SingHealth/NHG” is selected in W5. (b))**

Click or tap here to enter text.

[ ]  (ii) Other location

**W5. (b) (ii) (I) Please state the reason for storage on this location. (if “other location is selected in W5. (b))**

Click or tap here to enter text.

**W5. (b) (ii) (II) How will these stored biological materials be identified? (if “other location” is selected in W5. (b))**





**W5. (b) (ii) (II) (B) Who will maintain the codes linking the stored human biological materials and its donor? (If “The stored human biological materials are coded” is selected in W5. (b) (ii) (II))**

Click or tap here to enter text.



**W5. (b) (ii) (II) (C) Please elaborate: (if “By other methods” is selected in W5. (b) (ii) (II))**

Click or tap here to enter text.

## Section X: Data & Safety Monitoring

***Please complete this Section if "Application Form” is selected in D1 and either or some or all of these, “Human Biological Material”/ “Medical Device”/ “Surgical / Radiotherapy Procedure”/ “Interventions” and “Invasive procedures”/ is(are) selected in D3.***

**The purpose of the Data and Safety Monitoring Plan is to ensure the safety and well-being of research participants, and the integrity of the data collected for the study. Depending on the type and risk level of the study, this may include the Principal Investigator, experts within the department or institution, independent consultants or a combination of the said persons.**

**X1. Who will perform the data and safety monitoring?**





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| **X1. Attachment # (If “Data Safety Monitoring Board (DSMB), please attach the DSMB charter, if available” is selected in X1)** |
| Click or tap here to enter text. |



**X1. (a) Please elaborate: ((if “Other” is selected in X1)**

Click or tap here to enter text.

**X2. Please describe the Data and Safety Monitoring Plan.**

The following should be included:

* + - 1. Safety monitoring: Frequency of review, Type of data (e.g., adverse events/serious adverse events/ unanticipated problems involving risk to participants or others/ other safety parameters) that will be monitored and rules for withdrawing participants from study intervention(s).
			2. Data Monitoring Plan: Frequency of review (e.g., daily, weekly, quarterly) and how data integrity is assured?
			3. Stopping criteria for the research study based on efficacy, futility and safety criteria.
			4. Please state the route of dissemination of any data and safety information to the study sites, as well as the person/ team responsible for doing so.

Click or tap here to enter text.

## Other Attachments

**Note: Additional documents may be attached here. Documents relevant to the respective sections should not be attached here.**

|  |
| --- |
| **Other Attachments** |
| Click or tap here to enter text. |