**STATEMENT OF CONFIRMATION BY PI FOR**

**PROJECT NOT REQUIRING SUBMISSION TO CIRB**

|  |  |
| --- | --- |
| **Project Title:** | Click or tap here to enter text. |
| **Objectives:** | Click or tap here to enter text. |

The purpose of this form is for Principal Investigators (PI) to determine and declare that the project involves any of the following and do not need to be submitted to CIRB for approval:

1. Part 1 - [Use of anonymised data and / or human biological materials (HBM)](#_PART_1:_Use); or
2. Part 2 - [Quality Assurance (QA) and Service Improvement (SI) projects.](#_PART_2:_Quality)

This form should be submitted to the Principal Investigators’ HOD and Institution Representative to obtain approval for the conduct of this project.

If either the Department Representative or the Institutional Representative is not agreeable to the declaration, submission to CIRB is required. Please note that review fees will apply after submission to CIRB regardless of the review outcome. (Refer to Annex 1 on the workflow)

**Note:**

* Submission to CIRB is required for research projects involving the following:

1. Restricted human biomedical research as described in the Fourth Schedule of the HBRA (Refer to Annex 2),
2. Creation of a tissue bank or conduct of any tissue banking activities with HBM,
3. Use of individually-identifiable HBM and data,
4. Use of anonymised HBM but involves any of the following:

(a) human gametes or human embryos;

(b) cytoplasmic hybrid embryos;

(c) the introduction of any human-animal combination embryo into an animal or a 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); or

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

(*Section 3(3) of the HBRA*).

* Prohibited human biomedical research as described in the Third Schedule of the HBRA (Refer to Annex 2) cannot be conducted.

|  |
| --- |
| **PART 1: Use of anonymised data and / or human biological materials (HBM)** |
| “Anonymised data” refers to a data set that has removed all 15 Direct Identifiers (DI) and cannot be re-associated with the data or the underlying individual, or of relatives, employers, or household members. Recipients of the anonymised data should not attempt to re-identify the data. (*SHS-MI-R-201SingHealth Cluster Data Policy – Use of Clinical, Operational and Research Data for Purpose of Research*)   1. Applicable Scenarios: 2. The Principal Investigator / project team receives the data / HBM without any identifiers or links to identifiers; 3. An institutional appointed Trusted Third Party (TTP) is engaged in extracting or providing the data / HBM\* in an anonymised manner.   \*The HBM in an anonymised manner can be referred to:   * HBM from registered Tissue Bank; or * Legacy HBM rendered non‑identifiable within the meaning of section 27(3) of the HBRA at any time before 1 November 2019.  1. Not Applicable Scenarios: 2. PI / project team extracts data from electronic or physical medical records with identifiers, and de-identifies for research use. 3. PI / project team views electronic or physical medical records, and records down the non-identifiable subject data for research use. 4. PI / project team performing B1 or B2 followed by de-identification through a process described in A1 or A2. |

|  |  |
| --- | --- |
| 1. **Please declare that you and the project team will not use & do not have access to the list of identifiers throughout your project.**   *Please refer to SHS-MI-R-201 SingHealth Cluster Data Policy – Use of Clinical, Operational and Research Data for Purpose of Research for the list of 15 Direct Identifiers.* | |
|  | PI and project team will not use and do not have access to the list of identifiers. |
|  | If PI and project team will use or have access to the identifiers, please submit to CIRB for review. |

|  |  |
| --- | --- |
| 1. **Information** | |
| **Data / HBM Source:** | Click or tap here to enter text. |
| **Data / HBM Owner:** | Click or tap here to enter text. |
| **TTP anonymising the Data / HBM\*:** | Click or tap here to enter text. |
| **Project Team Members handling the Data / HBM:** | Click or tap here to enter text. |

|  |
| --- |
| **PART 2: Quality Assurance (QA)/ Service Improvement (SI) projects** |

Quality Assurance (QA) and Service Improvement (SI) projects *generally do not* require IRB approval. However, QA/SI projects with research intent (research outcomes) or additional risk or burden to the participants will require Institutional Review Board (IRB) review and approval prior to its conduct. The following checklist can be used to determine if a QA/SI project requires IRB review prior to its conduct.

**Checklist to determine if IRB review is required**

Where **all** the responses to the questions in the checklist below are “**Yes**”, then the project is considered a QA/SI which does not require IRB review and approval to proceed. The project should still be conducted in an ethical manner and be compliant with any applicable policies, acts and regulations, e.g. SingHealth Personal Data Protection Act (PDPA) policies.

Where **any one** of the responses to the questions below is indicated with a “**No**”, the project requires IRB review and approval/IRB exemption prior to its conduct.

|  |  |  |  |
| --- | --- | --- | --- |
| **Questions** | | **Yes** | **No** |
| 1 | Is the project designed to assess, audit or improve healthcare service delivery/patient care and outcomes in SingHealth?  Note: QA/SI projects with *research intent* requires IRB approval. |  |  |
| 2 | Will the results of the project only be reported and used within SingHealth/Ministry of Health (MOH) or to be published (eg. in a journal, poster, conference) as a QA/SI?  For publication of QA/SI:   * *QA/SI results may be published, however conditions to use the QA/SI results for publications would depend on the journal or publisher’s requirement. Project team should explain to the journal on the nature of the project (QA/SI) if the journal requires an IRB approval.* * *The publication should not be described as research and will need to state clearly that the project is a QA/SI where IRB approval has not been obtained for the QA/SI.* * *When QA/SI is published or presented, the intent is to discuss local improvements, strategies rather than to develop or contribute to ‘generalizable’ knowledge.* * *A QA/SI project cannot be viewed as a Human Biomedical Research (HBR), as there has been no IRB review and no consent obtained from the patients for use in research.* * *The act of presenting or publishing a QA/SI project does not change its classification to be research.* |  |  |
| 3 | Does the project involve collection and analysis of data which the SingHealth project team has **or** will have the authorized rights to access?  *Note: If the project team does not have existing authorized right to access to the data, the project team should obtain the necessary approvals before starting the study.* |  |  |
| 4 | Does the project only involve observation, surveys, interview and/or data collection, without affecting clinical care?  *Note: When* ***one or more conditions below is met****, this question should be ticked as “No”*   1. *The implied consent from subjects is inadequate and /or the activity is inconsistent with subjects’ privacy and confidentiality* 2. *The proposed QA/SI activity pose risks for subjects beyond those of their routine care* 3. *The proposed QA/SI activity pose a burden on subjects beyond that experienced in their routine care* 4. *The proposed QA/SI activity to be conducted by a person who does not normally have access to the subjects’ records for clinical care or outside the usual permissible QA/SI activities* 5. *The proposed QA/SI activity risk breaching the confidentiality of any individuals’ personal information, beyond that experienced in the provision of routine care* 6. *The proposed QA/SI activity involve any clinically significant departure from the routine clinical care provided to the subjects* 7. *The proposed QA/SI activity involve prospective randomization or the use of a control group or placebo* 8. *The proposed QA/SI activity seek to gather information about the subject beyond that collected in routine clinical care* 9. *The proposed QA/SI activity potentially infringe the rights, privacy or professional reputation of careers, healthcare providers or institutions* |  |  |

| **Declaration by Principal Investigator** | |
| --- | --- |
| I declare that all the information given by me in this form are true to the best of my knowledge and that I have not willfully suppressed any material fact.   |  |  | | --- | --- | |  | | | Signature/ e-Signature and Date | | | Name: | | Click or tap here to enter text. | | | Designation | | Click or tap here to enter text. | | | Department | | Click or tap here to enter text. | | | Institution: | | Click or tap here to enter text. | | | |
|  | |
| **Endorsement by Department Representative** | |
| **PART 1: Use of anonymised data and / or human biological materials (HBM)** | |
|  | I agree with the declaration made by the Principal Investigator, that the project involves anonymised data and/or HBM\* and does not require CIRB review. |
|  | The project involves use of / access to identifiable data and/or HBM and requires submission to CIRB for review. |
| **PART 2: Quality Assurance (QA)/ Service Improvement (SI) projects** | |
|  | I agree with the declaration made by the Principal Investigator, that the project is a QA/SI project and does not require CIRB review. |
|  | The project is a research project that requires submission to CIRB for review. |
| |  |  | | --- | --- | |  | | | Signature/ e-Signature and Date | | | Name: | | Click or tap here to enter text. | | | Designation | | Click or tap here to enter text. | | | Department | | Click or tap here to enter text. | | | Institution: | | Click or tap here to enter text. | | | |
|  | |
| **Endorsement by Institution Representative** | |
| **PART 1: Use of anonymised data and / or human biological materials (HBM)** | |
|  | I agree with the declaration made by the Principal Investigator, that the project involves anonymised data and/or HBM\* and does not require CIRB review. |
|  | The project involves use of / access to identifiable data and/or HBM and requires submission to CIRB for review. |
| **PART 2: Quality Assurance (QA)/ Service Improvement (SI) projects** | |
|  | I agree with the declaration made by the Principal Investigator, that the project is a QA/SI project and does not require CIRB review. |
|  | The project is a research project and requires submission to CIRB for review. |
| |  | | | --- | --- | | Signature/ e-Signature and Date | | | Name: | | Click or tap here to enter text. | | | Designation | | Click or tap here to enter text. | | | Department | | Click or tap here to enter text. | | | Institution: | | Click or tap here to enter text. | | | |

References:

1. [SHS-MI-R-201 SingHealth Cluster Data Policy – Use of Clinical, Operational and Research Data for Purpose of Research](https://shhqdocupedia.shs.com.sg/SingHealthCorporateOffice/MI/PaP/PublishedDocuments/SHS-MI-R-201%20SingHealth%20Cluster%20Data%20Policy%20%E2%80%93%20Use%20of%20Clinical,%20Operational%20and%20Research%20Data%20for%20Purpose%20of%20Research.pdf) (*intranet required*)
2. [Checklist for Quality Assurance (QA)/ Service Improvement (SI) projects](https://infopedia.shs.com.sg/SingHealth/SPECIAL/Personal%20Data%20Protection%20Act/Documents/QASIchecklist_01Aug2019.pdf) (*intranet required*)
3. [Human Biomedical Research Act 2015](https://sso.agc.gov.sg/Act/HBRA2015)

**Annex 1**

**SUBMISSION WORKFLOW**

PI to fill and sign the Form (via hardcopy or electronically).

DR and IR to endorse (via hardcopy or electronically).

Form to be submitted to relevant departments for the release of data and HBM for the project (if applicable).

DR and/or IR is not agreeable with the declaration.

Submit Application Form on ECOS for review (Review fee applies).

**Annex 2**

**HUMAN BIOMEDICAL RESEARCH ACT**

**THIRD SCHEDULE: PROHIBITED HUMAN BIOMEDICAL RESEARCH**

* 1. Human biomedical research involving the development of human-animal combination embryos referred to in paragraph 2(a)(i) or (iii) of the Fourth Schedule beyond 14 days or the appearance of the primitive streak, whichever is the earlier.
  2. Human biomedical research involving the implantation —

1. of a human-animal combination embryo mentioned in paragraph 2(a)(i) or (iii) of the Fourth Schedule into the uterus of an animal; or
2. of a human-animal combination embryo into the uterus of a human.
   1. Human biomedical research involving the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of living great apes whether prenatal or postnatal.
   2. Human biomedical research involving the breeding of animals which have had any kind of human pluripotent stem cells (including induced pluripotent stem cells) introduced into them.

**FOURTH SCHEDULE: RESTRICTED HUMAN BIOMEDICAL RESEARCH**

1. Human biomedical research involving human eggs or human embryos.
2. Human biomedical research involving —
3. the following types of human-animal combination embryos:
4. cytoplasmic hybrid embryos;

(ii) human-animal combination embryos created by the incorporation of human

stem cells (including induced pluripotent stem cells);

(iii) human-animal combination embryos created in-vitro by using —

(A) human gametes and animal gametes; or

(B) one human pronucleus and one animal pronucleus;

1. the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo;
2. the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal;
3. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; or
4. any entity created as a result of any process referred to in sub-paragraphs (b), (c) and (d).
5. Nothing in this Schedule is to be construed to permit any human biomedical research that is prohibited under the Third Schedule.