**Type of Study Determination Form**

This Form is to help Investigators to determine on the type of study.

For new applications on iSHaRe, question 2 of the section “Selection of Application Form” should be available for investigators to determine on the type of study.

For those who have drafted the application where question 2 is not available, we recommend to put up a new application form with question 2 and delete the old drafted form.

**Section 1**

|  |  |
| --- | --- |
| **1** | **Please check if the study falls under any of the following categories:** |
| [ ]  | 1. Clinical Trials regulated by the Health Products Act (HPA)/ Medicines Act (MA);

*Only for trials that will be submitted to H.S.A to obtain CTC/CTA/CTN.* |
| The following types of studies are not considered Research. These studies do not need to be submitted for CIRB review.  |
| [ ]  | 1. Quality Assurance (QA)/ Service Improvement (SI)/ Service Evaluation Projects;

*Please refer to this* [*checklist*](http://shhqdocupedia/SingHealthCorporateOffice/GR/OoRIaC/OD/PublishedDocuments/QASIchecklist_01Aug2019.pdf) *to determine if your project falls under QA/ SI. If IRB review is required, please continue with Section 2 and also upload the QA/SI checklist together with this Form at “Other Attachment” of the CIRB Application Form.* |
| [ ]  | 1. Case Report of one to two patients;

*If the case report/ case series of more than three patients, please complete section 2.* |
| [ ]  | 1. Clinical Audit;
 |
| [ ]  | 1. Surveillance;
 |
| [ ]  | 1. Outbreak Investigations.
 |
| [ ]  | 1. If none of the above applies, please complete section 2.
 |
| **Note: The deifinition of “Service Evaluation”, “Clinical Audit”, “Surveillance” and “Outbreak Investigations” can be located in this** [**table**](https://www.singhealthdukenus.com.sg/research/rice/Documents/table-differentiating-research-from-research-like-activities_31jan2018.pdf) **from MOH. These categories are not research.** |

**Section 2**

This section is only applicable if 1(g) is selected.

If the research meets one of the definitions in 2 and 3, the research is a human biomedical research regulated under the Human Biomedical Research Act (HBRA).

|  |  |
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| **2** | **Please check if the research intends to study:** |
| [ ]  | 1. The prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;
 |
| [ ]  | 1. The restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques;
 |
| [ ]  | 1. The performance or endurance of human individuals.
 |
| [ ]  | 1. None of the above. Please explain why the above do not apply.

Click here to enter text. |

|  |  |
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| **3** | **Please check if the research involves the following:** |
| [ ]  | 1. 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;
 |
| [ ]  | 1. The use of any individually-identifiable human biological material;
 |
| [ ]  | 1. The use of any individually-identifiable health information.
 |
| [ ]  | 1. None of the above. Please explain why the above do not apply.

Click here to enter text. |

If your research involves any of the items in 4, it will be considered a human biomedical research regulated under the HBRA.

|  |  |
| --- | --- |
| **4** | **Please check if the research involves the following:** |
| [ ]  | 1. Human gametes or human embryos;
 |
| [ ]  | 1. Cytoplasmic hybrid embryos;
 |
| [ ]  | 1. The introduction of any human-animal combination embryo into an animal or a human;
 |
| [ ]  | 1. 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);
 |
| [ ]  | 1. Any entity created as a result of any process referred to in paragraph (c) or (d).
 |
| [ ]  | 1. None of the above.
 |

NOTE:

1. For further confirmation whether your research is a prohibited human biomedical research, please refer to the Third Schedule of the HBRA.
2. To confirm if your research is a restricted human biomedical research, please refer to the Fourth Schedule of the HBRA and submit the Restricted Human Biomedical Research Form (the form can be downloaded from CIRB website).

|  |  |
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| **5** | **Declaration** |
| **I, the Principal Investigator confirm that the information provided in this document is true and accurate.**

|  |  |
| --- | --- |
| Click here to enter text. | Click here to enter text. |
| *Principal Investigator’s Signature/ e-Signature* | *Date* |
| *Full Name:* | Click here to enter text. |
| *Institution:* | Click here to enter text. |
| *Department:* | Click here to enter text. |

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Note: Signature of Principal Investigator is not required when submitting together with the new application/ submission on iSHaRe.