

Ministry of Health

A Guide to TIARAS (Tissue and Research Application System)

Human Biomedical Research Act



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1 INTRODUCTION

This document provides the fields that Research Institutions (RIs) using Tissue and Research Application System (TIARAS) need to enter when setting up the RI's profile, submitting the Notification of Operation, Notification of Appointment of Institutional Review Board (IRB) and application for MOH approval to conduct restricted human biomedical research. The mandatory fields are marked with a red asterisk *.

2 SET UP RESEARCH INSTITUTION'S PROFILE & NOTIFICATIONS

2.1 STEP 1: CREATE NEW USER PARTICULARS

Create New User Particulars

- * Salutation
- * Name
- * Contact No
- * Email Address

2.2 STEP 2: SELECT ORGANISATION TYPE

Select Organisation Type

- * Choose one:
 - New Research Institution
 - Existing Research Institution

For existing research institution that is submitting the notification of operation more than 30 days after 1 November 2017:

- * Reasons for Late Notification

2.3 STEP 3: CREATE INSTITUTION PROFILE

Research Institution Profile

- * Institution Name

Public Contact Information:

- * Contact No
- * Email Address

Address of Site(s) in which Research is Conducted

*For research sites in Singapore
(mandatory for at least one site):*

* Postal Code

* Country

City

State

* Block No

* Street Name

Level

Unit

Building

Department

Contact No

Email Address

*For research sites outside Singapore
(optional):*

Postal Code

Country

City

State

Block No

Street Name

Level

Unit

Building

Department

Contact No

Email Address

Nature of Human Biomedical Research

Select the relevant checkboxes that apply.

Other Relevant Information

How many individuals are there in the research institution?

How many years has the research institution carried on any research activity on or before the appointed day?

Describe the governance framework to ensure the safety of research subjects and the ethical conduct of human biomedical research.

2.4 STEP 4: CREATE INSTITUTION USER PROFILE

Create Institution User Profile

* ID Type

* ID No

* Salutation

* Name

Designation

Institution Role:

* Role

If Role is OE:

* OE Type

Contact Information:

* Contact No

* Email Address

2.5 STEP 5: CREATE NOTIFICATION OF OPERATION

Details of Research Institution

* Institution Name

Contact Information

Place of Business:

* Postal Code

* Country

* Block No

* Street Name

Level

Unit

Building

Department

* Contact No

* Email Address

For Existing Research Institution:

Conduct of Restricted Human Biomedical Research (Refer to the Fourth Schedule of the Human Biomedical Research Act)

* Is your research institution currently conducting any restricted research which commenced before 1 November 2017?

- Yes
- No

For New Research Institution:

Commencement Date of the First Human Biomedical Research

* Commencement Date

For new research institution that is submitting the notification of operation less than 30 days before the commencement of its first human biomedical research:

* Reasons for Late Notification

Details of Principal Person in Charge

* ID Type

* ID No

* Salutation

* Name

* Designation

Contact Information

* Postal Code

- * Country
- * Block No
- * Street Name
- Level
- Unit
- Building
- Department
- * Contact No
- * Email Address

2.6 STEP 6: CREATE NOTIFICATION OF INSTITUTIONAL REVIEW BOARD

Institutional Review Board

Name of Institutional Review Board

Area of Research

Chairperson

- * ID Type
- * ID No
- * Salutation
- * Name
- * MCR No
- * Occupation

Period of Appointment

Chairperson's Contact Information

- * Postal Code

* Country

* Block No

* Street Name

Level

Unit

Building

Department

* Contact No

* Email Address

3 APPLICATION

Only research institutions intending to conduct restricted human biomedical research as defined in the Fourth Schedule of the Human Biomedical Research Act are required to submit an application to MOH for approval using TIARAS.

3.1 STEP 1: GENERAL INFORMATION

Read the instructions on the General Information page and click on the “Next” button to continue. No information from the research institution is required.

3.2 STEP 2: CREATE APPLICATION PROFILE

Application Users

Details of rHBR Endorser and rHBR Administrator

Select the name from the dropdown list and the rest will be populated

* Name

* Role

If Role is RE:

* rHBR Endorser Type

Details of Non-Account Holder (IF APPLICABLE)

* ID Type

* ID No

* Salutation

* Name

Designation

* Contact No

* Email Address

Source of Funding

* Type of Funding:

- Public
- Private
- Self-Funded
- Others, please specify

* Name of Funding Body

Grant Name

* Status of Grant Application

Grant Amount

Valid Period of Grant

3.3 STEP 3: CREATE APPLICATION DETAILS

Section 1: Study Information

* Title of Research Project

Section 2: Principal Researcher Information

Select the name from the dropdown list and the rest will be populated. If the name is not in the dropdown list, enter the following:

* ID Type

* ID No

* Salutation

* Name

Designation

* Contact No

* Email Address

Principal Researcher's Administrative Contact

* ID Type

* ID No

* Salutation

* Name

Designation

* Contact No

* Email Address

Section 3: Individuals Involved in the Research

* Select from the dropdown list which contains the names of rHBR Endorser, rHBR Administrator and Non-Account Holder listed in **Step 2: Create Application Profile**

Section 4: IRB Approval Information

* IRB Approval Period

(If the IRB approval does not have an end date, you may enter the IACUC end date. For embryo and oocyte research, there should not be an indefinite IRB approval period.)

Select from the dropdown list:

* IRB Chairperson

Section 5: Research Site(s)

* Name of Research Site

* Address

Section 6: Research that Requires MOH Approval

* Choose the categories below which best describes your research (Note that more than one category may apply):

- Category A

Research involving human eggs or human embryos. This includes derivation of new human embryonic stem cell lines from donated human embryos.

- * Information stipulated in Annex A
- * Declaration by Principal Researcher
- * IRB Declaration form
- Category B

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

 - 1) cytoplasmic hybrid embryos; or
 - 2) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells); or
 - 3) human-animal combination embryos created in vitro by using-
 - A. human gametes and animal gametes; or
 - B. one human pronucleus and one animal pronucleus
 - * Information stipulated in Annex B
 - * Declaration by Principal Researcher
 - * IRB Declaration form
- Category C

Research involving any of the following:

 - 1) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo; or
 - 2) 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; or
 - 3) the use of any entity created as a result of (1) or (2) above.
 - * Information stipulated in Annex C
 - * Declaration by Principal Researcher
 - * IRB Declaration form
- Category D

Research involving any of the following:

1) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; or

2) the use of any entity created as a result of (1) above.

* Information stipulated in Annex D

* Declaration by Principal Researcher

* IRB Declaration form

Section 7: Other Supporting Documents

* Other Supporting Documents:

- i. Approved IRB study protocol or application form & approval letter
- ii. Approved IACUC application form & approval letter (if applicable)

– END OF DOCUMENT –