Tissue and Research Application System (TIARAS)
Screenshots for – declaration of compliance and updates to TIARAS

Version Date: January 2019
Outline

1. Getting Started
   - Which research institution should submit declaration
   - When is the compliance period to declare for
   - How much is the declaration costs
   - What is a research site to be declared
   - Who can submit declaration
   - Updating institution profile page

2. Declaration of Compliance
   - Submitting declaration

3. Updates to TIARAS
   - Landing page
   - Institution profile page
   - Deactivate TIARAS users who left institution
   - Switch payment mode to credit/debit card
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For Declaration of Compliance in 2019

- Research institutions which submitted notification to MOH indicating:
  - It has commenced human biomedical research (HBR) before 1 Nov 2017, i.e. before the HBR framework was activated
  - It has intention to commence HBR on/before 31 Dec 2018
- Research institutions required to submit declaration of compliance will:
  - Receive automated email reminders before 1 Mar 2019
  - See “Declaration” in the menu navigation from 1 Mar 2019
- Research institutions should update in the institution profile page:
  - Number of research sites
  - If the research institution has been granted approval by MOH to conduct restricted research during the compliance period
When is the compliance period to declare for

For Declaration of Compliance in 2019

<table>
<thead>
<tr>
<th>Research institutions indicating</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>It has commenced HBR before 1 Nov 2017, i.e. before the HBR framework was activated</td>
<td>1 Nov 2017</td>
<td>31 Dec 2018</td>
</tr>
<tr>
<td>It has intention to commence HBR on/before 31 Dec 2018</td>
<td>Commencement date indicated in the notification of operation</td>
<td>31 Dec 2018</td>
</tr>
</tbody>
</table>
How much is the declaration

**Second Schedule of HBR Regulations**

<table>
<thead>
<tr>
<th>During the compliance period</th>
<th>Conducting restricted research with MOH’s approval</th>
<th>Not conducting restricted research with MOH’s approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>First research site</td>
<td>$4,000</td>
<td>$1,000</td>
</tr>
<tr>
<td>Each additional site</td>
<td>$500 per site</td>
<td>$500 per site</td>
</tr>
</tbody>
</table>

Where activities relating to research are conducted at 2 or more premises located within the same building (bearing the same postal code in each premises’ address) and under the supervision and control of a single research institution, these premises are counted as a single research site.
What is a research site to be declared

- Where HBR activities are carried out in the premises that are under your research institution’s governance, it will be considered a research site.

- If your research activities are conducted at 2 or more premises located within the same building (bearing the same postal code), these premises are counted as a single research site.

- Where research activities are conducted at residential homes or shopping centres, these public places need not be declared as a site.

- Where research activities are conducted at an academic institution with multiple faculties/schools, each faculty/school may declare as one site (i.e. even if the faculty/school is spread over multiple buildings with different postal codes).
Who can submit declaration

For Declaration of Compliance

- OEs and OAs are able to submit the declaration on behalf of the research institution
  - OE/OA who is also the principal person in charge is able to submit the declaration straightaway
  - Other OE/OA would need to upload a signed Declaration from the principal person in charge
Updating institution profile page

Login to TIARAS

- Go to https://elis.moh.gov.sg/tiaras
For Declaration of Compliance

- Research institutions should update in the institution profile page:
  - Number of research sites
  - If the research institution has been granted approval by MOH to conduct restricted research during the compliance period
Updating institution profile page

Add research site

- Enter the postal code
- Block number, street name and building (if applicable) will be populated
- Complete the rest of the address of research site

Address of Site(s) in which Research is Conducted

- Postal Code: 169853
- Block No: 14
- Street Name: COLLEGE ROAD
- Building: HARROWER HALL

Add Research Site

<table>
<thead>
<tr>
<th>S/N</th>
<th>Country</th>
<th>Address</th>
<th>Department</th>
<th>Contact No</th>
<th>Email Address</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Singapore</td>
<td>Blk 16 COLLEGE ROAD, COLLEGE OF MEDICINE BUILDING #01-01 Singapore 169854</td>
<td>61234567</td>
<td><a href="mailto:moh@moh.gov.sg">moh@moh.gov.sg</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Updating institution profile page

Add research site

• Click “Add Research Site”
• Address of research site will be populated in the table
• Continue to add the research sites in the research institution

Note: This page can be managed and revised as and when research sites change.
If the research institution has been granted approval by MOH to conduct restricted research during the compliance period, tick the box.
1. Getting Started
- Which research institution should submit declaration
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- How much is the declaration
- What is a research site to be declared
- Who can submit declaration
- Updating institution profile page

2. Declaration of Compliance
- Submitting declaration

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Submitting Declaration of Compliance

Submit Declaration of Compliance

- Click on “Declaration” in the menu navigation
Submitting Declaration of Compliance

Who can submit

- OEs and OAs are able to submit the declaration on behalf of the research institution
  - OE/OA who is also the principal person in charge is able to submit the declaration straightaway
  - Other OE/OA would need to upload a signed Declaration from the principal person in charge

OE/OA who is also the principal person in charge

OE/OA who is not the principal person in charge
Submitting Declaration of Compliance

Submit Declaration of Compliance

• Declaration of compliance section is the same as the First Schedule of the HBR Regulations

DECLARATION OF COMPLIANCE

I declare, on behalf of Ministry of Health, all of the following:

1. I have read and understood the Human Biomedical Research Act 2015 (Act 29 of 2015), and all regulations and codes of practice or ethics issued under that Act (collectively called the Act).

2. Except for such offences and contraventions as may have been notified to the Director of Medical Services in accordance with section 23(3) of the Human Biomedical Research Act 2015, all human biomedical research conducted under the supervision and control of the research institution between 01/11/2017 and 31/12/2018 comply with the Act.

3. The composition and appointment of all the institutional review boards of the research institution comply with the Act.

4. The research institution —
   (a) has formulated and implemented appropriate standards, policies and procedures to supervise, review and monitor the conduct of the human biomedical research conducted under its supervision and control;
   (b) supervises, reviews and proactively monitors the conduct of the human biomedical research conducted under its supervision and control;
   (c) has formulated and implemented a policy on whether or not the research subject should be re-identified and informed in the case of an incidental finding and has informed all institutional review boards and researchers under its purview of this policy;
   (d) ensures that the human biomedical research conducted under its supervision and control complies with the Act, and is conducted in accordance with the standards, policies and procedures mentioned to in sub-paragraph (a);
   (e) investigates any areas of concern and takes such remedial measures as appropriate;
   (f) in respect of human biomedical research conducted jointly or in collaboration with more than one research institution, has agreed among the research institutions for one research institution to be appointed as the lead research institution for the purpose of coordinating the research;
   (g) has performed such other functions and duties as may be prescribed by the Minister; and
   (h) regularly reviews —
      (i) the standards, policies and procedures formulated and implemented by the Research Institution to supervise, review and monitor the conduct of the human biomedical research conducted under its supervision and control;
      (ii) all serious adverse events (including unexpected serious adverse events);
      (iii) all safety lapses;
      (iv) all reports of any data and safety monitoring board established by the research institution; and
      (v) the performance of all institutional review boards appointed by the research institution.
Submitting Declaration of Compliance

Submit Declaration of Compliance

- Verify the number of research sites and if the research institution has been granted approval by MOH to conduct restricted research during the compliance period.

Research institution that is conducting restricted research & has one research site

Research institution that is not conducting restricted research & has two research sites

Please verify the following:

- Your research institution is conducting restricted human biomedical research.
- Address of site(s) in which research is conducted:

<table>
<thead>
<tr>
<th>S/N</th>
<th>Country</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Singapore</td>
<td>Blk 16 COLLEGE ROAD, COLLEGE OF MEDICINE BUILDING Singapore 169854</td>
</tr>
</tbody>
</table>

The above is extracted from the research institution's Institution Profile page.

Please verify the following:

- Your research institution is not conducting restricted human biomedical research.
- Address of site(s) in which research is conducted:

<table>
<thead>
<tr>
<th>S/N</th>
<th>Country</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Singapore</td>
<td>Blk 16 COLLEGE ROAD, COLLEGE OF MEDICINE BUILDING Singapore 169854</td>
</tr>
<tr>
<td>2</td>
<td>Singapore</td>
<td>Blk 14 COLLEGE ROAD, HARROWER HALL Singapore 169853</td>
</tr>
</tbody>
</table>

The above is extracted from the research institution's Institution Profile page.
Submitting Declaration of Compliance

Submit Declaration of Compliance

- Total fees payable will displayed
- Click “Proceed to Submit”

Research institution that is conducting restricted research & has one research site

Research institution that is not conducting restricted research & has two research sites

<table>
<thead>
<tr>
<th>Fees</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Where activities relating to research are conducted at 2 or more premises located within the same building (bearing the same postal code in each premises’ address) and under the supervision and control of a single research institution, these premises are counted as a single research site.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number</th>
<th>Fee per site ($)</th>
<th>Sub-Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First research site</td>
<td>1</td>
<td>4000</td>
</tr>
<tr>
<td>Additional research site</td>
<td>0</td>
<td>500</td>
</tr>
<tr>
<td>Total fees payable ($)</td>
<td></td>
<td>4000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fees</th>
<th></th>
</tr>
</thead>
<tbody>
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<tr>
<th>Number</th>
<th>Fee per site ($)</th>
<th>Sub-Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First research site</td>
<td>1</td>
<td>1000</td>
</tr>
<tr>
<td>Additional research site</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>Total fees payable ($)</td>
<td></td>
<td>1500</td>
</tr>
</tbody>
</table>

Cancel Proceed to Submit

Submit Declaration of Compliance
Submitting Declaration of Compliance

Payment Selection

- Select the preferred mode of payment
- Click “Confirm Payment”

For research institutions that made payment by GIRO previously:
- Last three digits of the bank account will be displayed
- No need to resubmit the GIRO Application form. The amount will be automatically deducted.

For payment by GIRO (first time):
- Download the GIRO Application Form
- Complete and return the form to MOH

For payment by cheque:
- Make the cheque payable to Ministry of Health
- On the reverse side of the cheque, please write your institution name, institution reference ID, bill reference number and contact number.
- Send the crossed cheque to MOH

Address:
Biomedical Research Regulation Branch,
Ministry of Health,
College of Medicine Building,
16 College Road,
Singapore 169854.
Submitting Declaration of Compliance

Payment Page

- Enter payment details
- Click "Pay"
Submitting Declaration of Compliance

Payment Acknowledgement

- Declaration of Compliance has been submitted to MOH
- This page may be printed for reference
- An email acknowledgement will be sent to the principal person in charge, all OEs, and all OAs
- The status of the Declaration of Compliance is now “Submitted”
- The icon ![icon] serves to remind research institutions that selected GIRO or Cheque to submit payment. The GIRO form or Cheque has to reach MOH within 30 days. The icon will be removed after MOH receives the payment.

Selected Credit/Debit card

Selected GIRO/Cheque
Submitting Declaration of Compliance

Dashboard

- Submitter may click “Home” to access his dashboard
- The status of the Declaration of Compliance is now “Submitted”

Selected Credit/Debit card

<table>
<thead>
<tr>
<th>Reference ID:</th>
<th>RI-123456</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution Name:</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>Status:</td>
<td>Submitted</td>
</tr>
<tr>
<td>Last Modified By/Date:</td>
<td>Lee Ah Boon</td>
</tr>
</tbody>
</table>

Selected GIRO/Cheque

<table>
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New layout

- Tissue bank module will only be available when the human tissue framework is activated
Institution profile page

Current layout

• With checkboxes

Nature of Human Biomedical Research

Please tick all box(es) that apply as of this date.

Research involving:

- Restricted human biomedical research (as defined in the Fourth Schedule of the Human Biomedical Research Act)
- Direct clinical intervention or invasive clinical procedures
- Adults who lack mental capacity (as defined in the Mental Capacity Act)
- Pregnant women
- People highly dependent on medical care who may be unable to give consent
- Persons whose autonomy might be prejudiced by being under the influence of, or obligated to, third parties (e.g. prisoners, uniformed personnel especially junior ranks, patients especially if the researcher is their attending physician, employees/junior collaborators or students)
- Minors (below 21 years of age and who have never been married)
- Deceased persons
- Other types of human biomedical research, please specify (e.g. exercise physiology)
New layout

- With radio buttons
- New question on whether the research institution is conducting research involving human tissue transplantation
- Check that the research institution’s nature of human biomedical research is still relevant

<table>
<thead>
<tr>
<th>Nature of Human Biomedical Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>My research institution is conducting human biomedical research involving the following:</strong></td>
</tr>
<tr>
<td>* 1. Human tissue transplantation</td>
</tr>
<tr>
<td>* 2. Restricted human biomedical research (as defined in the Fourth Schedule of the Human Biomedical Research Act)</td>
</tr>
<tr>
<td>* 3. Direct clinical intervention or invasive clinical procedures</td>
</tr>
<tr>
<td>* 4. Other types of human biomedical research, please specify (e.g. exercise physiology)</td>
</tr>
</tbody>
</table>

**Profile of my research subjects:**

| * 1. Adults who lack mental capacity (as defined in the Mental Capacity Act) | |
| * 2. Pregnant women | |
| * 3. People highly dependent on medical care who may be unable to give consent | |
| * 4. Persons whose autonomy might be prejudiced by being under the influence of, or obligated to, third parties (e.g. prisoners, uniformed personnel especially junior ranks, patients especially if the researcher is their attending physician, employees/junior collaborators or students) | |
| * 5. Minors (below 21 years of age and who have never been married) | |
| * 6. Deceased persons | |
Deactivate TIARAS users who left institution

- Enter the user’s profile page

**Search and edit user profile**

- **Name:** Tan Mu Lan
- **User Role:**
  - Select
  - Organisation Endorser (OE)
  - Organisation Administrator (OA)
  - Organisation Viewer (OV)
- **Institution Status:**
  - Active
  - Deactivated

**List of Users**

<table>
<thead>
<tr>
<th>S/N</th>
<th>ID No</th>
<th>Name</th>
<th>Role</th>
<th>Role Type</th>
<th>Designation</th>
<th>Email Address</th>
<th>Institution Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SXXXX587C</td>
<td>Tan Mu Lan</td>
<td>OE</td>
<td>Covering</td>
<td></td>
<td><a href="mailto:tanmulan@moh.gov.sg">tanmulan@moh.gov.sg</a></td>
<td>ACTIVE</td>
</tr>
</tbody>
</table>
Deactivate TIARAS users who left institution

Search and edit user profile

- Click “Deactivated”, “Save”, “Yes”
- Deactivated users would stop receiving automated emails from TIARAS
Change payment mode

For institutions which selected GIRO/Cheque but wishes to pay by credit/debit card

• Click “Change Payment Mode”
For institutions which selected GIRO/Cheque but wishes to pay by credit/debit card

- Select the credit/debit card option
- Click “Confirm Payment”
Change payment mode

Payment Page

- Enter payment details
- Click “Pay"
Change payment mode

**Payment Acknowledgement**

- User is brought to the payment acknowledgement page
- Payment has been made
- This page may be printed for reference
- The icon 🔴 has disappeared

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### Declaration of Compliance

Thank you.
You have successfully made the payment.
Please remember to print this page for your reference.

<table>
<thead>
<tr>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference ID: RI-xxxxxx</td>
</tr>
<tr>
<td>Last Modified By/Date: yyyy-mm-dd</td>
</tr>
<tr>
<td>Status: Submitted</td>
</tr>
</tbody>
</table>

### Payment Summary

<table>
<thead>
<tr>
<th>Bill Reference No: DC-190131185916-0036</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fee Type: Declaration of Compliance - Submission</td>
</tr>
<tr>
<td>Payment Mode: VISA</td>
</tr>
<tr>
<td>Transaction Number: 5489339408566717103006</td>
</tr>
<tr>
<td>Transaction Date: yyyy-mm-dd</td>
</tr>
<tr>
<td>Credit Card Number: xxxxxxx0000111</td>
</tr>
<tr>
<td>Total Amount Paid: SGD xxxxx</td>
</tr>
</tbody>
</table>

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For further enquiries, you may email hbr_enquiries@moh.gov.sg