

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

Version Date: February 2021

Declaration of Compliance 2021



1. Getting Started

- Which tissue bank should submit declaration
- When is the compliance period to declare for
- How much is the declaration
- What is a tissue bank site to be declared
- Who can submit declaration
- Updating institution profile page

2. Declaration of Compliance

• Submitting declaration

3. Updates & Other Functions

- Things to note
- Switch payment mode to credit/debit card
- Payment modes

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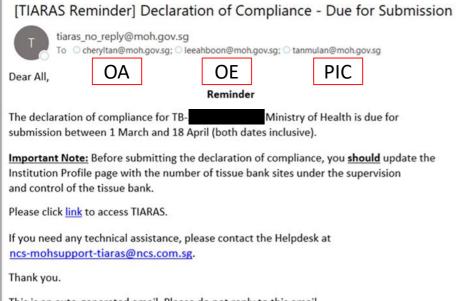
3. Updates & Other Functions

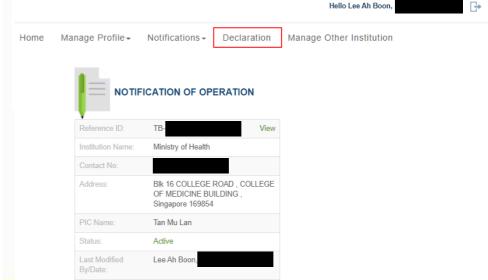
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Which tissue bank should submit declaration

For Declaration of Compliance in 2021

- Tissue banks which had submitted notification to MOH indicating:
 - It has commenced tissue banking activity before 1 Nov 2019, i.e. before the human tissue framework was activated
 - It has intention to commence tissue banking activity on/before 31 Dec 2020
- Tissue banks required to submit declaration of compliance will:
 - Receive automated email reminders before 1 Mar 2021
 - Need to click on "Declaration" in the menu navigation from 1 Mar 2021
- Tissue banks should update the following information in the institution profile page:
 - Number of tissue bank sites during the compliance period
 - If the tissue bank is storing or supplying tissue for use in research involving human tissue transplantation during the compliance period





When is the compliance period to declare for

For Declaration of Compliance in 2021

Tissue banks indicating	Start Date	End Date
It has commenced tissue banking activity before 1 Nov 2019, i.e. before the human tissue framework was activated	1 Nov 2019	31 Dec 2020
It has intention to commence tissue banking activity on/before 31 Dec 2020	Commencement date indicated in the notification of operation	31 Dec 2020

How much is the declaration

Second Schedule of HBR (Tissue Banking) Regulations

During the compliance period	Storing or supplying tissue for use in research involving human tissue transplantation	Not storing or supplying tissue for use in research involving human tissue transplantation
First tissue bank site	\$4,000	\$1,000
Each additional site	\$500 per site	\$500 per site

Where tissue is stored at 2 or more premises located within the same building (bearing the <u>same postal code</u> in each premises' address) and under the supervision and control of a <u>single tissue bank</u>, these premises are counted as a <u>single tissue bank site</u>.

What is a tissue bank site to be declared

- Where tissue banking activities are carried out in the premises that are under your tissue bank's governance, it will be considered a tissue bank site
- If your tissue banking 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 tissue bank site
- Where tissue banking activities are conducted at residential homes or shopping centres, these public places need not be declared as a site. Nonetheless, the tissue bank should always have supervision and control over <u>all</u> the tissue banking activities conducted regardless of whether the premises have been declared as sites during the declaration of compliance. Regulatory audits may also take place in any premises where tissue banking activities are carried out, regardless of declaration.
- Where tissue banking 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

- For OE/OA who is also the principal person in charge, you can submit the declaration directly to MOH in TIARAS
- For OE/OA who is <u>not</u> the principal person in charge, you would need to upload a signed Declaration from the principal person in charge if you would like to submit the Declaration directly to MOH in TIARAS

Login to TIARAS

Go to https://elis.moh.gov.sg/tiaras















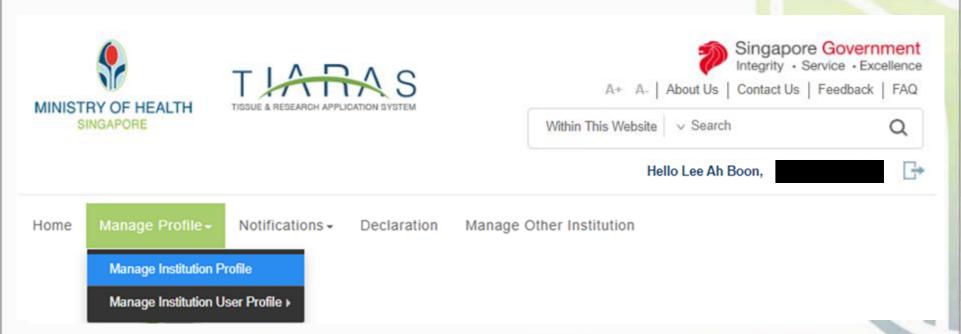


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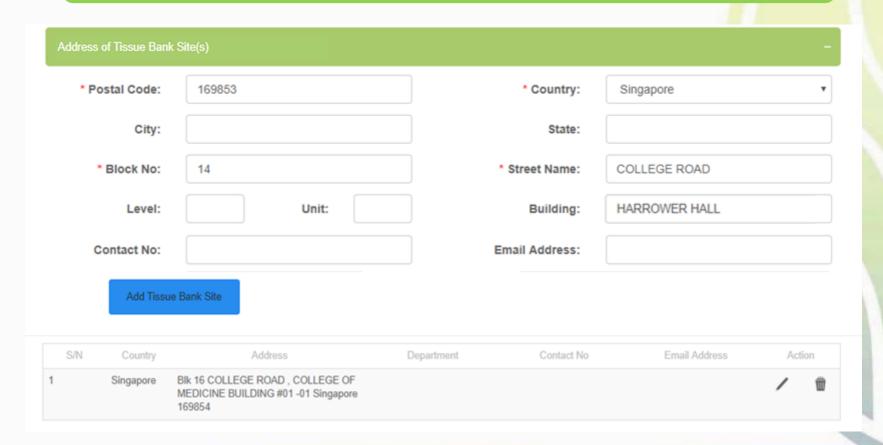
For Declaration of Compliance

- Tissue banks should update the following information in the institution profile page:
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Add tissue bank site

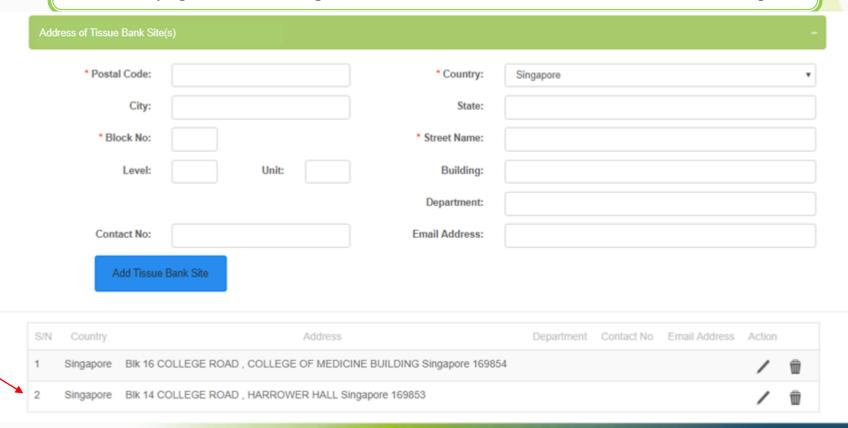
- Enter the postal code
- Block number, street name and building (if applicable) will be populated
- Complete the rest of the address of tissue bank site



Add tissue bank site

- Click "Add Tissue Bank Site"
- Address of tissue bank site will be populated in the table
- Continue to add the tissue bank sites in the tissue bank

Note: This page can be managed and revised as and when tissue bank sites change.



Conduct of tissue banking activities to facilitate research involving human tissue transplantation

 If the tissue bank is storing or supplying tissue for use in research involving human tissue transplantation during the compliance period, indicate "Yes"

Nature of Tissue Banking Activities			
My tissue bank is conducting tissue banking activities to facilitate:	Yes	No	/
* 1. Research involving human tissue transplantation	•		
* 2. Restricted human biomedical research (as defined in the Fourth Schedule of the Human Biomedical Research Act)			
* 3. Removal of tissue from tissue donors for use in research			
Profile of my tissue donors:			
* 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)		0	
* 5. Minors (below 21 years of age and who have never been married)			7
* 6. Deceased persons			-
* 7. Other classes of tissue donors, please specify			

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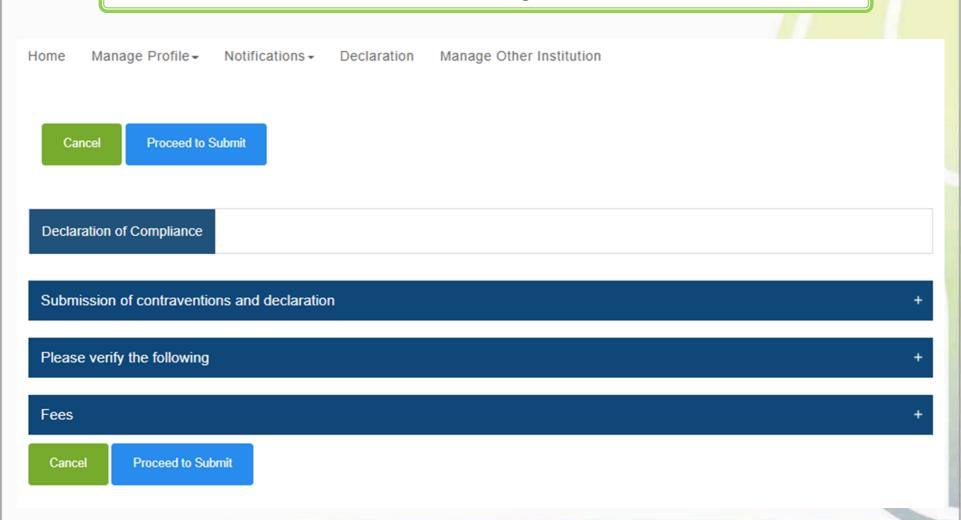
• Submitting declaration

3. Updates & Other Functions

- Things to note
- Switch payment mode to credit/debit card
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Submit Declaration of Compliance

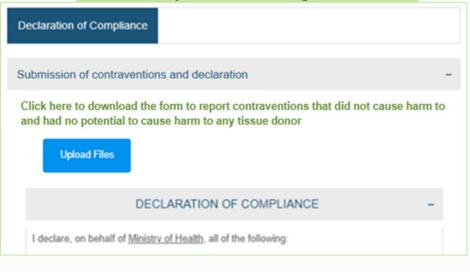
Click on "Declaration" in the menu navigation



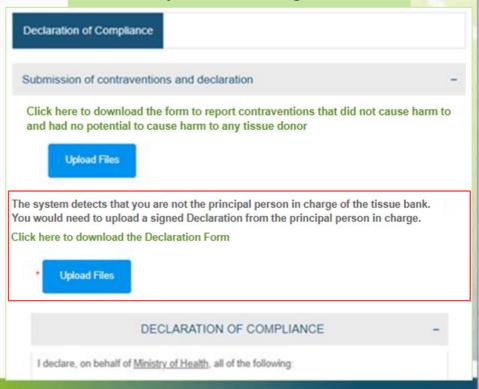
Who can submit

- For OE/OA who is also the principal person in charge, you can submit the declaration directly to MOH in TIARAS
- For OE/OA who is <u>not</u> the principal person in charge, you would need to upload a signed Declaration from the principal person in charge if you would like to submit the declaration directly to MOH in TIARAS

OE/OA who is also the principal person in charge

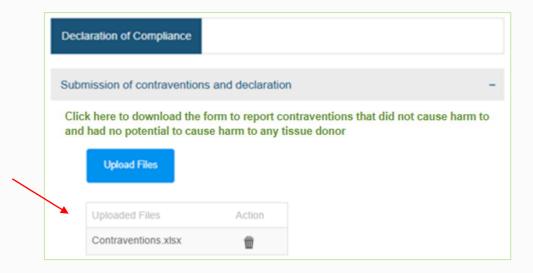


OE/OA who is not the principal person in charge



Submit suspected offences or contraventions (SOCs)

- These are SOCs that occurred during the compliance period
- Please submit the SOCs which <u>did not cause harm to and had no potential to cause harm</u>
 to any tissue donor using the excel template provided
- File uploaded will be populated



Submit Declaration of Compliance

Declaration of compliance section is the same as the First Schedule of the HBR (Tissue Banking)
 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 35(3) of the Human Biomedical Research Act 2015 or regulation 9 of the Human Biomedical Research (Tissue Banking) Regulations 2019 (G.N. No. S 702/2019), all tissue banking activities conducted under the supervision and control of the tissue bank between 01/11/2019 and 31/12/2020 comply with the Act.
- 3. The tissue bank -
- (a) has formulated and implemented appropriate standards, policies and procedures to supervise, review and monitor the conduct of the tissue banking activity conducted under its supervision and control:
- (b) supervises, reviews and proactively monitors the conduct of the tissue banking activity conducted under its supervision and control;
- (c) ensures that the tissue banking activity conducted under its supervision and control, including those that are conducted by a third party under a contractual agreement, complies with the Act, and is conducted in accordance with the standards, policies and procedures mentioned in subparagraph (a);
- (d) has formulated and implemented a policy on whether or not the donor should be re-identified and informed in the case of an incidental finding and has informed all donors and recipients of the details of the policy and if the policy provides for the donor to be re-identified and informed, whether the donor has expressed a wish to be re-identified and informed;
- (e) investigates any areas of concern and takes such remedial measures as appropriate;
- (f) performs such other functions and duties as may be prescribed in legislation; and
- (g) regularly reviews -
- (i) the standards, policies and procedures formulated and implemented by the tissue bank to supervise, review and monitor the conduct of the tissue banking activity conducted under its supervision and control;
- (ii) all serious adverse events and untoward occurrences; and
- (iii) all safety lapses.

Submit Declaration of Compliance

 Verify the number of tissue bank sites and if the tissue bank is storing or supplying tissue for use in research involving human tissue transplantation during the compliance period

Tissue bank that is storing or supplying tissue for use in research involving human tissue transplantation & has one tissue bank site

Please verify the following

• Your tissue bank is storing or supplying tissue for the purpose of use in research involving human tissue transplantation

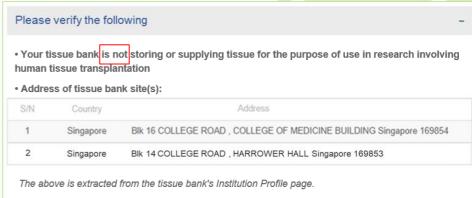
• Address of tissue bank site(s):

S/N Country Address

1 Singapore Blk 16 COLLEGE ROAD , COLLEGE OF MEDICINE BUILDING Singapore 169854

The above is extracted from the tissue bank's Institution Profile page.

Tissue bank that is not storing or supplying tissue for use in research involving human tissue transplantation & has two tissue bank sites

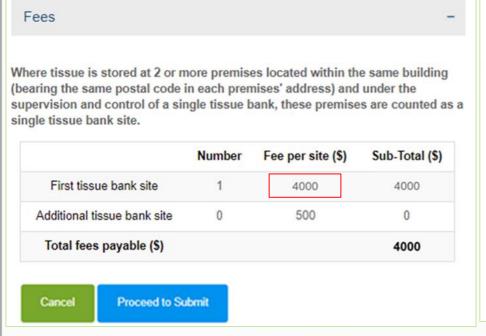


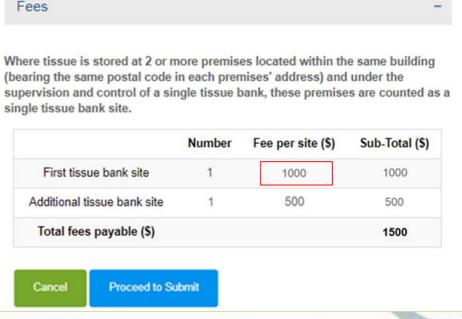
Submit Declaration of Compliance

- Total fees payable will displayed
- Click "Proceed to Submit"

Tissue bank that is storing or supplying tissue for use in research involving human tissue transplantation & has one tissue bank site

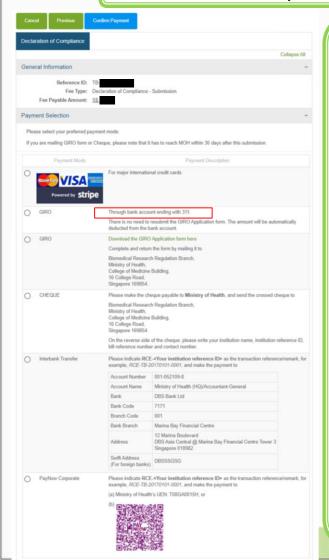
Tissue bank that is not storing or supplying tissue for use in research involving human tissue transplantation & has two tissue bank sites





Payment Selection

- Select the preferred mode of payment
- Click "Confirm Payment"



For tissue banks 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.

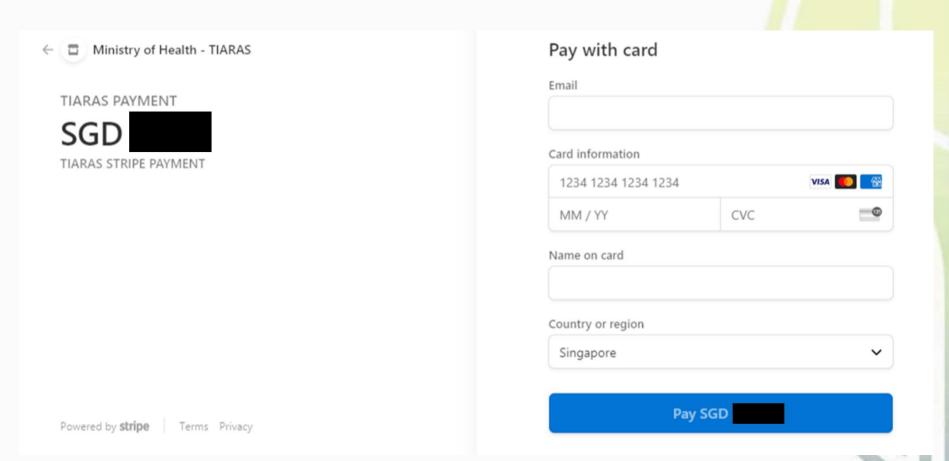
Note: MOH <u>will not</u> be accepting cheque payment from 1 September 2021.

<u>For payment by Interbank Transfer</u> and PayNow Corporate:

- Indicate RCE-<Your institution reference ID> as the transaction reference/remark, for e.g., RCE-TB-20170101-0001
- your Follow the crediting details on the ution screen

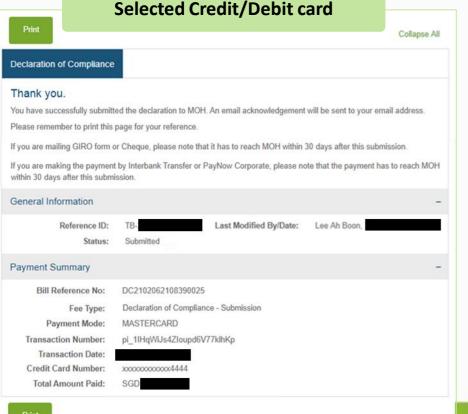
Payment Page

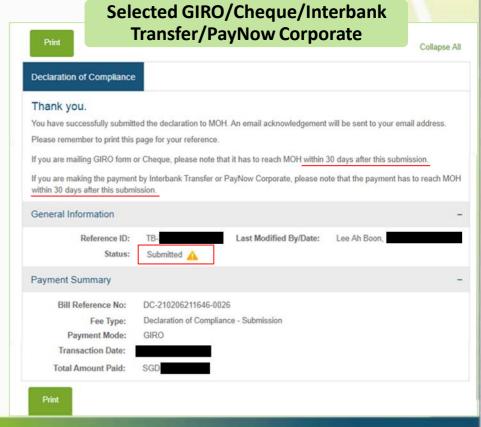
- Enter payment details
- Click "Pay"



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 serves to remind tissue banks that selected GIRO, Cheque, Interbank Transfer or PayNow Corporate to submit payment. The GIRO form, Cheque or Interbank Transfer, or PayNow payment has to reach MOH within 30 days. The icon will be removed after MOH receives the payment.

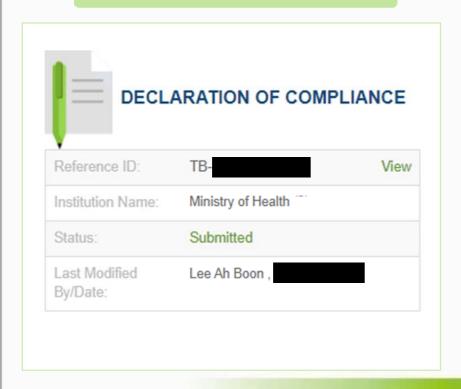




Dashboard

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

Selected Credit/Debit card



Selected GIRO/Cheque/Interbank Transfer/PayNow Corporate



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Things to note

When using a signed Declaration Form

- Use the Declaration Form provided by MOH
- Enter the tissue bank's name as it is on TIARAS
- Enter the compliance period as it is on TIARAS
- Enter the name of the principal person in charge

The system detects that you are not the principal person in charge of the tissue bank. You would need to upload a signed Declaration from the principal person in charge.

Click here to download the Declaration Form

Upload Files

DECLARATION OF COMPLIANCE

I declare, on behalf of Ministry of Health, lalf 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 35(3) of the Human Biomedical Research Act 2015 or regulation 9 of the Human Biomedical Research (Tissue Banking) Regulations 2019 (G.N. No. S 702/2019), all tissue banking activities conducted under the supervision and control of the tissue bank between 01/11/2019 and 31/12/2020 empty with the Act.

DECLARATION OF COMPLIANCE BY TISSUE BANK

UNDER SECTIONS 35(1) AND 36(1) OF THE HUMAN BIOMEDICAL RESEARCH ACT

Name of Tissue Bank

Declaration

I declare, on behalf of _____ (name of tissue bank), all of the following:

- 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 35(3) of the Human Biomedical Research Act 2015 or regulation 9 of the Human Biomedical Research (Tissue Banking) Regulations 2019 (G.N. No. S 702/2019), all tissue banking activities conducted under the supervision and control of the tissue bank between Click here to enter a date and Click here to enter a date comply with the Act.

Details of Principal Person in Charge

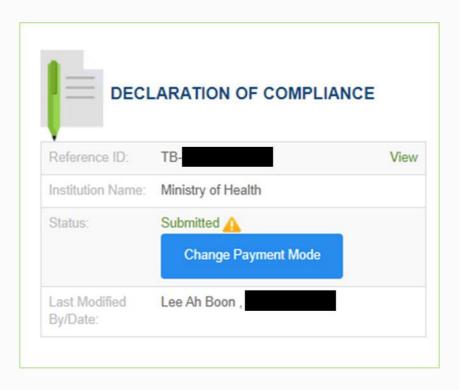
Name Designation

Signature Date of Declaration

Click here to enter a date

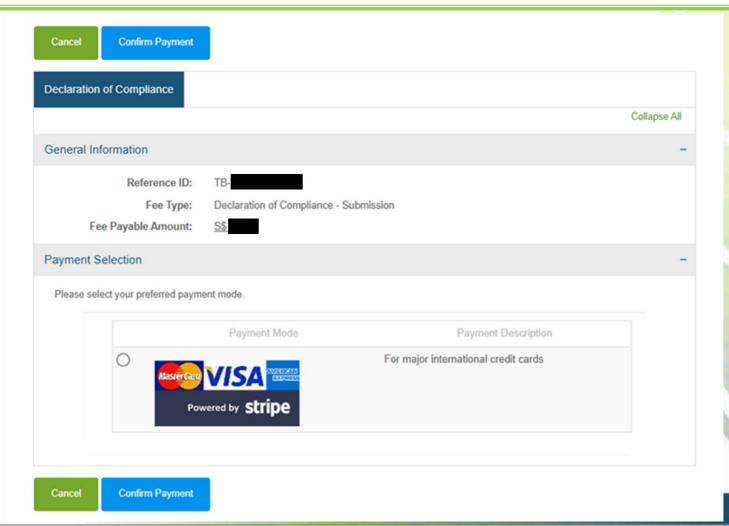
For tissue banks which selected GIRO/Cheque/Interbank Transfer/PayNow Corporate but wishes to pay by credit/debit card

Click "Change Payment Mode"



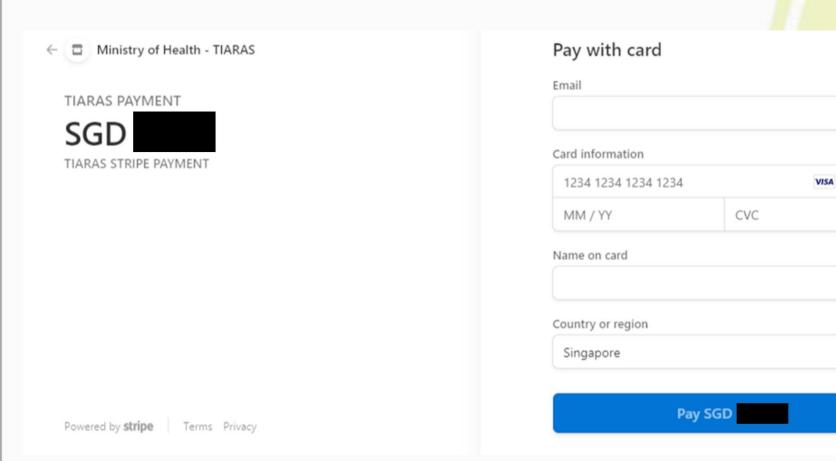
For tissue banks which selected GIRO/Cheque/Interbank Transfer/PayNow Corporate but wishes to pay by credit/debit card

- Select the credit/debit card option
- Click "Confirm Payment"



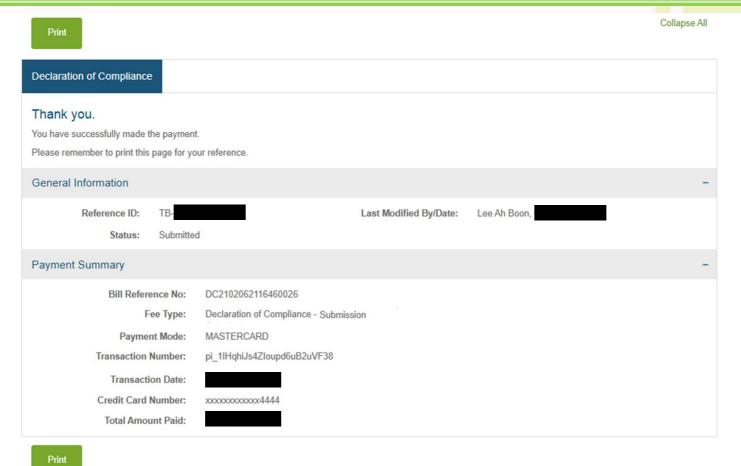
Payment Page

- Enter payment details
- Click "Pay"



Payment Acknowledgement

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



Payment modes in TIARAS

As part of Whole-of-Government move towards 100% electronic transactions, the payment modes on TIARAS will be updated

- VISA/MasterCard/American Express
- GIRO
- Cheque Will be removed from 1 September 2021
- Interbank Transfer Introduced in March 2020
 - An electronic fund transfer to MOH's bank account
 - Payment can be made from Corporate's or Individual's bank accounts
 - Payment can be made over a few days if the amount payable exceeds daily transfer limit
- PayNow Corporate Introduced in March 2020
 - An electronic fund transfer via Quick Response (QR) code
 - Payment can be made from Corporate's or Individual's bank accounts
 - Payment can be made over a few days if the amount payable exceeds daily transfer limit



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