

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

Version Date: February 2021

Declaration of Compliance 2021



1. Getting Started

- Which research institution should submit declaration
- When is the compliance period to declare for
- 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

3. Updates & Other Functions

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

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• Submitting declaration

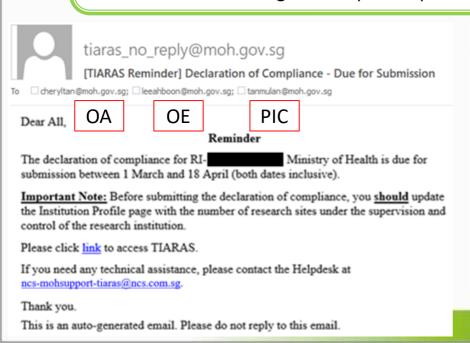
3. Updates & Other Functions

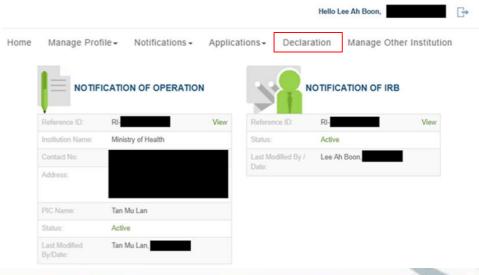
- Things to note
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Which research institution should submit declaration

For Declaration of Compliance in 2021

- Research institutions which had submitted notification to MOH indicating:
 - It has commenced/intention to commence human biomedical research (HBR) on/before 31 Dec 2020
- Research institutions 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
- Research institutions should update the following information in the institution profile page:
 - Number of research sites during the compliance period
 - 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 2021

Research institutions indicating	Start Date	End Date
1. All RIs except those described in Point 2 below	1 Jan 2020	31 Dec 2020
2. RIs with commencement date in 2020	Commencement date indicated in the notification of operation	31 Dec 2020

How much is the declaration

Second Schedule of HBR Regulations

During the compliance period	Conducting restricted research	Not conducting restricted research
First research site	\$4,000	\$1,000
Each additional site	\$500 per site	\$500 per site

Where activities relating to research are conducted 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 research institution</u>, 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 HBR 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 HBR activities are conducted at residential homes or shopping centres, these public places need not be declared as a site. Nonetheless, the research institution should always have supervision and control over <u>all</u> the HBR 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 HBR activities are carried out, regardless of declaration.
- 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

- 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















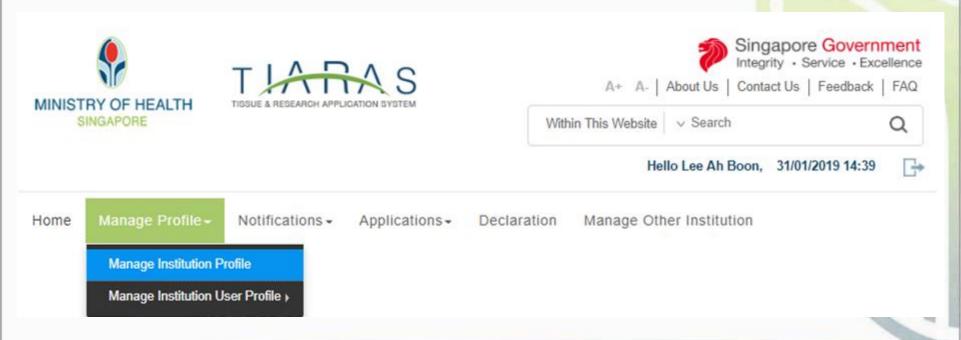


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This site is best viewed using IE10 & above, screen resolution 1024x768

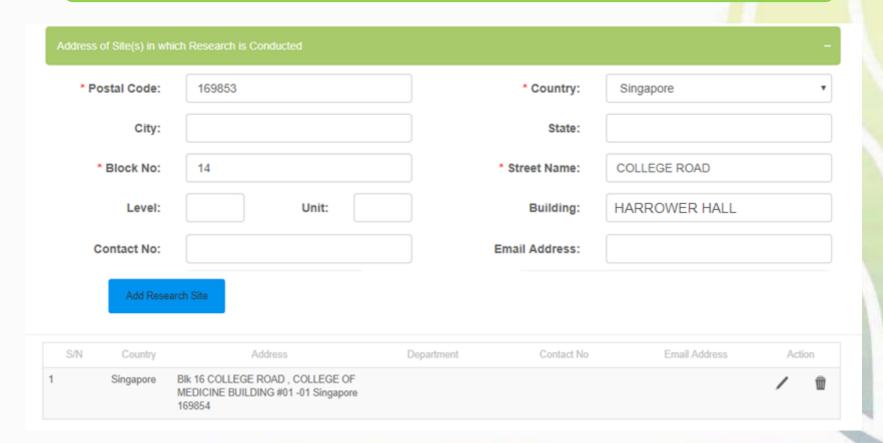
For Declaration of Compliance

- Research institutions should update the following information in the institution profile page:
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Add research site

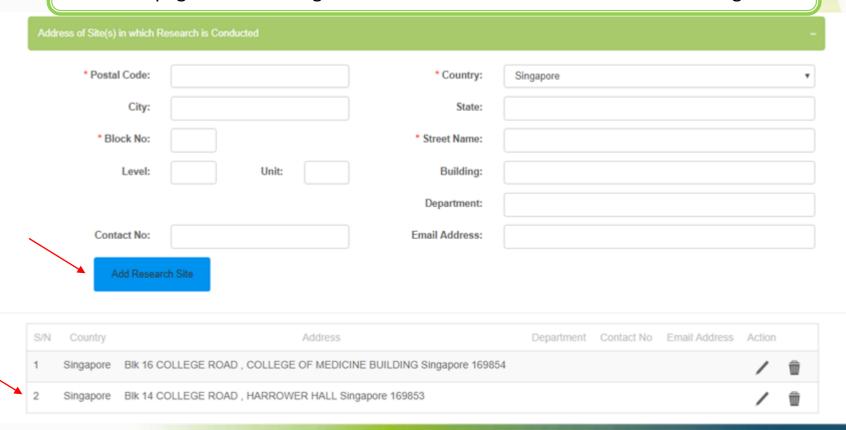
- Enter the postal code
- Block number, street name and building (if applicable) will be populated
- Complete the rest of the address of research site



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.



Conduct of restricted research

• If the research institution has been granted approval by MOH to conduct restricted research during the compliance period, indicate "Yes"

Nature of Human Biomedical Research		-	
My research institution is conducting human biomedical research involving the following:	Yes	No	
* 1. Human tissue transplantation	0	0	
* 2. Restricted human biomedical research (as defined in the Fourth Schedule of the Human Biomedical Research Act)	•	0	
*3. Direct clinical intervention or invasive clinical procedures	0	0	
 4. Other types of human biomedical research, please specify (e.g. exercise physiology) 	0	0	
Profile of my research subjects:			
* 1. Adults who lack mental capacity (as defined in the Mental Capacity Act)	0		
*2. Pregnant women	0	0	
*3. People highly dependent on medical care who may be unable to give consent		0	
* 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	0	1
 5. Minors (below 21 years of age and who have never been married) 	0	0	
* 6. Deceased persons	0	0	

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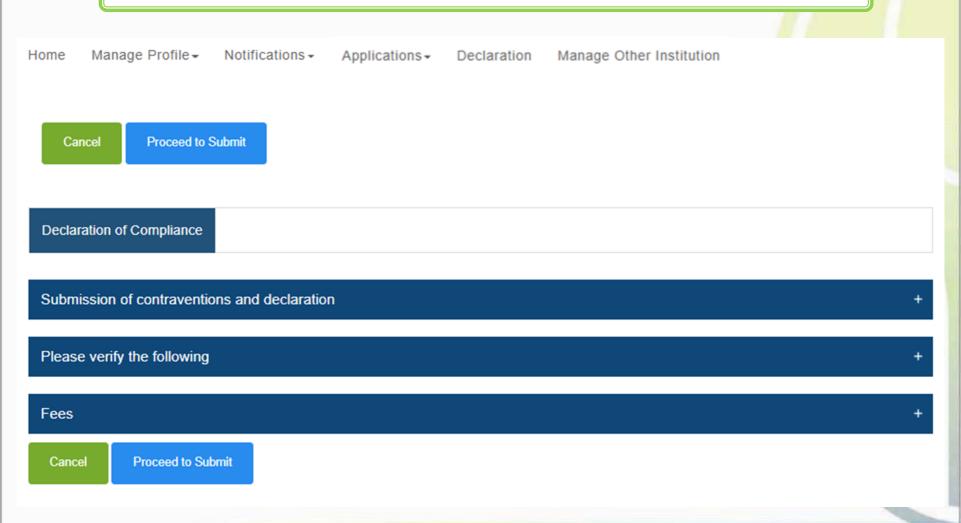
• Submitting declaration

3. Updates & Other Functions

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

Submit Declaration of Compliance

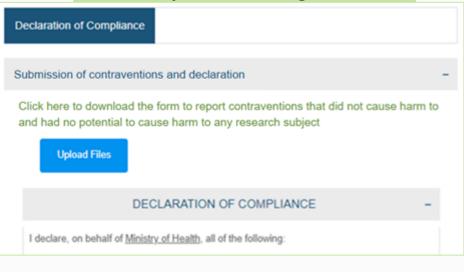
Click on "Declaration" in the menu navigation



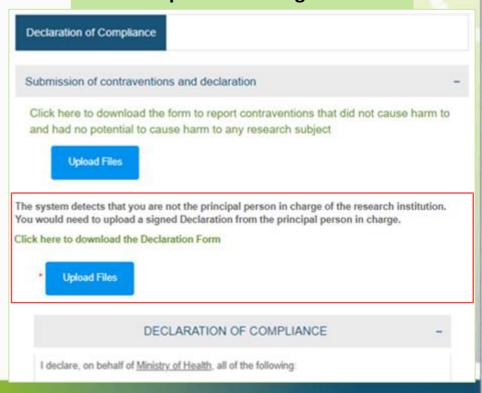
Who can submit

- 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

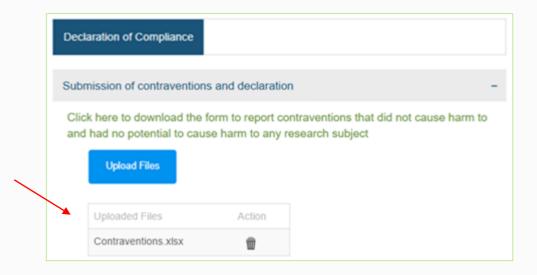


OE/OA who is not the principal person in charge



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 research subject 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 Regulations

DECLARATION OF COMPLIANCE

I declare, on behalf of Ministry of Health, 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).
- 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 or regulation 8 of the Human Biomedical Research Regulations 2017 (G.N. No. S 621/2017), all human
 biomedical research conducted under the supervision and control of the research institution between 01/01/2020 and 31/12/2020 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.

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

Please verify the following

Your research institution is conducting restricted human biomedical research

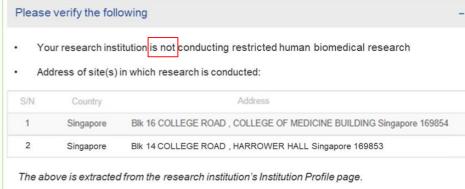
Address of site(s) in which research is conducted:

S/N Country Address

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

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

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



Submit Declaration of Compliance

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

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

has one research site

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.

	Number	Fee per site (\$)	Sub-Total (\$)
First research site	1	4000	4000
Additional research site	0	500	0
Total fees payable (\$)			4000

Cancel

Proceed to Submit

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

Fees

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.

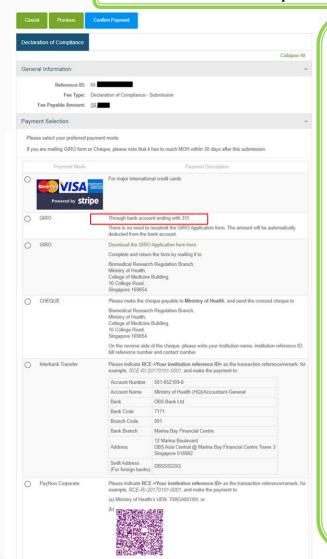
	Number	Fee per site (\$)	Sub-Total (\$)
First research site	1	1000	1000
Additional research site	1	500	500
Total fees payable (\$)			1500

Cancel

Proceed to Submit

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.

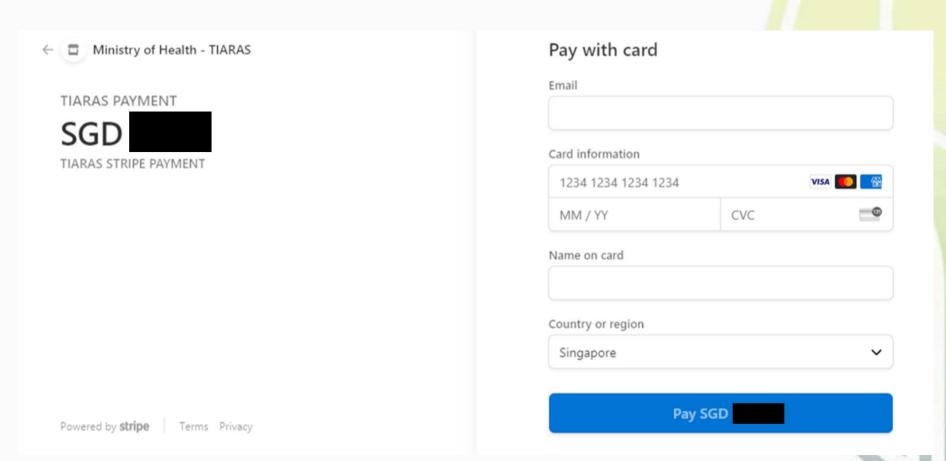
Note: MOH <u>will not</u> be accepting cheque payment from 1 September 2021.

<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-RI-20170101-0001
- your Follow the crediting details on the ution screen

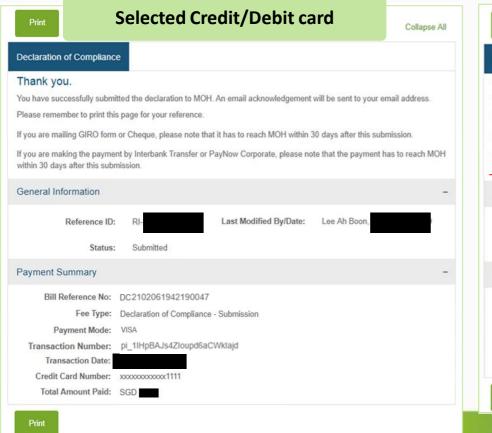
Payment Page

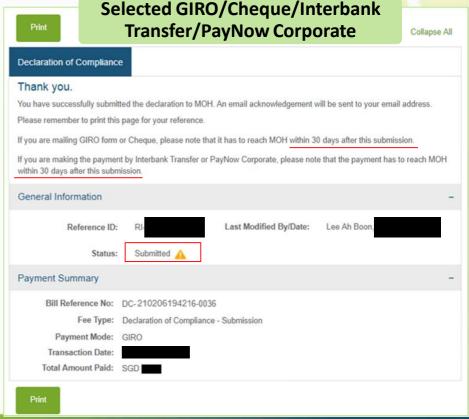
- Enter payment details
- Click "Pay"



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 A serves to remind research institutions 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.





23

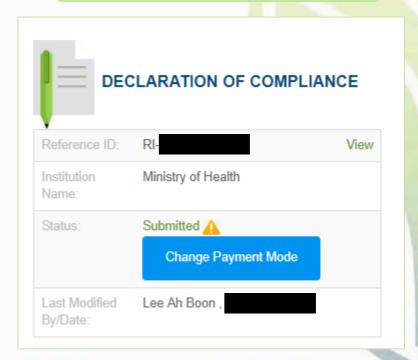
Dashboard

- 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 research institution'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

Declaration

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

• Upload Files

Click here to download the Declaration Form

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 or regulation 8 of the Human Biomedical Research Regulations 2017
- (G.N. No. S 621/2017), all human biomedical research conducted under the supervision and control of the research institution between 01/01/2020 and 31/12/2020 comply with the Act.

DECLARATION OF COMPLIANCE BY RESEARCH INSTITUTION

UNDER SECTIONS 23(1) AND 24(1) OF THE HUMAN BIOMEDICAL RESEARCH ACT

Name of Research Institution

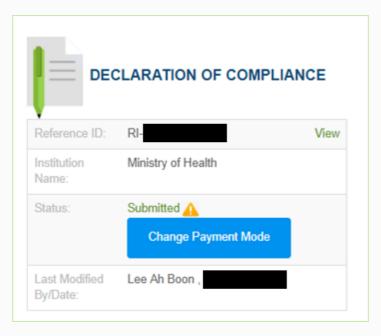
Declaration

I declare, on behalf of _____ (name of research institution), all of the following:

- 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 or regulation 8 of the Human Biomedical Research Regulations 2017 (G.N. No. S 621/2017), all human biomedical research conducted under the supervision and control of the research institution between Click here to enter a date and Click here to enter a date comply with the Act.

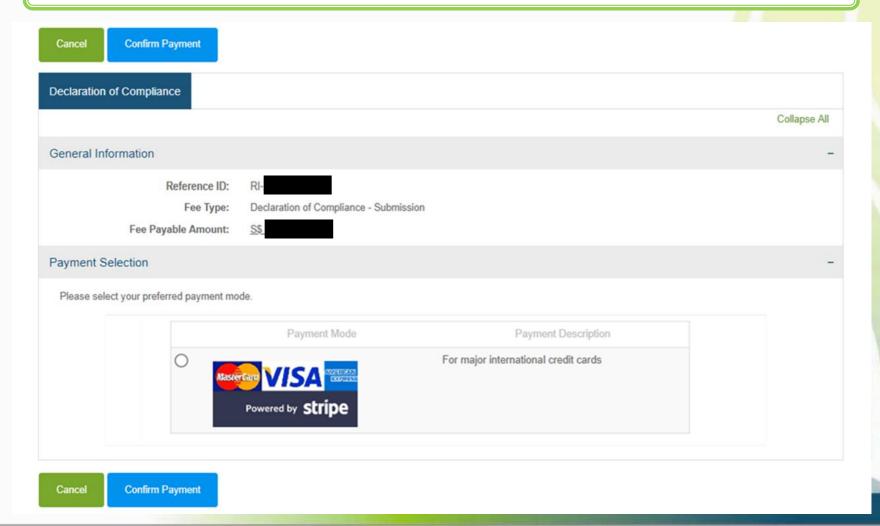
For research institutions which selected GIRO/Cheque/Interbank Transfer/PayNow Corporate but wishes to pay by credit/debit card

Click "Change Payment Mode"



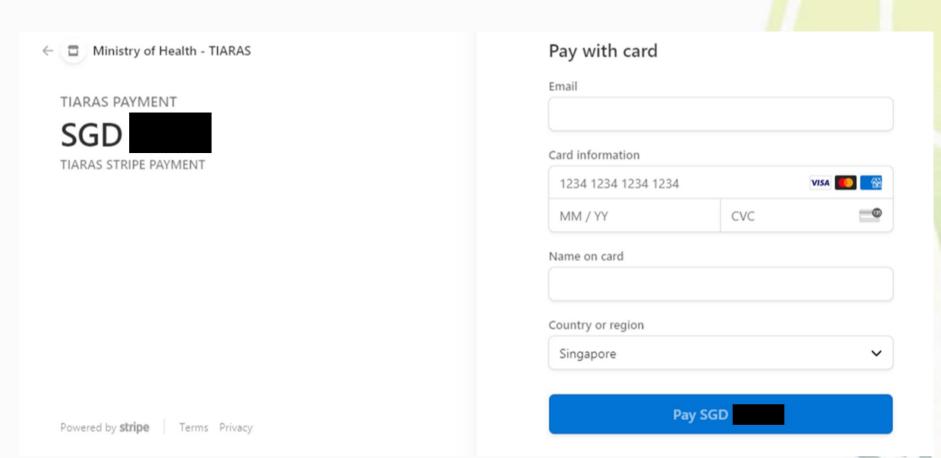
For research institutions which selected GIRO/Cheque/Interbank Transfer/PayNow Corporate but wishes to pay by credit/debit card

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



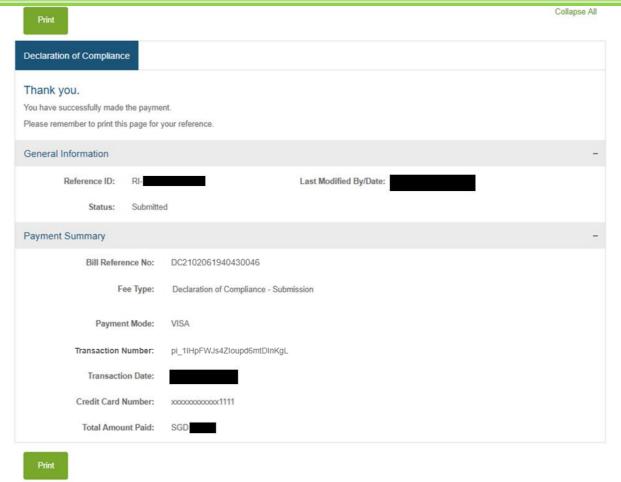
Payment Page

- 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 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