



# Singapore Sport Institute – Institutional Review Board

Information Sharing Session #2

14 August 2020

LIVE BETTER THROUGH SPORT



# SSI INSTITUTIONAL REVIEW BOARD SECRETARIAT

## Secretariat

### Permanent Secretariat Member

#### **Mr. Chow Kin Ming (Steve)**

Physiology Laboratory Officer  
Singapore Sport Institute  
[Chow\\_Kin\\_Ming@sport.gov.sg](mailto:Chow_Kin_Ming@sport.gov.sg)

### Secretariat Team

#### **Mr. Desmond Boey**

Sport Biomechanist  
Singapore Sport Institute  
[Desmond\\_Boey@sport.gov.sg](mailto:Desmond_Boey@sport.gov.sg)

#### **Ms. Goh Wan Xiu**

Sport Biomechanist  
Singapore Sport Institute  
[Goh\\_Wan\\_Xiu@sport.gov.sg](mailto:Goh_Wan_Xiu@sport.gov.sg)

#### **Ms. Andrea Chen**

Sport Physiotherapist  
National Youth Sports Institute  
[Andrea\\_Chen@nysi.org.sg](mailto:Andrea_Chen@nysi.org.sg)

#### **Mr. Kelvin Chua**

Strength & Conditioning Coach  
Singapore Sport Institute  
[Kelvin\\_Chua@sport.gov.sg](mailto:Kelvin_Chua@sport.gov.sg)

# SSI INSTITUTIONAL REVIEW BOARD MEMBERS

## Chairman

### **Dr. Jason Chia**

Head & Senior Consultant  
Sports Medicine & Surgery Clinic  
Tan Tock Seng Hospital

## Members

### **Prof. Michael Chia**

Professor, Faculty Staff Mentor  
Faculty Affairs  
National Institute of Education

### **Mr. Lau Kok Keng**

Head  
Intellectual Property, Sports & Gaming  
Rajah & Tann Singapore LLP

### **Dr. Alex Ong**

Assistant Director  
Capability Development  
Republic Polytechnic

### **A/Prof. Chow Jia Yi**

Associate Dean  
Office of Teacher Education  
National Institute of Education

### **Dr. Low Chee Yong**

Head  
Sports Science  
National Youth Sports Institute

### **Dr. Ivy Lim**

Consultant  
Sport & Exercise Medicine  
Changi General Hospital

### **Dr. Ong Joo Haw**

Consultant  
Sports Medicine Centre  
Khoo Teck Puat Hospital

### **Dr. Frankie Tan**

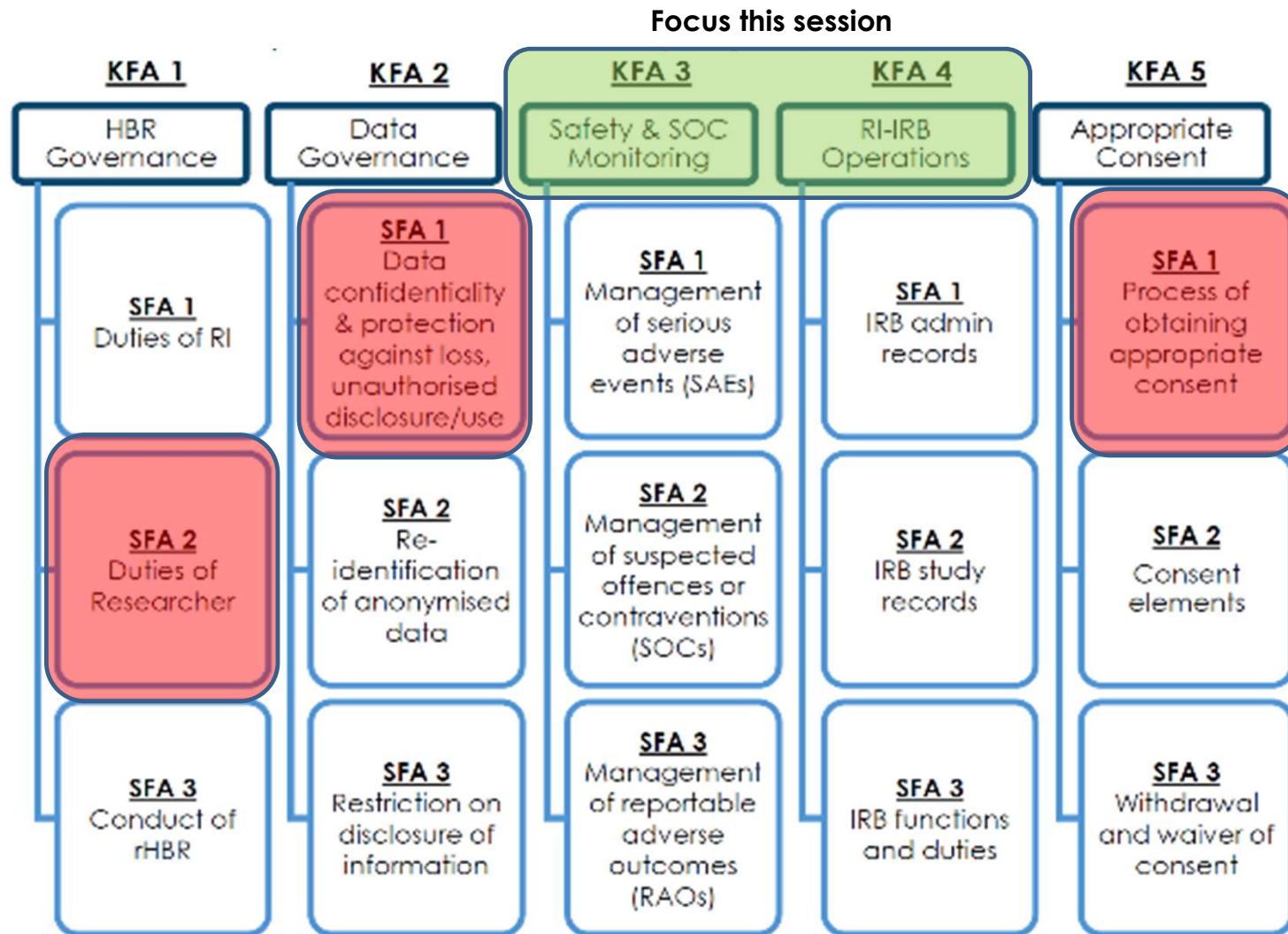
Director  
Sport Science & Medicine Centre  
Singapore Sport Institute

### **Ms. Tan Bee Lian**

Director  
Sports  
Singapore Sports School



# MINISTRY OF HEALTH (MOH) - KEY FOCAL AREAS (KFA)



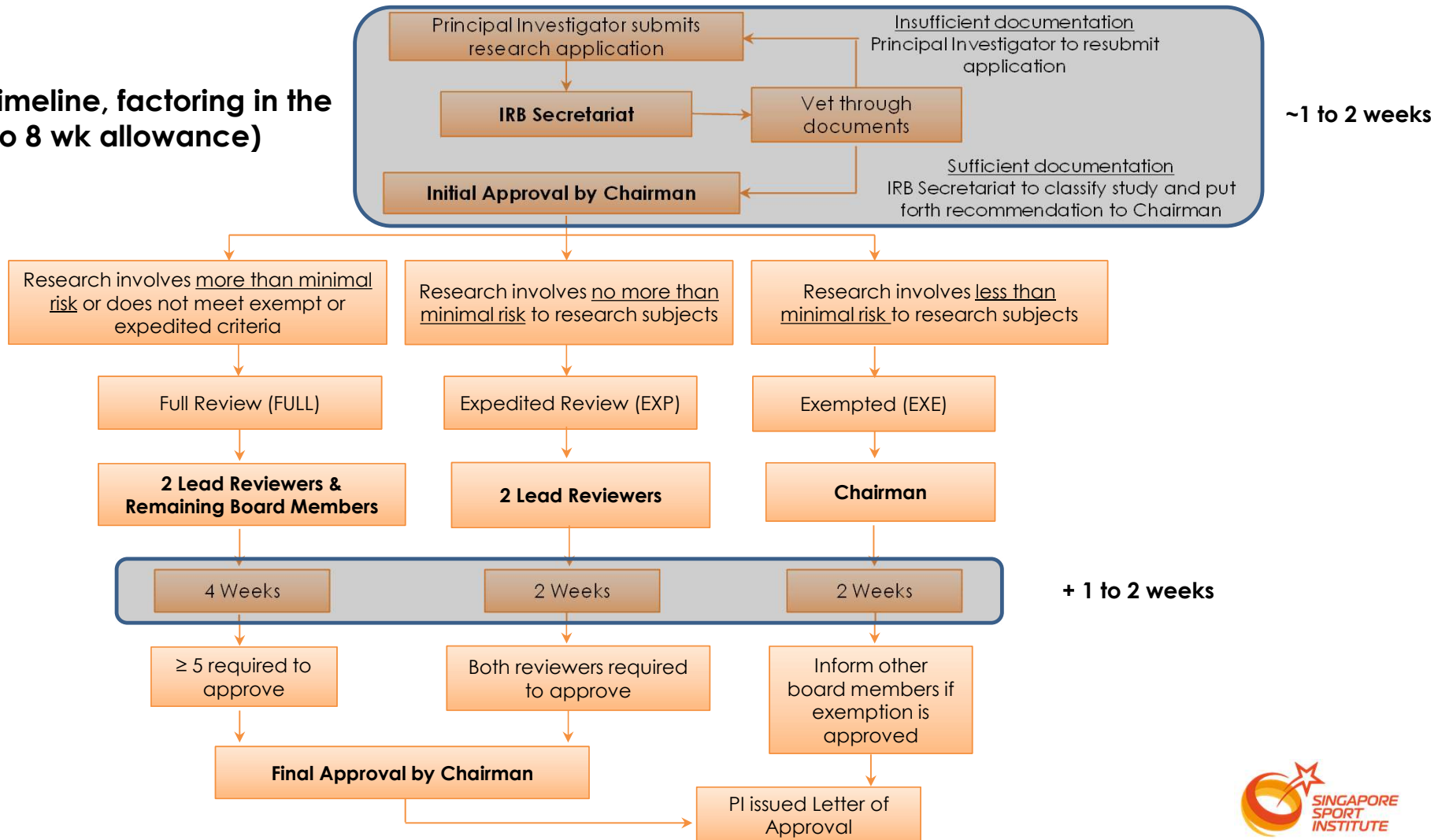
Covered topics in April's sharing session

# SHARING CONTENT

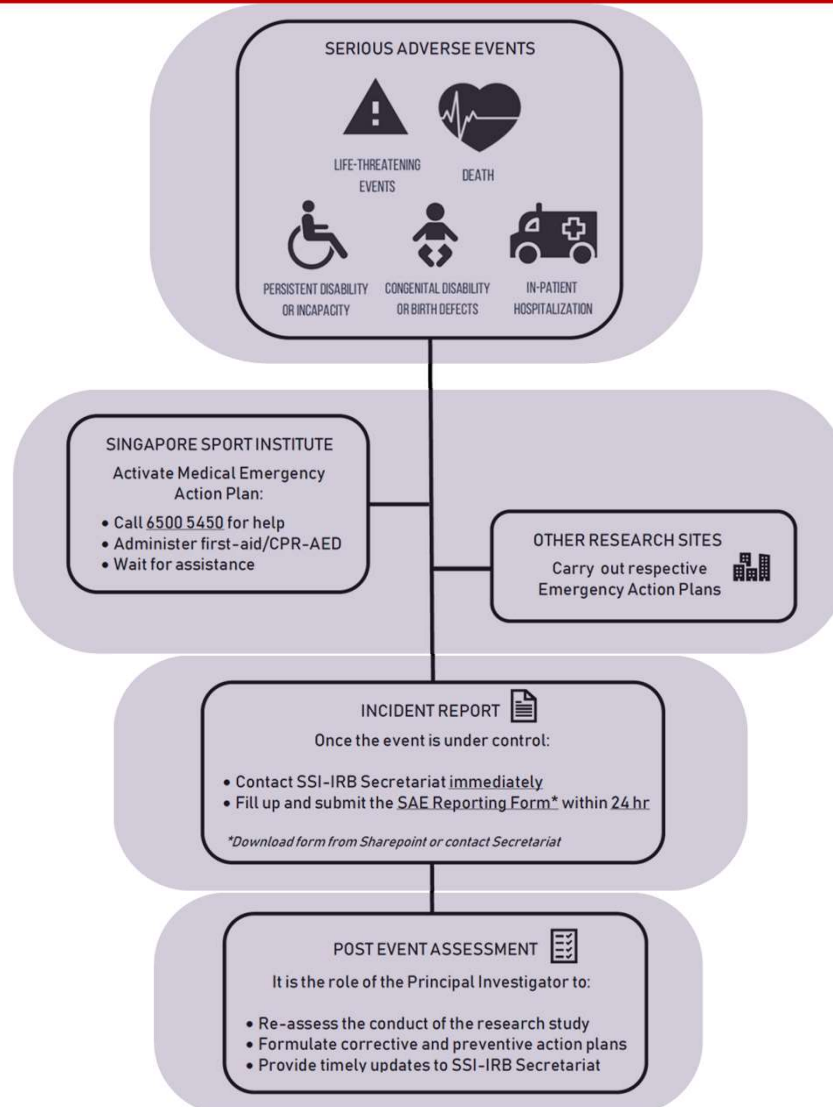
- Review Process
- Incident Reporting
  - Serious Adverse Events
  - Suspected Offences or Contraventions
- Research Monitoring (Internal Audit)
  - Study Amendments
- Online Consent Taking
- Q&A

# Review Process

**\*Provide a realistic timeline, factoring in the review process (~6 to 8 wk allowance)**



# Incident Reporting – Serious Adverse Events



## Serious Adverse Events (SAEs)

- Results in death
- Life threatening etc.

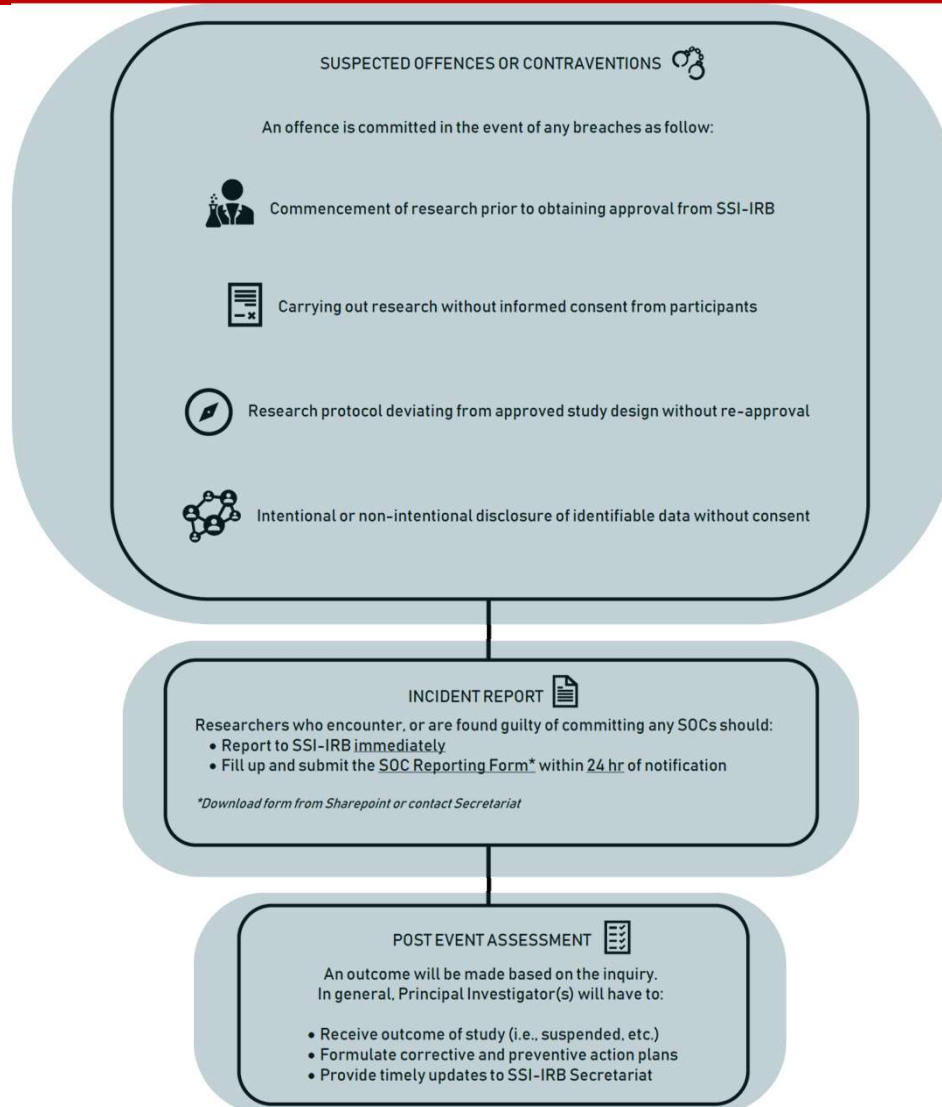
## Manage the situation on the ground

### Report Incident:

- 1) SSI-IRB Secretariat
- 2) SAE Reporting Form

## Post-Event Assessment

# Incident Reporting – Suspected Offences or Contraventions



## Suspected Offences or Contraventions (SOCs)

**Any individuals encountering such incidents, please report to:**

- 1) SSI-IRB Secretariat
- 2) SOC Reporting Form

## Post-Event Assessment



# Penalties for Suspected Offences or Contraventions

S/N	List Of Contraventions And Section Reference	Penalties
1	<p>Duties of researchers conducting HBR – Section 22</p> <ul style="list-style-type: none"> <li>· Proposed research has been <b>reviewed and approved</b> (or exempted) by an IRB;</li> <li>· <b>Appropriate consent obtained</b> from research subject.</li> <li>· Research <b>does not deviate</b> from approved research proposal unless (i) the deviation has been reviewed and approved by IRB, or (ii) is necessary to <b>mitigate an immediate risk of harm</b> to a research subject.</li> <li>· Research is immediately discontinued if IRB has withdrawn its approval for the research</li> <li>· If consent of research subject is withdrawn, the further participation of the research subject or further use of the individually-identifiable biological material or health information of the research subject should be discontinued immediately.</li> <li>· A researcher must ensure that a minor who lacks sufficient understanding and intelligence, or an adult or minor who lacks mental capacity to give consent, must not be a research subject in any biomedical research unless there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of persons to which the minor or adult belongs.</li> </ul>	<p>Fine: not exceeding \$50,000. Imprisonment: not exceeding 5 years.</p>
2	<p>Compelling person to participate in research - Section 26</p> <ul style="list-style-type: none"> <li>· Coercion or intimidation to compel another person <b>against that person's will</b> to participate or continue to participate as a research subject.</li> </ul>	<p>Fine: not exceeding \$100,000 Imprisonment: not exceeding 10 years.</p>
3	<p>Duty to <b>protect health information</b> and human biological material against loss, unauthorised disclosure, etc. - Section 27</p> <ul style="list-style-type: none"> <li>· Every person who has obtained individually-identifiable information or human biological material must take all reasonable steps and safeguards as may be necessary, including rendering information or material non-identifiable, to protect such information or material against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification.</li> </ul>	<p>Fine: not exceeding \$10,000 Imprisonment: not exceeding 12 months.</p>

# Penalties for Suspected Offences or Contraventions

S/N	List Of Contraventions And Section Reference	Penalties
4	<p><b>No re-identification of anonymised information</b> or biological material without consent - Section 28</p> <ul style="list-style-type: none"> <li>No person who is in possession of or in contact with any information or human biological material can take any action to identify the person from whom such information or material was obtained, except with the consent of the research subject.</li> </ul>	<p>Fine: not exceeding \$20,000 Imprisonment: not exceeding 2 years.</p>
5	<p>Restrictions on disclosure of information - Section 29</p> <ul style="list-style-type: none"> <li>Individually-identifiable information obtained from any research subject should not be disclosed, except with the consent of the research subject.</li> </ul>	<p>Fine: not exceeding \$20,000 Imprisonment: not exceeding 2 years.</p>
6	<p>Prohibited human biomedical research - Section 30</p> <ul style="list-style-type: none"> <li>No person can conduct any prohibited human biomedical research specified in the Third Schedule of HBRA.</li> </ul>	<p>Fine: not exceeding \$100,000 Imprisonment: not exceeding 10 years.</p>
7	<p>Restricted human biomedical research - Section 31</p> <ul style="list-style-type: none"> <li>No person can conduct any restricted human biomedical research specified in the Fourth Schedule except:               <ul style="list-style-type: none"> <li>- Prior IBR approval obtained; and</li> <li>- Prior MOH approval obtained.</li> </ul> </li> </ul>	<p>Fine: not exceeding \$100,000 Imprisonment: not exceeding 10 years.</p>

# Research Monitoring – Research Status Update

## Status Update of Research

### STATUS UPDATE OF RESEARCH

It is the responsibility of the Principal Investigator(s) to:

- Provide status update of on-going research online (~3 min)
- By the end of every June & December
- Via [bit.ly/2Bd11AU](https://bit.ly/2Bd11AU)



To be implemented end Aug/Sept 2020.

Researchers will be notified respectively through emails.

### FAILURE TO UPDATE STATUS OF RESEARCH

Researchers who fail to comply:

- Given a warning; to submit research status within 7 calendar days
- Disciplinary actions will be taken



INSTITUTIONAL REVIEW BOARD

## SSI-IRB: Half-Yearly Updates on Research Project

Please provide an update to your research study every half-yearly (i.e., by 30 June and 31

December)

\* Required

At present stage (today), my research \*

Select at most 2 options that best match current status of your research.

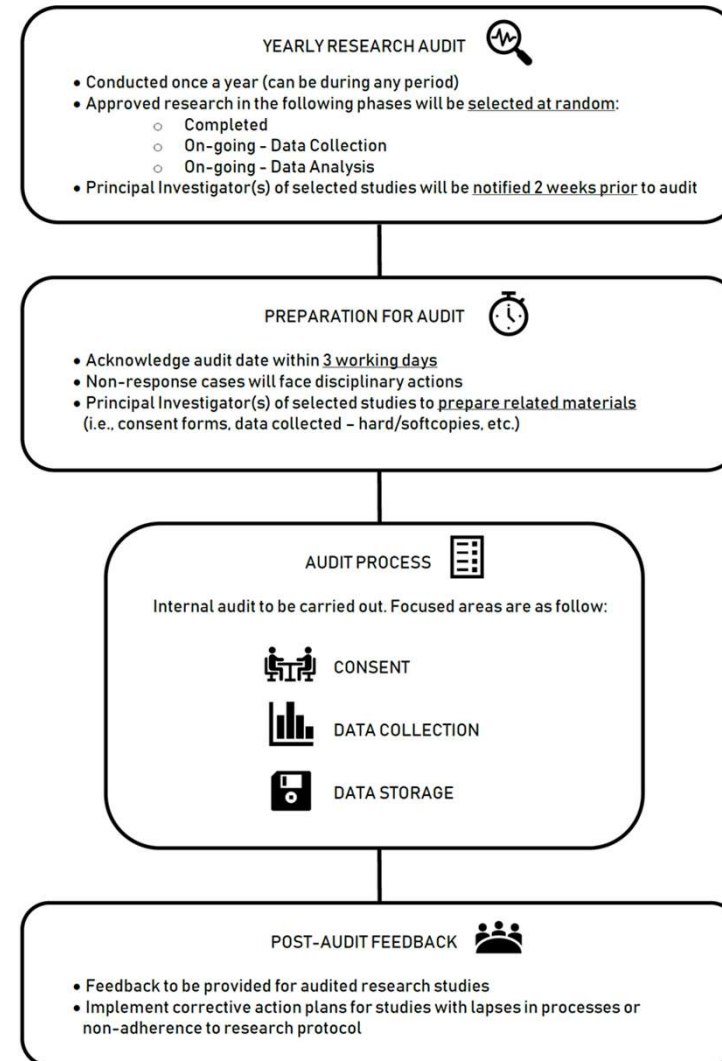
- is in recruitment phase (getting participants)
- is undergoing data collection phase
- has completed data collection phase
- is in the data analysis phase
- has concluded (finished all the above phases)
- is undergoing manuscript drafting
- is awaiting manuscript review from a journal
- has concluded and work has been published
- Other: \_\_\_\_\_

# Research Monitoring – Internal Audit

- Internal audit to be performed once a year by the Secretariat Team
- Areas of focus:
  - Consent taking
  - Data collection procedures
  - Data storage

To be implemented first half of 2021.

Researchers will be notified respectively through emails.



# Research Monitoring – Research Amendment

## SINGAPORE SPORT INSTITUTE INSTITUTIONAL REVIEW BOARD – Amendment Form for IRB Review



Kindly fill in ALL field; do NOT leave any blanks. Enter 'NA' or 'NIL' should you not wish to enter any content.

SECTION 1: STUDY INFORMATION	
IRB Reference Number:	
IRB Approval Date:	
Title of Project:	
Principal Investigator (PI):	<hr/> Signature
Designation:	
Department / Division / Organisation:	
Contact Details (Tel / Email):	/

## SECTION 2: AMENDMENT INFORMATION

### 2.1. Please select the type of amendment you are requesting (select all that apply):

- Change in protocol (design, methodology, procedures, etc.)\*
- Change to number of participants and/or selection criteria
- Change in recruitment materials (flyers, emails, compensation, etc.)\*
- Change in study materials (surveys, questionnaires, etc.)\*
- Change in consent form\*
- Change in research personnel
- Change in timeline\*
- Other changes

\*Please ensure all revised/new documents with the changes **highlighted** are attached.

Amendment form to be submitted if researchers are seeking to make changes to their approved study such as:

- Protocol
- Consent form
- Timeline
- Number of participants
- Study/Recruitment Materials etc.



# Extension to Applications affected by Covid-19

## SINGAPORE SPORT INSTITUTE INSTITUTIONAL REVIEW BOARD – Amendment Form for IRB Review



Kindly fill in ALL field; do NOT leave any blanks. Enter 'NA' or 'NIL' should you not wish to enter any content.

SECTION 1: STUDY INFORMATION	
IRB Reference Number:	
IRB Approval Date:	
Title of Project:	
Principal Investigator (PI):	<hr/> Signature
Designation:	
Department / Division / Organisation:	
Contact Details (Tel / Email):	/

SECTION 2: AMENDMENT INFORMATION
<p><b>2.1. Please select the type of amendment you are requesting (select all that apply):</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> Change in protocol (design, methodology, procedures, etc.)*</li><li><input type="checkbox"/> Change to number of participants and/or selection criteria</li><li><input type="checkbox"/> Change in recruitment materials (flyers, emails, compensation, etc.)*</li><li><input type="checkbox"/> Change in study materials (surveys, questionnaires, etc.)*</li><li><input type="checkbox"/> Change in consent form*</li><li><input type="checkbox"/> Change in research personnel</li><li><input type="checkbox"/> Change in timeline*</li><li><input type="checkbox"/> Other changes</li></ul> <p><small>*Please ensure all revised/new documents with the changes <b>highlighted</b> are attached.</small></p>

- Extension will be provided on a case by case basis
- Fill up & submit the Amendment Form

Due to the Circuit Breaker disruption, we would like to seek extension for our research by an additional 8 months:

### Original timeline:

Estimated Commencement Date:	1 Apr 2020
Participant Recruitment Period:	4 Apr 2020 to 13 May 2020
Estimated Data Collection Period:	10 Apr 2020 to 28 Nov 2020
Estimated Completion Date:	31 Dec 2020

### New proposed timeline:

Estimated Commencement Date:	15 Aug 2020
Participant Recruitment Period:	15 Aug 2020 to 30 Dec 2020
Estimated Data Collection Period:	15 Sep 2020 to 30 Jun 2021
Estimated Completion Date:	31 Aug 2021



# Online Consent Taking Guidelines

## Context:

- To allow **non-HBR studies** to proceed with social distancing measures in place

## Process:

- Online consent-taking via a secure online platform such as FormSG
- Participant Information Sheet to be attached as an e-document in the form
- Signature sought via YES/NO check box with mandatory age declaration
- Parent/Guardian signature for minors via YES/NO check box

\*As per a physical paper consent form, participants and parents/guardians will provide their Names, Date of Birth, Email Address and Contact Number

## Instructions

Please kindly refer to the Data Protection Notice in the following link before providing consent below: <https://tinyurl.com/y9tnhcbz>

### 1. Name (as in

Please provide your

### 4. I declare that am above 21 years old

Kindly indicate "No" and get your Parent / Legal Guardian to continue filling this form. Parental / Legal Guardian's acknowledgement and consent is required for athletes below 21 years of age.

X NO

✓ YES

## Acknowledgement

### 2. Acknowledgement

I acknowledge that I have read and understand the terms and conditions of the collection, use, storage and related

## Statement of Informed Consent by Parent / Legal Guardian

This section is required for athletes below the age of 21 years. This section is to be filled in by the Parent / Legal Guardian of this athlete.

Please kindly refer to the Data Protection Notice in the following link before providing consent below: <https://tinyurl.com/y9tnhcbz>

### 3. Consent to

I consent to the sharing of my personal data to NYSI and Kinduct (Halifax, Nova Scotia, Canada) in order for me to receive

### 5. Statement of Informed Consent by Parent / Legal Guardian

I acknowledge and consent to my child/ward's personal data to be shared and stored by NYSI and Kinduct (Halifax, Nova Scotia, Canada) and understand that use of this personal data is for the purpose of sport science support.

X NO

✓ YES

### 4. I declare that am above 21 years old

Kindly indicate "No" and get your Parent / Legal Guardian to continue filling this form. Parental / Legal Guardian's acknowledgement and consent is required for athletes below 21 years of age.

X NO

✓ YES

# Questions?

**Mr. Chow Kin Ming**

Physiology Laboratory Officer  
Singapore Sport Institute  
[Chow\\_Kin\\_Ming@sport.gov.sg](mailto:Chow_Kin_Ming@sport.gov.sg)

**Mr. Kelvin Chua**

Strength & Conditioning Coach  
Singapore Sport Institute  
[Kelvin\\_Chua@sport.gov.sg](mailto:Kelvin_Chua@sport.gov.sg)

**Ms. Andrea Chen**

Sport Physiotherapist  
National Youth Sports Institute  
[Andrea\\_Chen@nysi.org.sg](mailto:Andrea_Chen@nysi.org.sg)

**Ms. Goh Wan Xiu**

Sport Biomechanist  
Singapore Sport Institute  
[Goh\\_Wan\\_Xiu@sport.gov.sg](mailto:Goh_Wan_Xiu@sport.gov.sg)

**Mr. Desmond Boey**

Sport Biomechanist  
Singapore Sport Institute  
[Desmond\\_Boey@sport.gov.sg](mailto:Desmond_Boey@sport.gov.sg)