Singapore Sport Institute – Institutional Review Board

Information Sharing & Recent Updates

18 June 2021

LIVE BETTER THROUGH SPORT

SSI IRB SECRETARIAT

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SHARING CONTENT

1. Internal Research Monitoring System
    a. Research Status Update
    b. Internal Audit
2. MOH Decisional Tools (to determine if study is HBR)
3. SSI-IRB Webpage
4. Amendment Process
5. Online Consent Taking
6. Updates to SSI-IRB Guidelines

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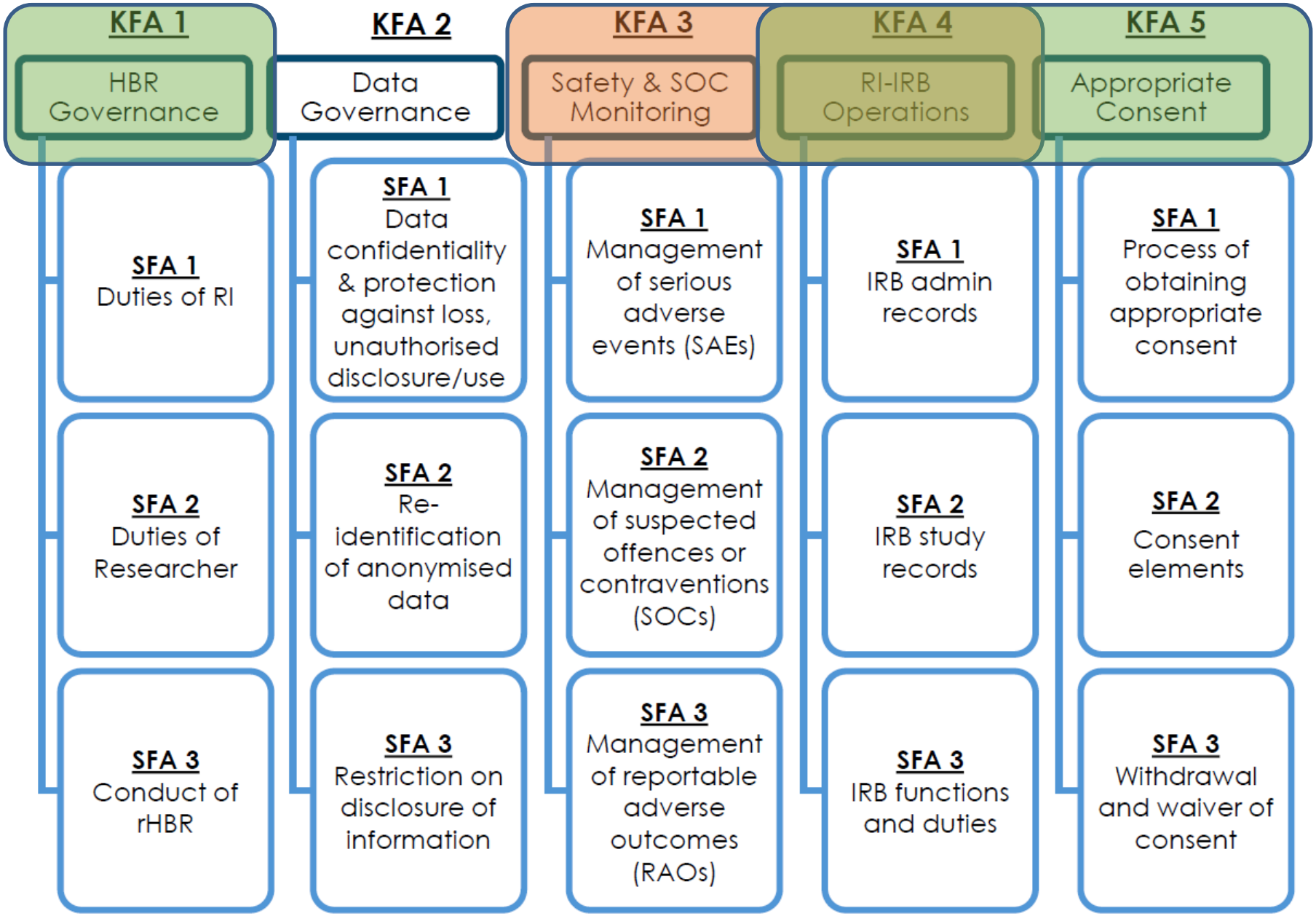
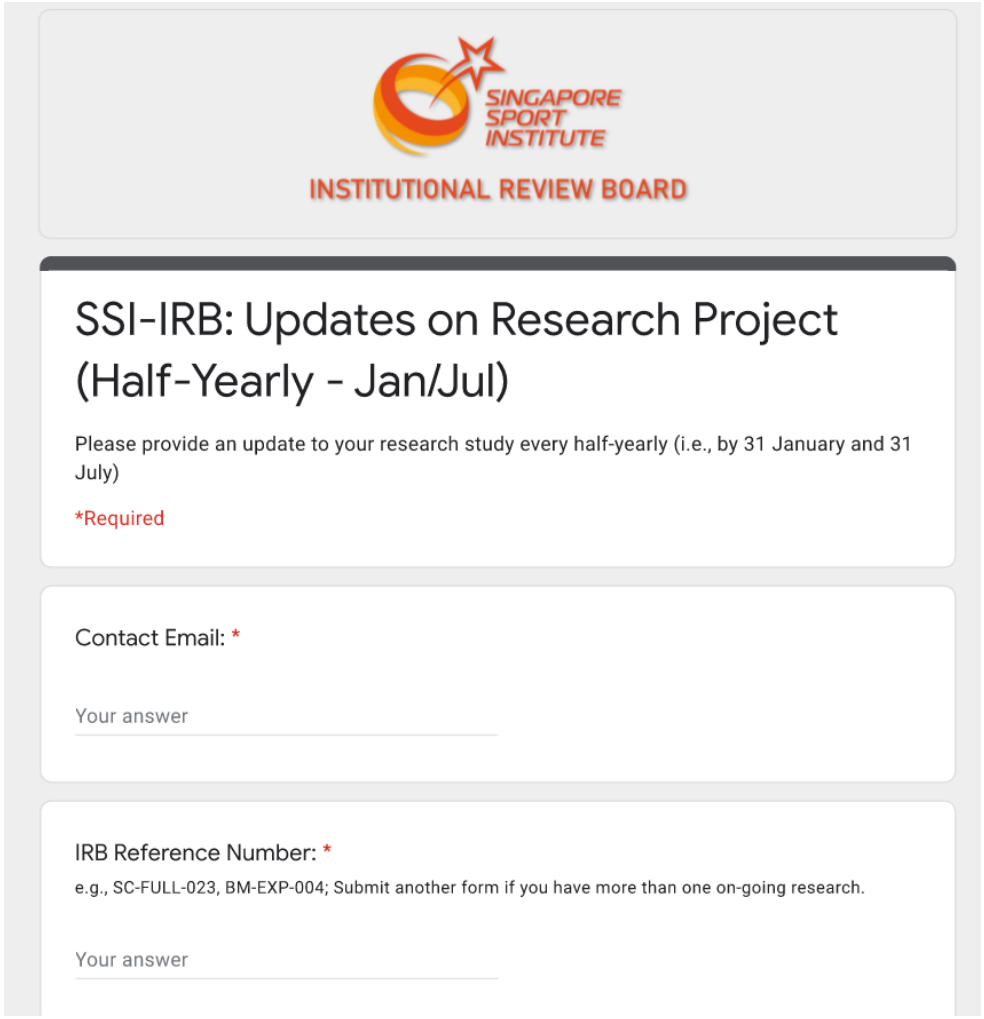
MINISTRY OF HEALTH (MOH) – KEY FOCAL AREAS (KFA)



RESEARCH MONITORING / INTERNAL AUDIT

- As of January 2021, SSI-IRB Secretariat has rolled out an internal research monitoring system.
- Principal Investigators will have to provide status updates of their research projects every half-yearly (End of January & July).

RESEARCH MONITORING / INTERNAL AUDIT



- For subsequent status update of research, do look out for email.
- Researchers who miss the stipulated reporting dates will be given a **warning** and are required to update the status within 7 calendar days.
- Failure to do so will result in internal disciplinary action (i.e., suspension of study).

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STUDIES CLEARED (JAN 2021 – TO-DATE)

- **7 studies** cleared by SSI-IRB
  - 2 FULL | 5 EXPEDITED | 0 EXEMPTED
  - 3 Collaborative Studies

- **5 studies** are being reviewed
  - 3 FULL | 2 EXPEDITED | 0 EXEMPTED

- Distribution of institutes submitting application
  - 75% SSI | 25% NYSI

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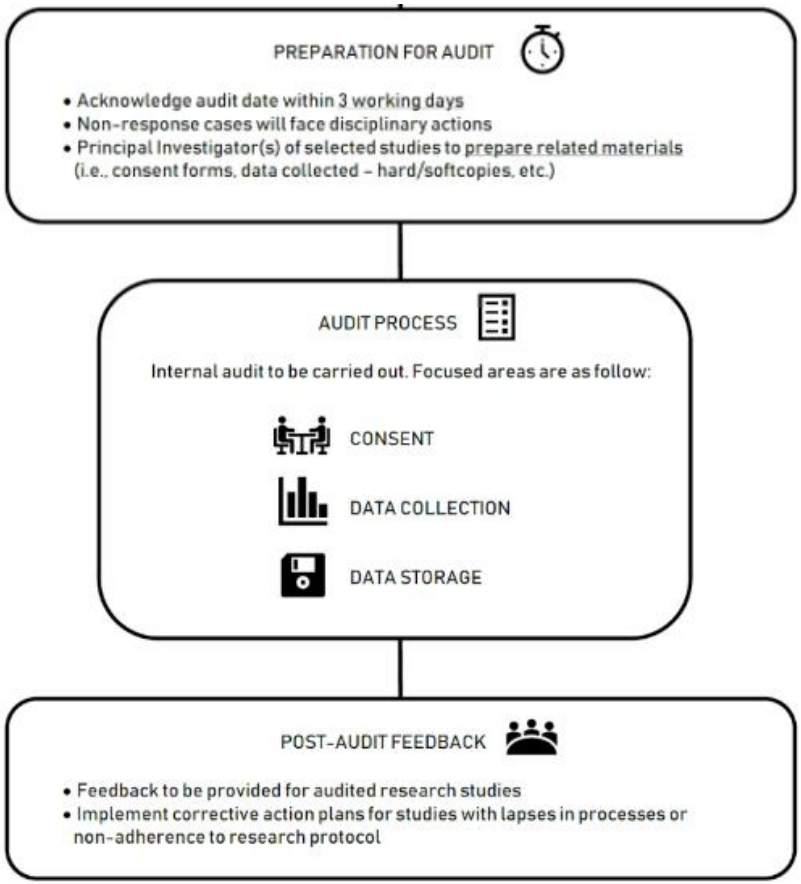
RESEARCH MONITORING / INTERNAL AUDIT



- Internal audit has been carried out by the Secretariat Team and is still on-going at this moment.
- Approved research in the following phases will be selected at random:
  - Completed
  - On-going Data Collection
  - On-going Data Analysis

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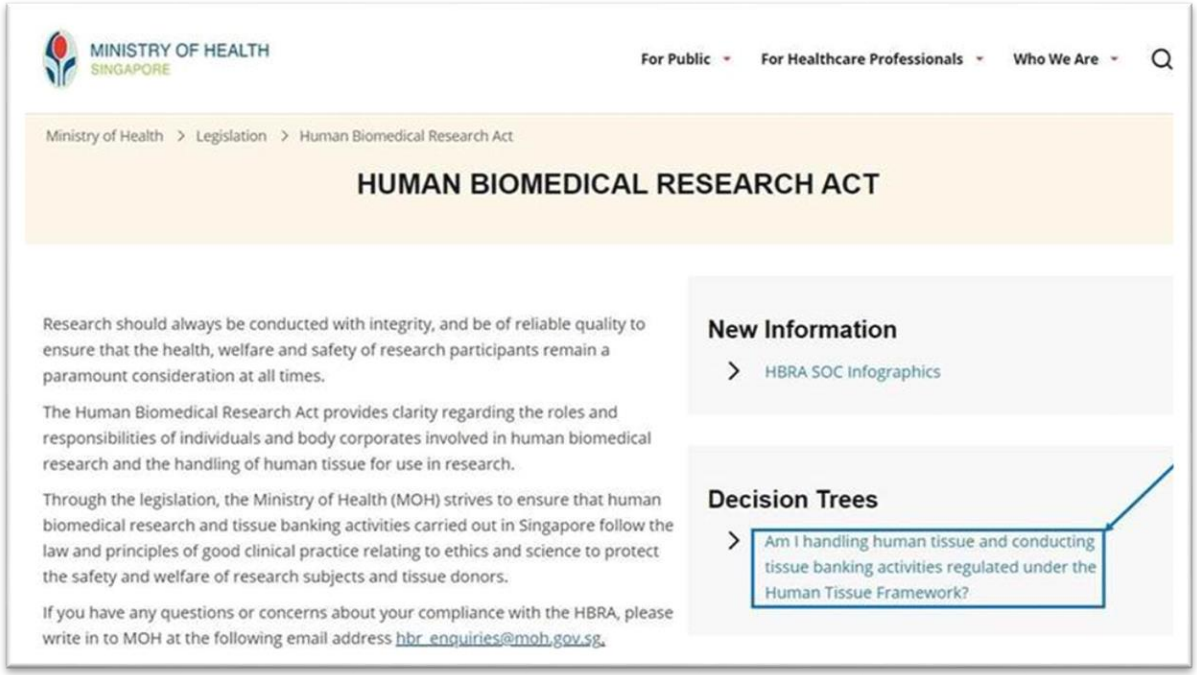
HUMAN TISSUE FRAMEWORK (HTF) DECISIONAL TOOL



- It is intended to guide stakeholders in deciding if they are handling human tissue and whether they are conducting tissue banking activities regulated under the HTF.
- You can access the tool under the section "Decision Trees" on the HBRA webpage.

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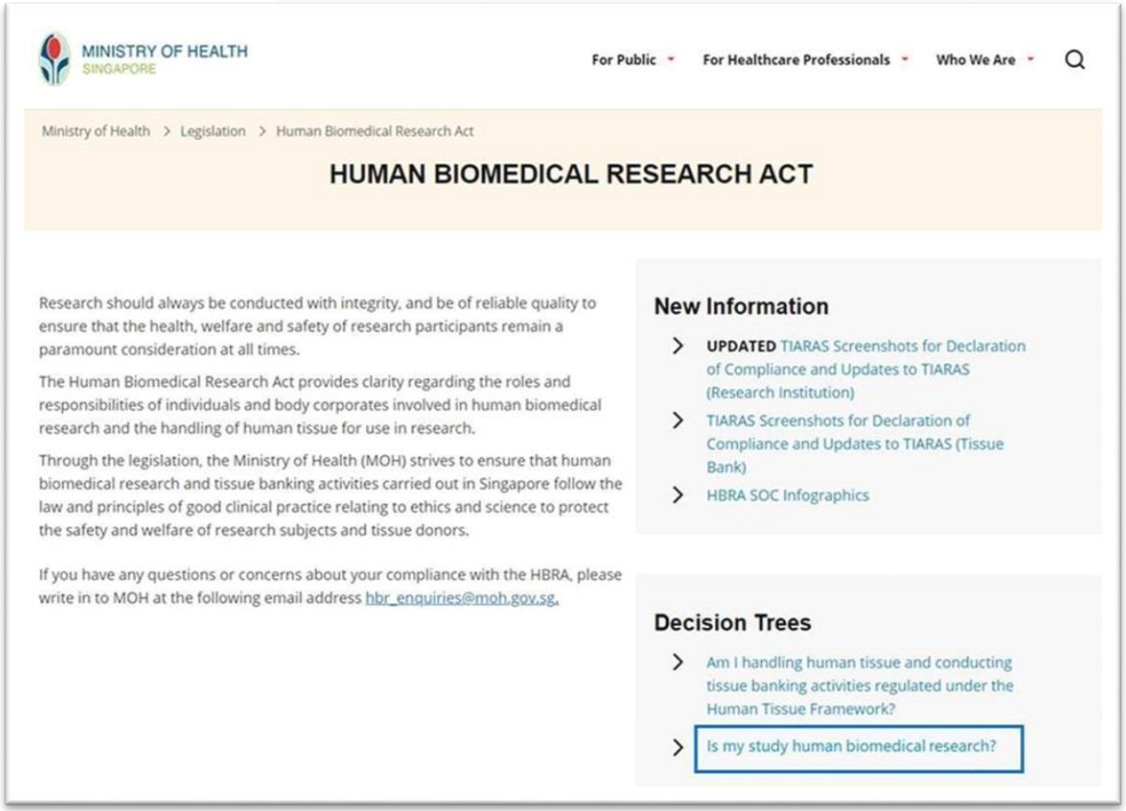
DECISIONAL TOOL BY MOH

HUMAN BIOMEDICAL RESEARCH (HBR) DECISIONAL TOOL

https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act/decision-tool-on-the-human-biomedical-research-framework



- It is intended to guide stakeholders in deciding if their study is human biomedical research under the HBRA.
- You can access the tool under the section "Decision Trees" on the HBRA webpage.

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WHAT CONSTITUTES A HBR STUDY?

Purpose	
Intended to study the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body?	✗
Intended to restore, maintain or promote the aesthetic appearance of human individuals through clinical procedures or techniques?	✗
Intended to study the performance or endurance of human individuals?	✓

Methodology	
Involve any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual?	✓
Involve the use of any individually-identifiable human biological material?	✗
Involve the use of any individually-identifiable health information?	✗

HBR Study

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DECISIONAL TOOL BY MOH

- Do note that these decision tools are meant as a guide, submitted studies will ultimately be classified on a case-by-case basis.

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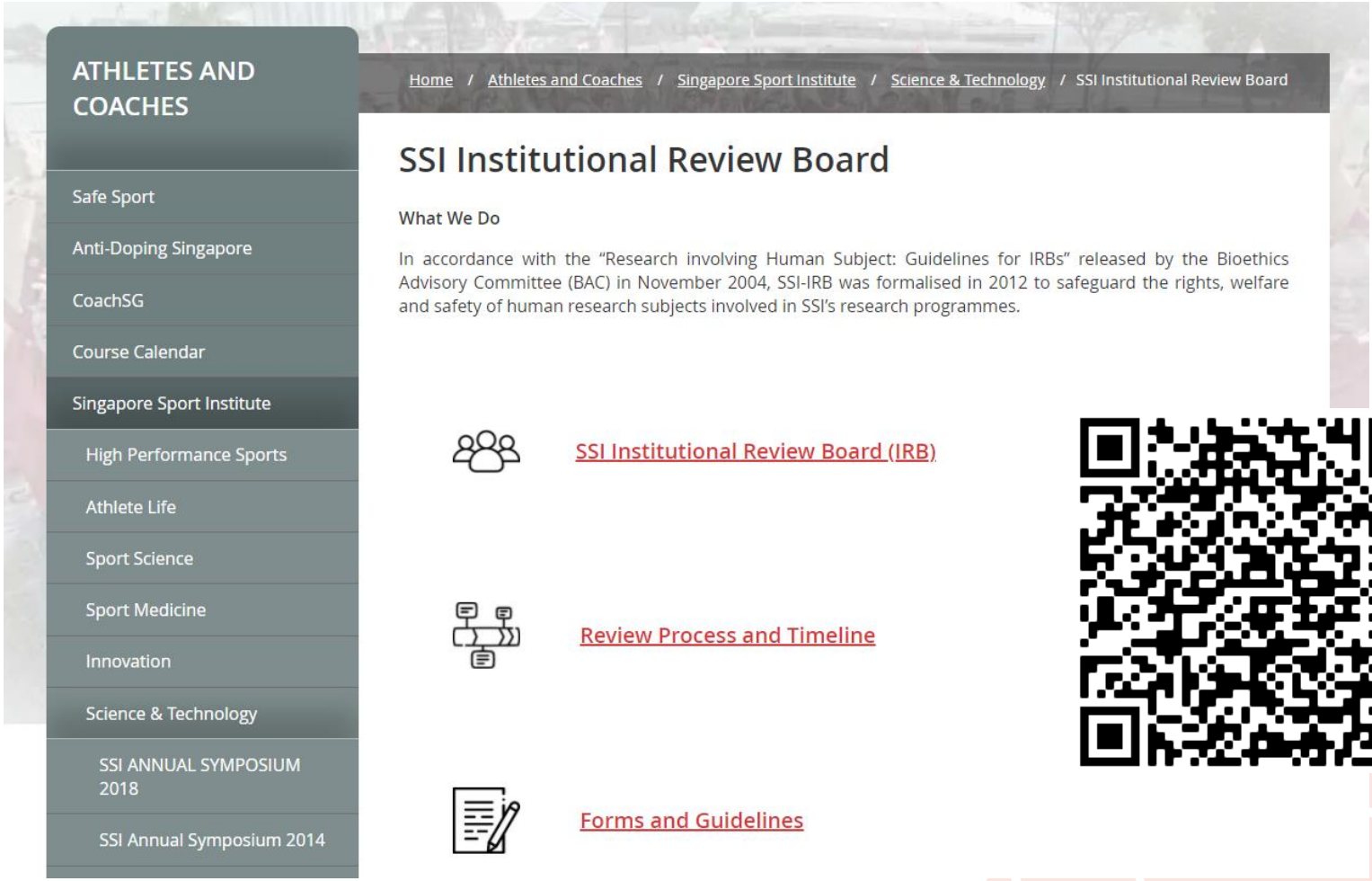
SSI-IRB WEBPAGE

https://www.sportsingapore.gov.sg/athletes-coaches/singapore-sport-institute/science-and-technology/ssi-institutional-review-board



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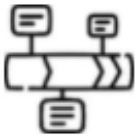
UPDATE TO SSI-IRB WEBPAGE

SSI Institutional Review Board (IRB)



Review Process and Timeline

It will show the application process and amendment process.

Forms and Guidelines

It will show all the latest forms and guidelines.

Research Monitoring

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PROCESS TO MAKE AMENDMENT

Amendment form has to be submitted if researchers are seeking to make:

- 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.*

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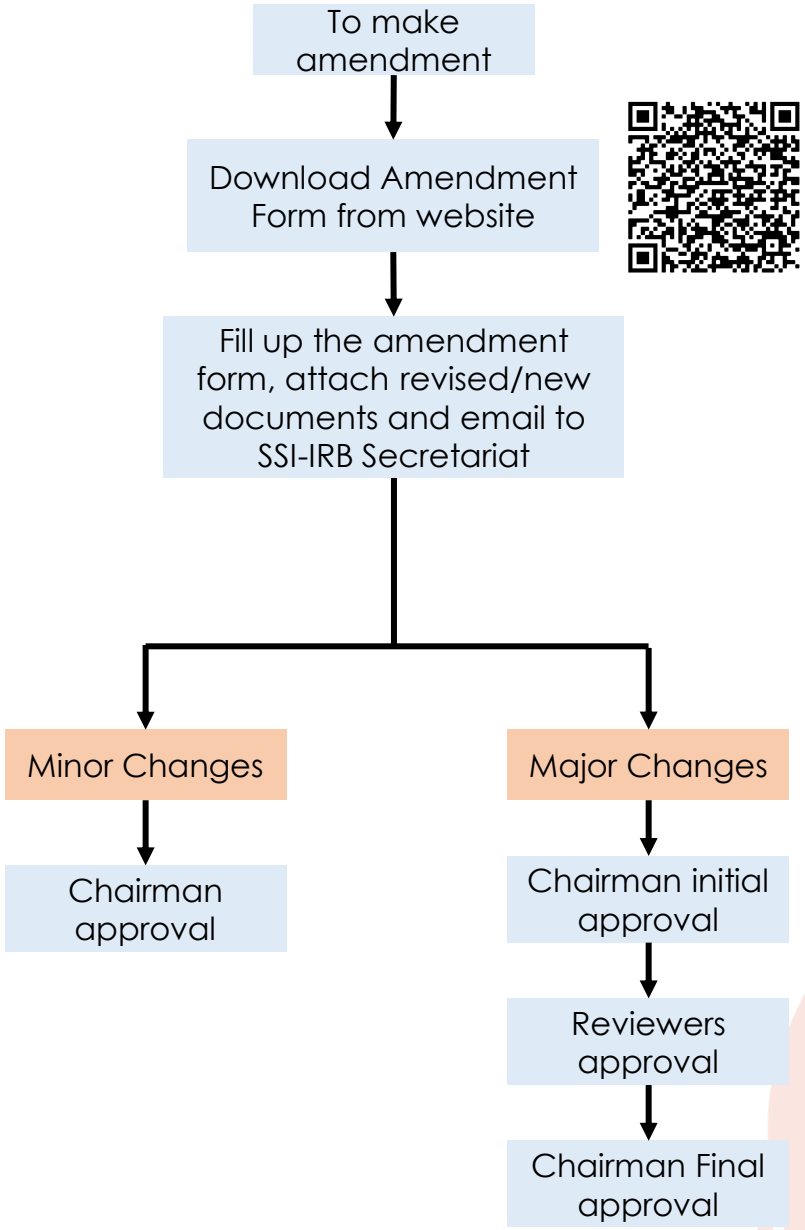
PROCESS TO MAKE AMENDMENT



To determine if the changes are minor or major, we will look at whether the requested changes will increase the risks to participants.

ONLINE CONSENT TAKING

Guidelines for online consent (for Non-HBR study only):

- To use a secure online platform such as FormSG
- A copy of the form should be sent to the participant's email and that of the parent/legal guardian's (for minors).
- Attachment of Participant Information Sheet as a downloadable e-document within the form.

Please print a copy of this consent form for your records and choose to download a copy of the Participant Information Sheet, if you so desire.

To download the Participant Information Sheet:
https://drive.google.com/file/d/1DHjHT3SL1Q6_9gspmK_r1aPJW9_PUTiu/view?usp=sharing

Provide an external link for Participants / Parents / Guardians to download a copy of PIS

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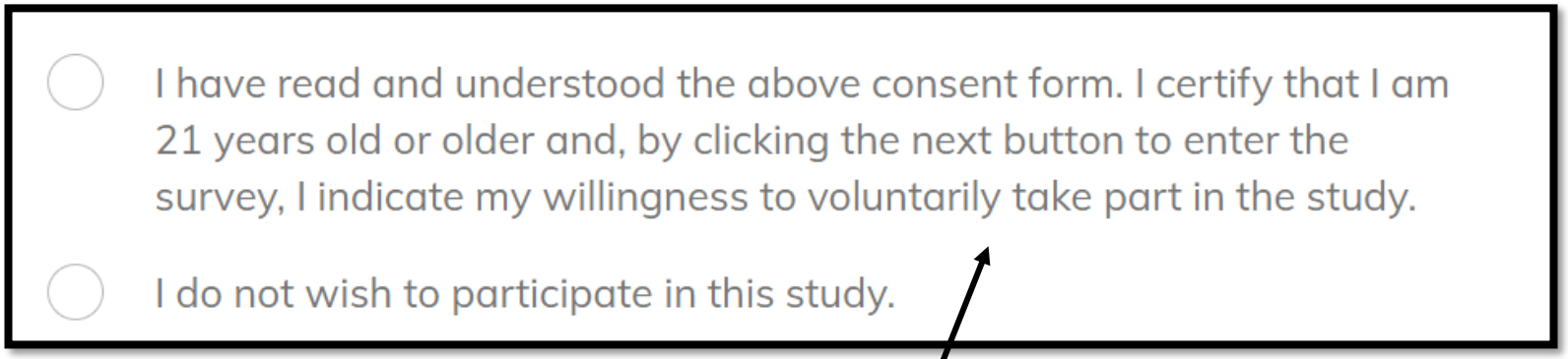
ONLINE CONSENT TAKING

Guidelines for online consent (for Non-HBR study only):

- For Participants over 21 years old,

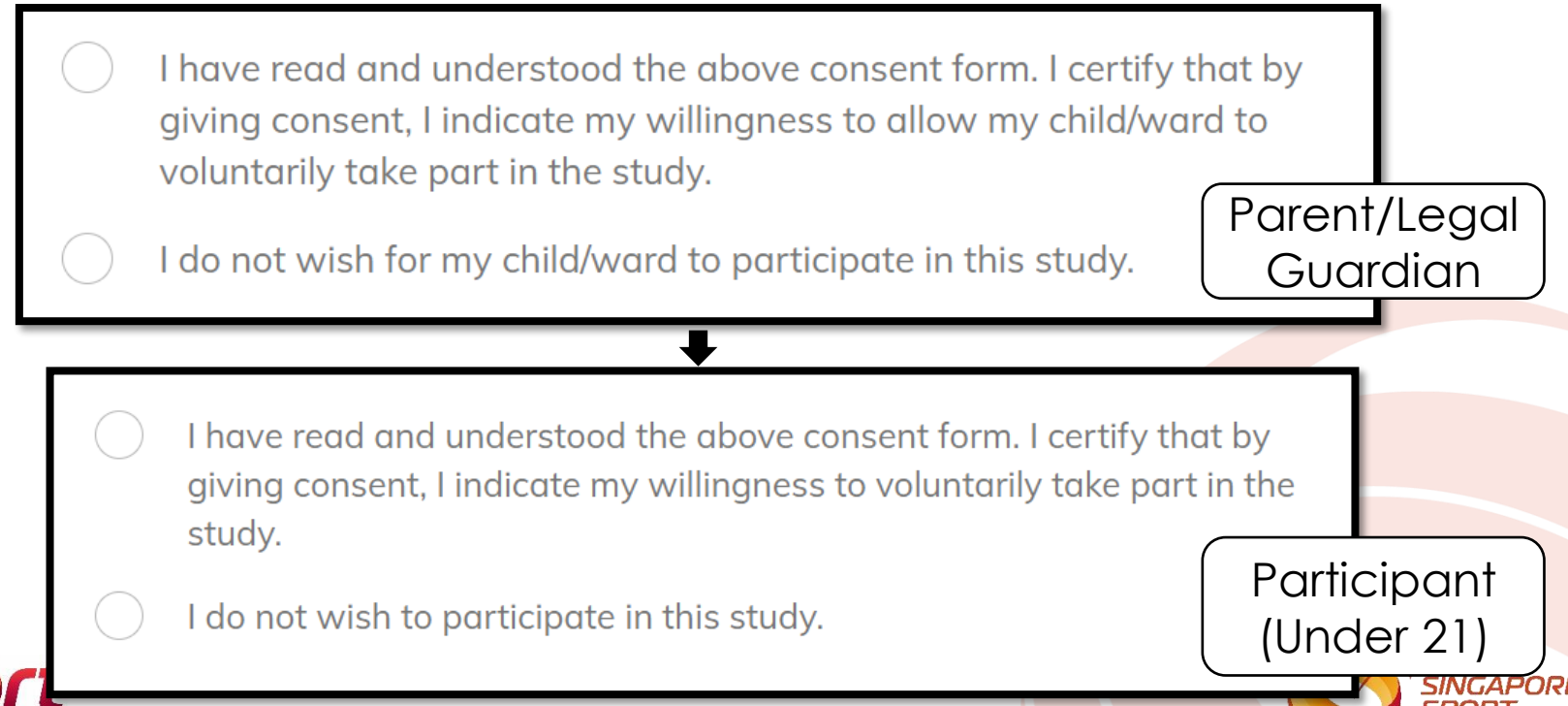


Signature sought via a YES/NO checkbox with mandatory age declaration.

ONLINE CONSENT TAKING

Guidelines for online consent (for Non-HBR study only):

- Parent/Legal Guardian signature for minors via YES/NO check box.
  - Note the time and date of BOTH the Parent/Legal Guardian's and the Minors' consent



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ONLINE CONSENT TAKING

Other possible methods of online consent-taking:

(for Non-HBR study only)

- Uploaded copy of signed consent form
- Tele-consultation for consent-taking
  - Note down the time and date of phone calls.
  - Phone call to be recorded.
- For minors, a separate email could be auto-generated to obtain parental/legal guardian consent.

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ONLINE CONSENT TAKING

Online Consent Taking Template (FormSG)

- Participant

https://form.gov.sg/60cc10abf0f3350011530fc4/use-template

- Parents/Guardians

https://form.gov.sg/60cc1081fc19080012dc44d2/use-template

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UPDATE TO SSI-IRB GUIDELINES

6 SSI-IRB Guidelines

- IRB Guidelines 01 – Expedited Review [Updated in 2020]
- IRB Guidelines 02 – Exemption from Review [Updated in 2020]
- IRB Guidelines 03 – Human Subjects
- IRB Guidelines 04 – Human Biological Research and Sample
- IRB Guidelines 05 – Requirement of Consent
- IRB Guidelines 06 – Data Management Policy [Updated in 2020]

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RESEARCH COLLABORATION AGREEMENT

New guideline on Research Collaboration Agreement (RCA):

- Research Collaboration Agreement is required if investigators of two or more Research Institutes (RIs) contribute to one research study.
- Information on what must be included in the RCA
- Research projects undertaken by Institute of Higher Learning (IHL) students attached to SSI, there is no need to establish an RCA between Singapore Sport Institute and the respective schools.
  - Apply to both HBR and non-HBR studies

Template of RCA can be found on SSI-IRB website.

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MOH UPDATES TO REQUIREMENT OF CONSENT

Appropriate consent under the HBRA

- Consent does not need to be obtained in the presence of a witness if research is not interventional, not invasive and not restricted HBR.

Interventional	Invasive
Involves any activities that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the research subject	Involves any procedure that is incisional. e.g. Finger-prick blood test

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QUESTIONS?

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