



Singapore Sport Institute – Institutional Review Board

Information Sharing & Recent Updates



18 June 2021



Permanent Secretariat Member

Mr. Chow Kin Ming

Physiology Laboratory Officer
Sport Science & Medicine Centre
Singapore Sport Institute
Chow_Kin_Ming@sport.gov.sg

Secretariat Team

Ms. Tan Hui Yi

Sport Science & Medicine Centre
Singapore Sport Institute
Hui_Yi_Tan_From.TP@sport.gov.sg

Ms. Joanna Li

Talent Identification Specialist
National Youth Sports Institute
Joanna_li@nysi.org.sg

Ms. Goh Wan Xiu

Sport Biomechanist
Sport Science & Medicine Centre
Singapore Sport Institute
Goh_Wan_Xiu@sport.gov.sg

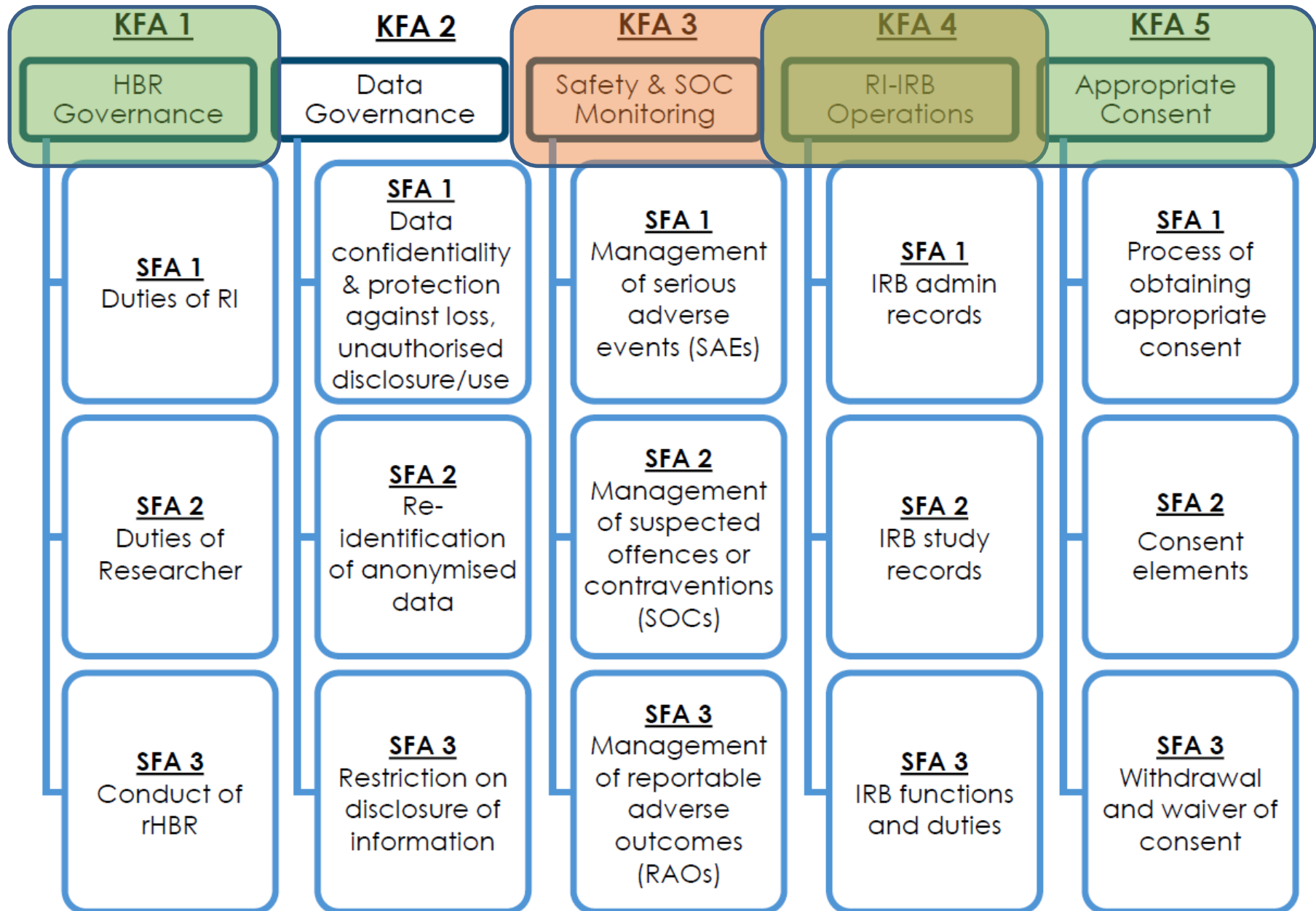
Mr. Kelvin Chua

Strength & Conditioning Coach
Sport Science & Medicine Centre
Singapore Sport Institute
Kelvin_Chua@sport.gov.sg

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

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



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 January & July
- Via bit.ly/39vUMWI



- 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).



INSTITUTIONAL REVIEW BOARD

SSI-IRB: Updates on Research Project (Half-Yearly - Jan/Jul)

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

*Required

Contact Email: *

Your answer

IRB Reference Number: *

e.g., SC-FULL-023, BM-EXP-004; Submit another form if you have more than one on-going research.

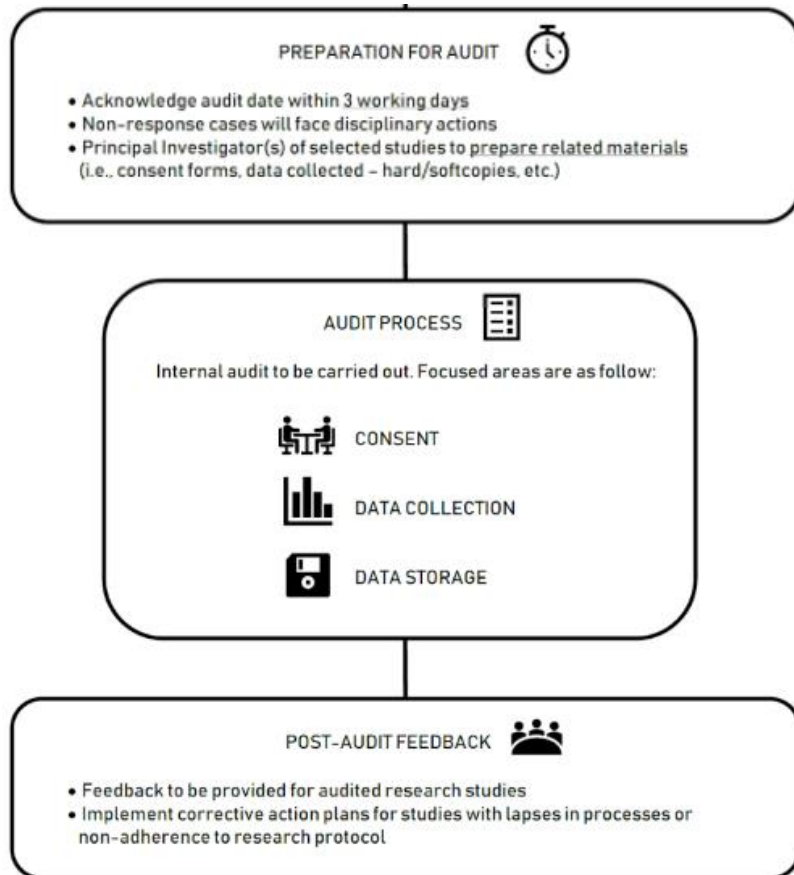
Your answer

- 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).

STUDIES CLEARED (JAN 2021 – TO-DATE)

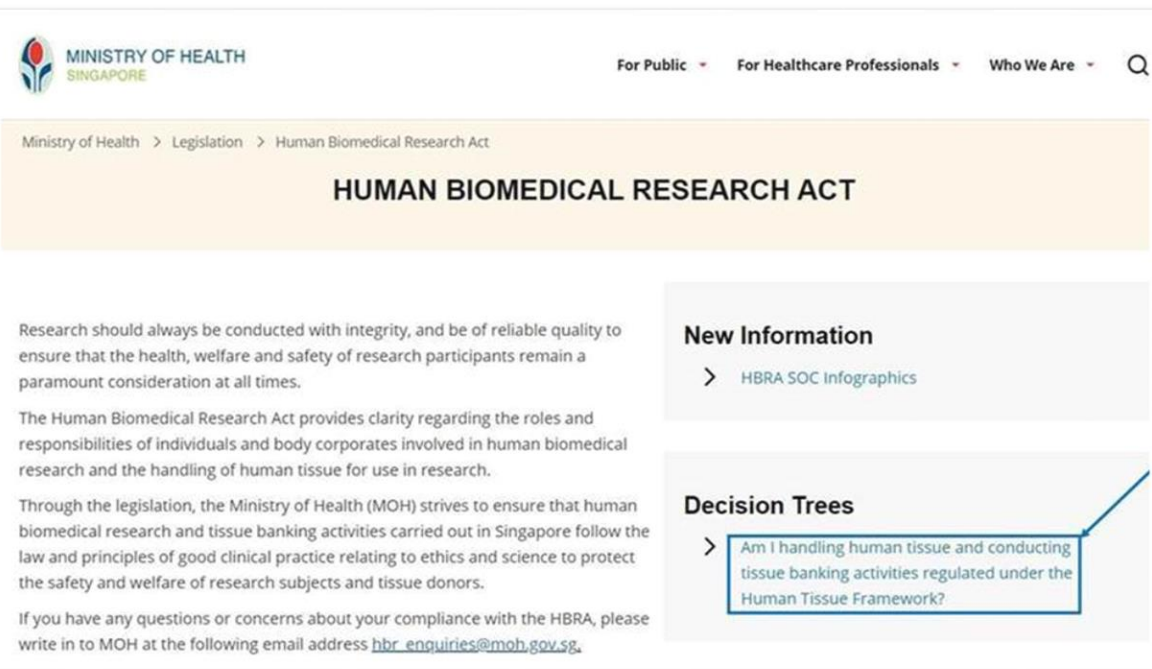
- **7 studies** cleared by SSI-IRB
 - 2 FULL | 5 EXPEDITED | 0 EXEMPTED
 - 3 Collaborative Studies
- **5 studies** are being reviewed
 - 3 FULL | 2 EXPEDITED | 0 EXEMPTED
- Distribution of institutes submitting application
 - 75% SSI | 25% NYSI

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

HUMAN TISSUE FRAMEWORK (HTF) DECISIONAL TOOL



MINISTRY OF HEALTH SINGAPORE

For Public ▾ For Healthcare Professionals ▾ Who We Are ▾

Ministry of Health > Legislation > Human Biomedical Research Act

HUMAN BIOMEDICAL RESEARCH ACT

Research should always be conducted with integrity, and be of reliable quality to ensure that the health, welfare and safety of research participants remain a paramount consideration at all times.

The Human Biomedical Research Act provides clarity regarding the roles and responsibilities of individuals and body corporates involved in human biomedical research and the handling of human tissue for use in research.

Through the legislation, the Ministry of Health (MOH) strives to ensure that human biomedical research and tissue banking activities carried out in Singapore follow the law and principles of good clinical practice relating to ethics and science to protect the safety and welfare of research subjects and tissue donors.

If you have any questions or concerns about your compliance with the HBRA, please write in to MOH at the following email address hbr_enquiries@moh.gov.sg.

New Information

- > [HBRA SOC Infographics](#)

Decision Trees

- > [Am I handling human tissue and conducting tissue banking activities regulated under the Human Tissue Framework?](#)

- 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.



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>

MINISTRY OF HEALTH SINGAPORE

For Public - For Healthcare Professionals - Who We Are - Q

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New Information

- > **UPDATED** TIARAS Screenshots for Declaration of Compliance and Updates to TIARAS (Research Institution)
- > TIARAS Screenshots for Declaration of Compliance and Updates to TIARAS (Tissue Bank)
- > HBRA SOC Infographics

Decision Trees

- > Am I handling human tissue and conducting tissue banking activities regulated under the Human Tissue 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.

WHAT CONSTITUTES A HBR STUDY?

Purpose		Methodology	
Intended to study the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body?	✗	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?	✓
Intended to restore, maintain or promote the aesthetic appearance of human individuals through clinical procedures or techniques?	✗	Involve the use of any individually-identifiable human biological material?	✗
Intended to study the performance or endurance of human individuals?	✓	Involve the use of any individually-identifiable health information?	✗

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.

SSI-IRB WEBPAGE

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


ATHLETES AND COACHES


Home / Athletes and Coaches / Singapore Sport Institute / Science & Technology / SSI Institutional Review Board


SSI Institutional Review Board


What We Do

In accordance with the "Research involving Human Subject: Guidelines for IRBs" released by the Bioethics Advisory Committee (BAC) in November 2004, SSI-IRB was formalised in 2012 to safeguard the rights, welfare and safety of human research subjects involved in SSI's research programmes.

 [SSI Institutional Review Board \(IRB\)](#)

 [Review Process and Timeline](#)

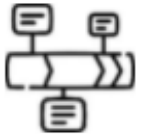
 [Forms and Guidelines](#)



UPDATE TO SSI-IRB WEBPAGE



[SSI Institutional Review Board \(IRB\)](#)



[Review Process and Timeline](#)



[Forms and Guidelines](#)



[Research Monitoring](#)

It will show the application process and amendment process.

It will show all the latest forms and guidelines.

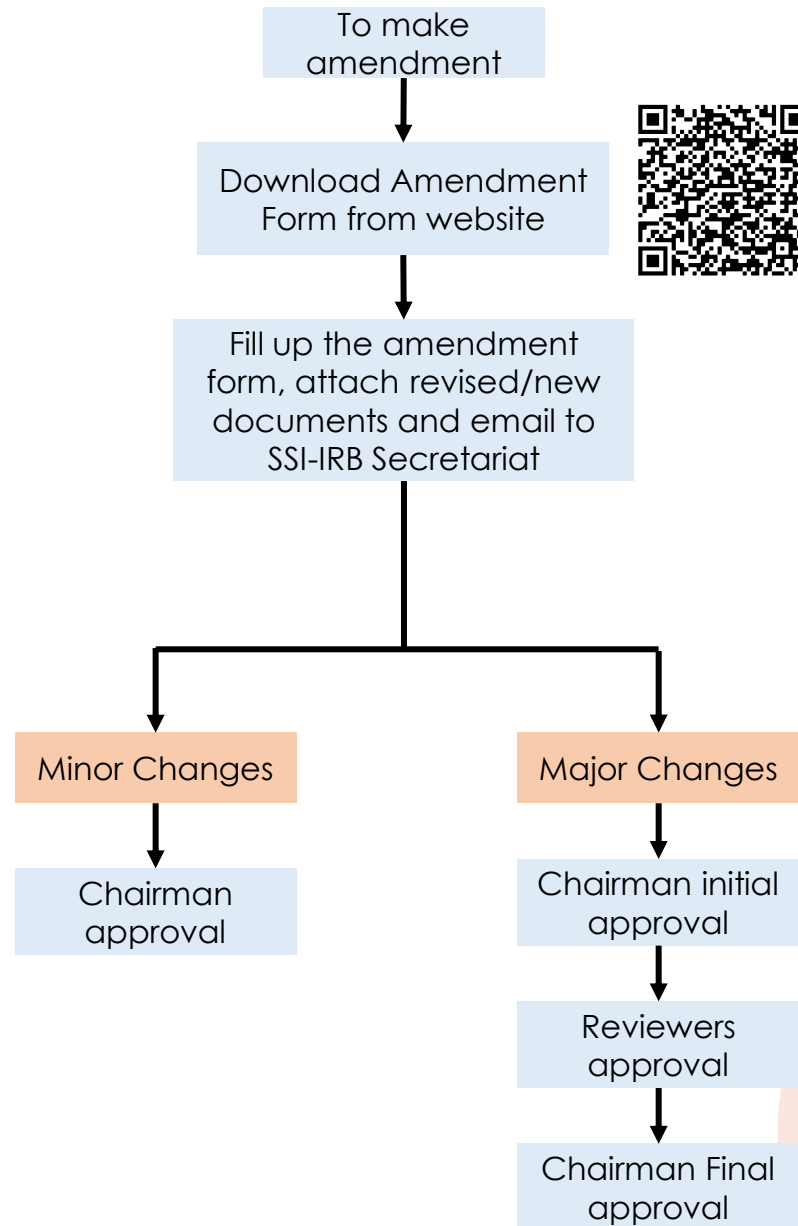
PROCESS TO MAKE AMENDMENT

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.*

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

ONLINE CONSENT TAKING

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

- For Participants over 21 years old,

- I have read and understood the above consent form. I certify that I am 21 years old or older and, by clicking the next button to enter the survey, I indicate my willingness to voluntarily take part in the study.
 - I do not wish to participate in this study.

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

I have read and understood the above consent form. I certify that by giving consent, I indicate my willingness to allow my child/ward to voluntarily take part in the study.

I do not wish for my child/ward to participate in this study.

Parent/Legal Guardian

I have read and understood the above consent form. I certify that by giving consent, I indicate my willingness to voluntarily take part in the study.

I do not wish to participate in this study.

Participant (Under 21)

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.

Online Consent Taking Template (FormSG)

- Participant

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

- Parents/Guardians

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

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]

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.

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 <u>physical, mental or physiological effect</u> (whether temporary or permanent) on the body of the research subject	Involves any procedure that is <u>incisional</u> . e.g. Finger-prick blood test

QUESTIONS?

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