Singapore Sport Institute – Institutional Review Board

Information Sharing & Recent Updates

24 April 2020

LIVE BETTER THROUGH SPORT

SSI INSTITUTIONAL REVIEW BOARD SECRETARIAT

Secretariat Team

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Singapore Sport Institute

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Physiology Laboratory Officer
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Mr. Desmond Boey
Member (Out-going: Sept 2020)
Sport Biomechanist
Singapore Sport Institute

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Sport Biomechanist
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Mr. Kelvin Chua
Member
Strength & Conditioning Coach
Singapore Sport Institute

Ms. Andrea Chen
Member (In-coming)
Sport Physiotherapist
National Youth Sports Institute

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AGENDA

1. Key Focal Areas for Human Biomedical Research (HBR)

2. Duties of Researchers
   - Review Process
   - Risk level
   - Application forms
   - Data Management, Security and Governance
   - Research Collaboration Agreements (RCA)

3. Appropriate Consent

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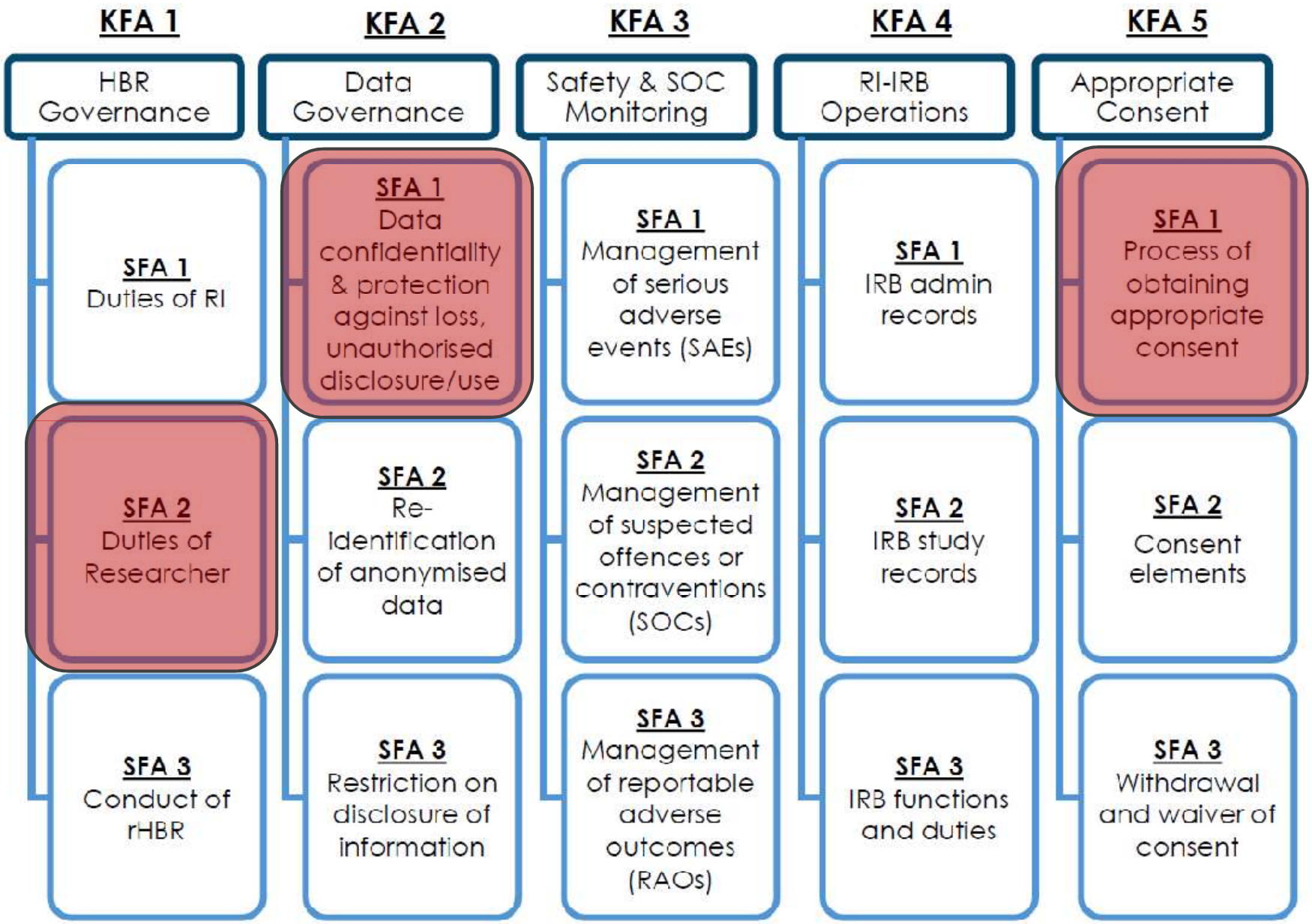
MINISTRY OF HEALTH (MOH) - KEY FOCAL AREAS (KFA)



ROLE OF SSI-IRB & SECRETARIAT

- Reviews ethics for studies conducted in SSI and NYSI
- Registered under MOH as a research institute that conducts Human Biomedical Research (HBR)

HUMAN BIOMEDICAL RESEARCH (HBR) CLASSIFICATION

What determines if a study is classified as HBR?

Does the **PURPOSE** of the study involve:

- The **prevention**, **prognostication**, **diagnosis** or alleviation of any disease disorder or injury affecting the human body; or
- The **restoration**, **maintenance** or **promotion** of aesthetic appearance of human individuals through clinical procedures or techniques; or
- The **performance or endurance** of human individuals

Does the study **METHODOLOGY** involve:

- **Subjecting an individual** to any intervention that has a **physical, mental or physiological effect on the body** of the individual; or
- The **use of** any **individually-identifiable biological material** obtained from the human body; or
- The **use of** any **individually-identifiable health information**

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RESEARCH APPLICATION FORM (*UPDATED JAN 2020)

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INSTITUTIONAL REVIEW BOARD
– Application Form for IRB Review

Kindly fill in ALL fields except for those that are *(highlighted)*; do NOT leave any blanks. Enter 'NA' or 'NIL' should you not wish to enter any content.

SECTION 1: GENERAL INFORMATION		
IRB Reference Number *(Secretariat Use)*:	Should be filled up when sent to reviewers [e.g. PS-EXP-123]	
Prior Ethics Approval:	☐ YES / ☐ NO *If YES, kindly attach Letter or Certificate of Approval and other details, where applicable.*	
Title of Project:		
Principal Investigator (PI):		Must have signature! Signature
Designation:		
Department / Division / Organisation:		
Contact Details (Tel / Email):		
		Must have all signatures! Signature

RESEARCH APPLICATION FORM (*UPDATED JAN 2020)

4.2. Justification of Data Collected:
Describe what the data / samples collected will be used for, if they are to be stored (tissue, blood), for how long, and reasons why those parameters were selected

Where no physical tissue is collected: What are the variables tested, and why?

4.3. Harmful Substances:
Where applicable, state if the participant will be exposed to any harmful substances, i.e. radioactive, potentially life-threatening or dangerous substances

4.4. Confidentiality of Information:
Describe how samples are de-identified; who will have access to participant data, samples, videotapes and photographs, if applicable; describe what happens to information after project is completed and where it will be stored. A minimum of 7 years is required for research data to be stored from completion of study or publication of research data, whichever is later. Please indicate where and for how long your data will be stored for.

Self-explanatory

4.5. Special Populations:
Kindly indicate if your research involves any of the following vulnerable populations of individuals including young children, prisoners, pregnant women, and the mentally-challenged

Indicate if there is any of the above highlighted population, or none

SECTION 6: RISK MITIGATION AND REPORTING

6.1. Describe the measures taken to mitigate the risks faced by the participants resulting from the conduct of the study:
For risks or potential adverse events mentioned in Section 5.3.2, list down control or preventive measures as to how such risks can be minimised

Application will be returned if this is not explicitly explained

PARTICIPANTS' SAFETY IS OF UTMOST IMPORTANCE

6.2. Describe the procedures for handling and reporting of any serious incidents / events:
In the event that serious incidents do happen, how will it be handled? What will the reporting structure be? (i.e., onsite research team reports to PI, PI report to SSI-IRB Secretariat) Please briefly state the reporting guidelines:

Application will be returned if this is not explicitly explained

PARTICIPANTS' SAFETY IS OF UTMOST IMPORTANCE

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SECTION 7: CLASSIFICATION OF STUDY AS HUMAN BIOMEDICAL RESEARCH

This section serves as a guideline to determine whether your study fulfils Ministry of Health's criteria for Human Biomedical Research (HBR).

7.1. PURPOSE

If unsure, tick the one that makes more sense

a. Is your research intended to study the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body?

☐ YES / ☐ NO

b. Is your research intended to restore, maintain or promote the aesthetic appearance of human individuals through clinical procedures or techniques?

☐ YES / ☐ NO

c. Is your research intended to study the performance or endurance of human individuals?

☐ YES / ☐ NO

7.2. METHODOLOGY

If unsure, tick the one that makes more sense

a. Does your research involve subjecting an individual to 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?

☐ YES / ☐ NO

b. Does your research involve the use of any individually-identifiable[1] human biological material?

☐ YES / ☐ NO

c. Does your research involve the use of any individually-identifiable[1] health information[2]?

☐ YES / ☐ NO

1. *Individually-identifiable* means that the individual can be identified from the health information being collected or the biological material.
2. *Health information* refers to information that was obtained in the course of providing healthcare services or relating to the study of a disease, disorder or injury.

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RESEARCH APPLICATION FORM (*UPDATED JAN 2020)

7.3. DAILY TRAINING RISK

Is the procedure or intervention used in your research study part of the participant's usual training or servicing routine?

☐ YES (proceed to 7.3.1) / ☐ NO (proceed to Section 8)

7.3.1. Please provide substantiation (e.g., training plans or servicing reports) that shows:

a. The procedure or intervention is part of the participant's regular training routine (attach as an annex if needed).

Attach training program

b. The procedure or intervention does not increase the participant's level of risk above what he/she is normally exposed to on a regular basis.

Provide justification based on training program attached

SECTION 11: APPLICATION FOR IRB REVIEW

11.1. The completed Form is in application for (check the appropriate box):

☐ **Full** Review by the SSI Institutional Review Board

[Study involves more than minimal risk to participants]

☐ **Expedited** Review by the SSI Institutional Review Board

[Study involves no more than minimal risk to participants]

☐ **Exemption** from Review by the SSI Institutional Review Board

[Study involves less than minimal risk to participants]

11.2. This research is classified as Human Biomedical Research (HBR) (please provide substantiation why – e.g., risk level) *(Secretariat Use)*

☐ YES

☐ NO

Yes or No, provide substantiation. Bullet points will suffice

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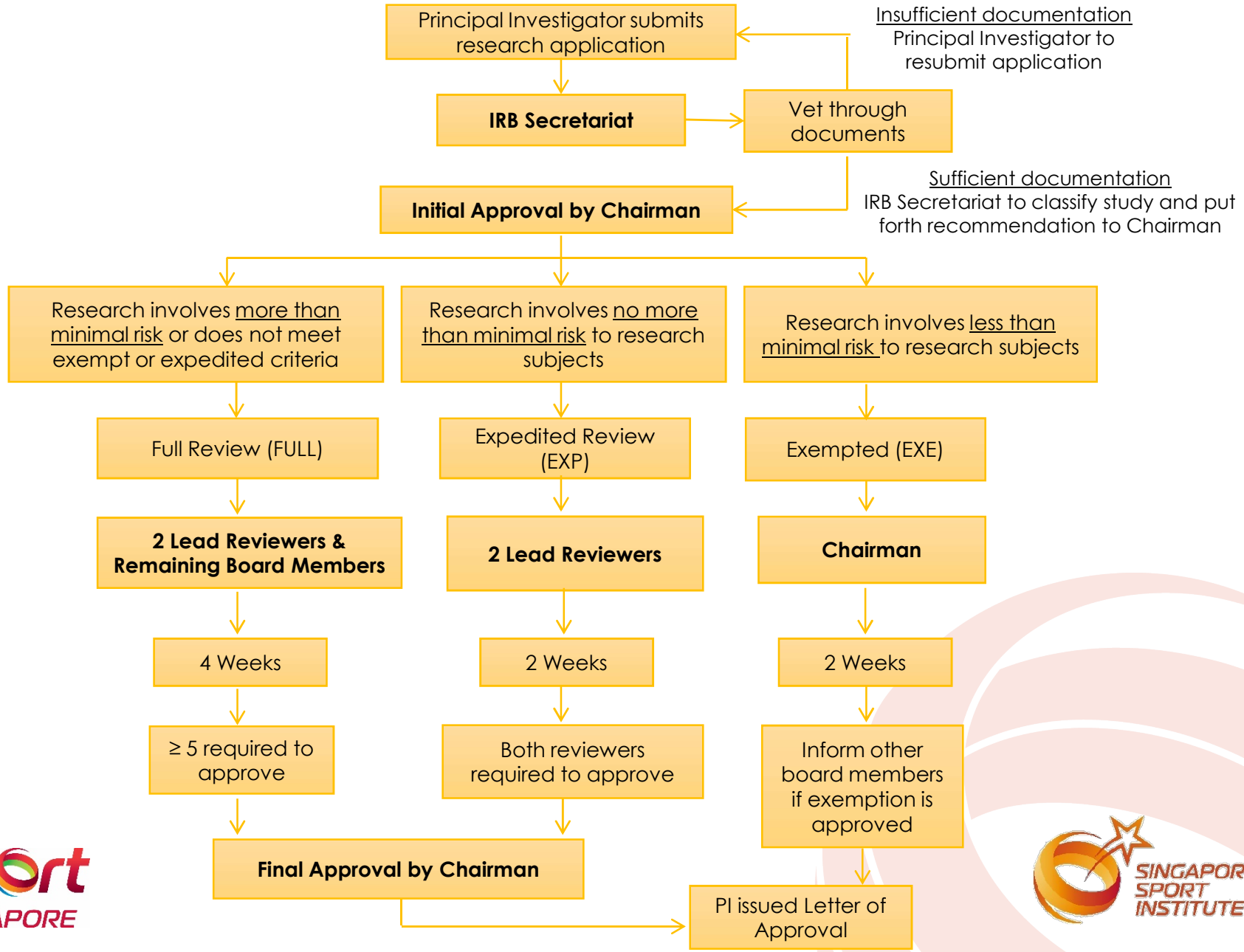
REVIEW PROCESS



EXPEDITED REVIEW & EXEMPT FROM REVIEW

- Determined by the level of risk faced by participants
- Whether there is more, less, or equal to daily amount of risk faced by target participant group?

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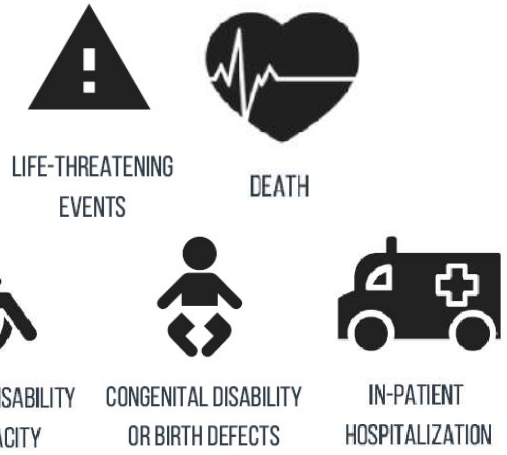
INCIDENT REPORTING – SEVERE ADVERSE EVENTS (SAE)

SERIOUS ADVERSE EVENTS



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Activate Medical Emergency Action Plan:

Call **6500 5450** for help
Administer first-aid/CPR-AED
Wait for assistance

INCIDENT REPORT

Once the event is under control:

Contact SSI-IRB Secretariat **immediately**
Fill up and submit the **SAE Reporting Form*** within **24 hrs**

OTHER RESEARCH SITES

Carry out respective Emergency Action Plans

POST EVENT ASSESSMENT

It is the role of the Principal Investigator to:

Re-assess the conduct of the research study
Formulate corrective and preventive action plans
Provide timely updates to SSI-IRB Secretariat

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INCIDENT REPORTING – SEVERE ADVERSE EVENTS (SAE)

SUSPECTED OFFENCES OR CONTRAVENTIONS

An offence is committed in the event of any breaches as follows:

- Commencement of research prior to obtaining approval from SSI-IRB
- Carrying out research without informed consent from participants
- Research protocol deviating from approved study design without re-approval
- Intentional or non-intentional disclosure of identifiable data without consent

INCIDENT REPORT

Researchers who encounter, or are found guilty of committing any SOCs should:

Report to SSI-IRB immediately

Fill up and submit the **SOC Reporting Form*** within **24 hr** of notification

**Download form from Sharepoint or contact Secretariat*

POST EVENT ASSESSMENT

An outcome will be made based on the inquiry.
In general, Principal Investigator(s) will have to:

Receive outcome of study (i.e., suspended, etc.)
Formulate corrective and preventive action plans
Provide timely updates to SSI-IRB Secretariat

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DATA MANAGEMENT & SECURITY

1. Data Collection
   - All data should be **anonymised** immediately during data collection (i.e. 001, 002, etc.)
   - Store the identification data in a password-protected document
2. Data Storage and Maintenance
   - No storage of identifiable data on personal devices; to be stored within encrypted thumb-drive during data collection phase
   - Upon completion of data collection, **only the appointed SSI-IRB Data Management Officer (DMO) has access** to the identification data document *unless* PI seeks approval from secretariat team
   - All data and documents pertaining to the research to be **stored in locked SSI-IRB research cabinet** for a minimum of 7 years, accessed via the DMO

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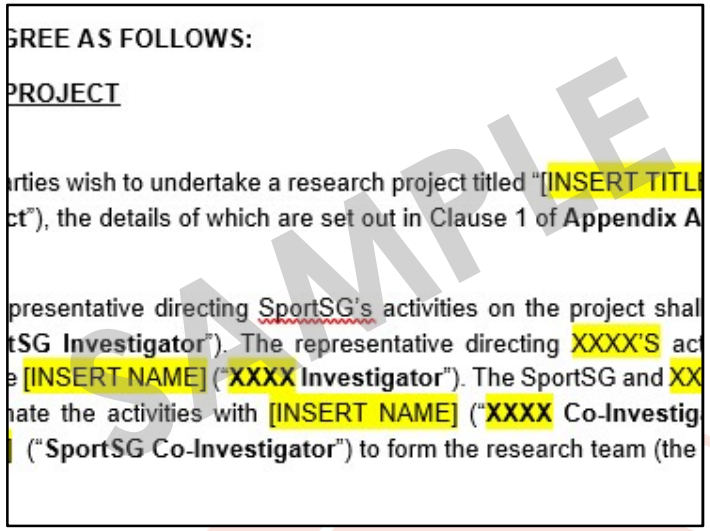
RESEARCH COLLABORATION AGREEMENT (RCA)

- RCA for **multi-party research**
  - To define clear roles and responsibilities for Research Institutes (RI) participating in the same research study

- Procedure for RCAs (SportSG)
  - Fill up template provided by Secretariat
  - Consult with SportSG Legal dept
  - Send to other institute to agree and sign
  - Keep signed copy in research file

- Procedure for other parties
  - Refer to your research coordinator



GREE AS FOLLOWS:

PROJECT

rties wish to undertake a research project titled "[INSERT TITL
ct"), the details of which are set out in Clause 1 of **Appendix A**

presentative directing SportSG's activities on the project shal
tSG Investigator"). The representative directing XXXX'S act
e [INSERT NAME] ("**XXXX Investigator**"). The SportSG and XX
nate the activities with [INSERT NAME] ("**XXXX Co-Investig**
("**SportSG Co-Investigator**") to form the research team (the

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CONSENT TAKING GUIDELINES

- Participant's consent must be taken before **any** form of data collection.
- Consent must be:
  - In writing
  - From the participant personally[1]
  - After the study has been explained clearly to them (methodology, risks, benefits)
  - In the presence of a witness[2]

1. With the exception of adults who lack mental capacity. For minors, consent of parent / legal guardian as well as consent of minor is required.
2. For studies classified as Human Biomedical Research (HBR).

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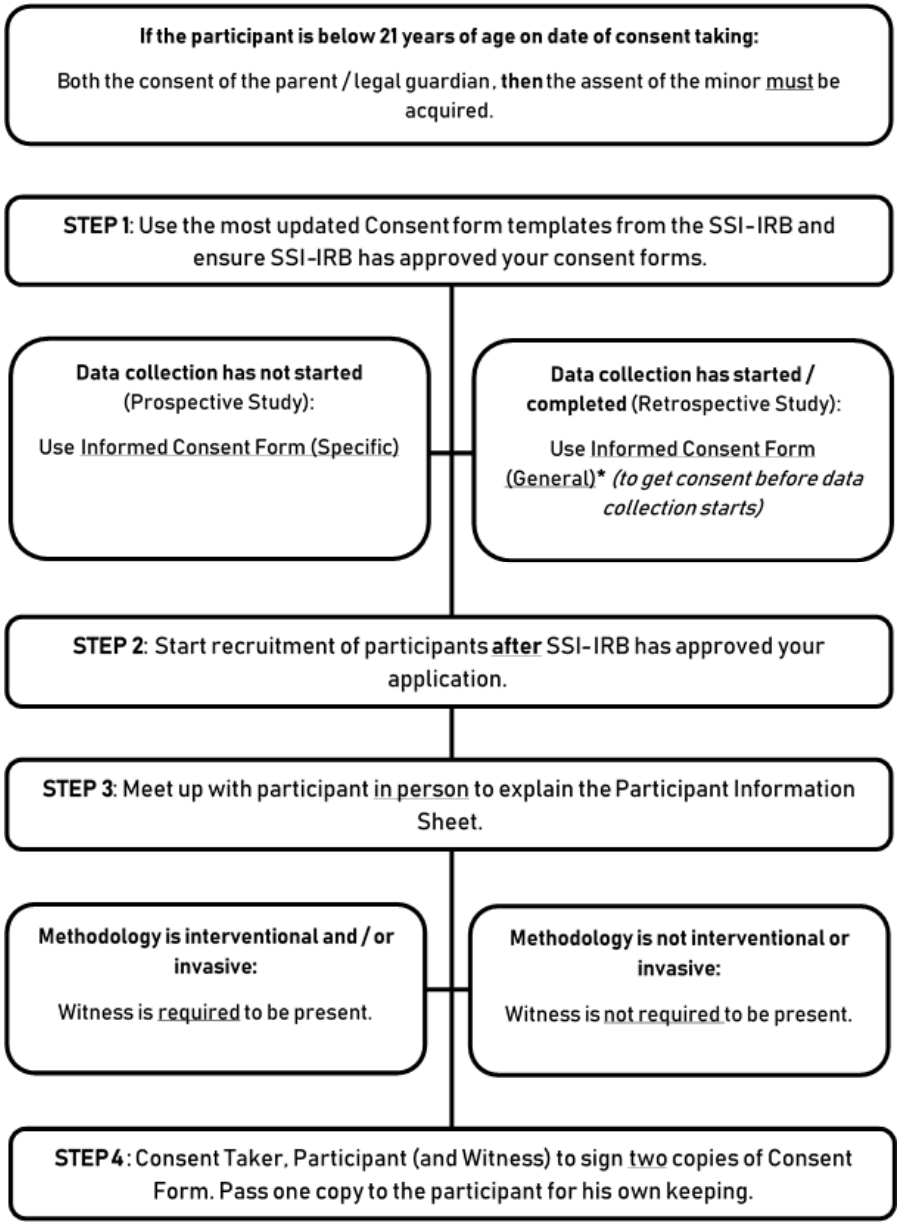
CONSENT TAKING GUIDELINES

- Encourage proper consent even during routine servicing activities
  - Usage of 'General consent form' during normal servicing activities, if intending to use data for future research

- Consent taking for minors
  - **Both** consent of parent / legal guardian, as well as assent of the minor is required



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Any doubts to clarify?