SINGAPORE SPORT INSTITUTE 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)*:		
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):		_____ Signature
Designation:		
Department / Division / Organisation:		
Contact Details (Tel / Email):		
Co-Investigators (Name / Designation, Organisation): *(Please attach the CV of each co-investigator, max. 2 pages)*		_____ Signature
		_____ Signature
		_____ Signature
		_____ Signature

SECTION 2: STUDIES SEEKING RETROSPECTIVE APPROVAL OF RESEARCH METHODOLOGY (IF APPLICABLE)

*This section refers to studies that have completed their data collection component **before** the submission of this Application Form. For studies seeking retrospective approval, please ensure proper tense is used throughout the document (i.e. past tense).*

Please ensure the following documents are attached:

- ☐ Signed Informed Consent – Participant and/or Parent/Guardian & Assent (if applicable)
- ☐ Participant Information Sheet
- ☐ Withdrawal/Dismissal Form *(if applicable)*
- ☐ Relevant Questionnaires/Data Recording Sheets

2.1. Rationale for seeking retrospective approval

Please justify why you are seeking retrospective approval

2.2. Please indicate the original purpose of the data collection (e.g., servicing, opportunistic case studies, etc.)

2.3. Please indicate whether re-consent is required *(To be filled up by reviewer)*

Retrospective studies will require the re-consent of the participant to agree to the new methodology to be conducted on their data. If waiver of consent is sought, please refer to Human Biomedical Research Act (2015), Part 3, Section 13, pt. 2. Waiver of consent requires the agreement of the Board.

RE-CONSENT: ☐ REQUIRED / ☐ NOT REQUIRED

SECTION 3: RESEARCH DETAILS

3.1. Research Abstract
Abstract should be 250 – 500 words, using non-technical jargon.

3.2. Specific Aims
What are the aims and hypotheses of your research project?

3.3. Description of Research:
Comment on literature gaps the project is going to fill, scientific value, sports application, and likely outcome of your research

3.4. Description of Preliminary Studies:
Pilot studies performed, or studies that were conducted, if applicable. Attach IRB Approval Letter

SECTION 4: RESEARCH METHODOLOGY

4.1. Detailed Experimental Design:
Discuss in detail the procedures to be used e.g., what does each participant go through and why; provide statistical analysis to be conducted

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

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. Protection of Participant's Personal Data:
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.

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

SECTION 5: PARTICIPANT INFORMATION

5.1. Target Group, if applicable:
Details of criteria or restrictions to your participant pool

5.2. Recruitment Process:
Detail the process and duration for recruitment of participants

5.3. Benefits and Risks Involved:
Detail the benefits and risks that the participant would face as a result of this study

5.3.1. Benefits:

5.3.2. Risks or Potential Adverse Events:

5.4. Health Declaration for Participants:
Include form if applicable, discuss if volunteers require health-screening

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

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:

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

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

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.

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.a) / ☐ NO (proceed to Section 7.3.1.b)

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).

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.

SECTION 8: INFORMED CONSENT

8.1. Participant Information Sheet *(please attach a copy)*

8.2. Participant Written Informed Consent Form *(please attach a copy)*

8.3. Parents/Guardians Consent Form *(required for participants below the age of 21)*

8.4. Assent Form *(required for participants below the age of 21)*

8.5. Waiver of Consent *(if applicable)*

SECTION 9: FUNDING DETAILS (IF APPLICABLE)

9.1. Funding Body or Sponsor:
Provide name of Sponsor or funding body and contact details of Point of Contact

9.2. Possible Conflict of Interests:
Highlight if any of the investigators are receiving financial support or incentives from this company, and address this issue

9.3. Research Budget:
Provide a list of expenditure for the project that is supported by the funding

SECTION 10: TIMELINE

Kindly provide a realistic timeline, factoring in the review process:

10.1. Estimated Commencement Date (DD/MM/YY):

10.2. Participant Recruitment Period (DD/MM/YY – DD/MM/YY):

10.3. Estimated Data Collection Period (DD/MM/YY – DD/MM/YY):

10.4. Estimated Completion Date (DD/MM/YY):

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

SECTION 12: DECLARATION OF SUSPENSION HISTORY

Have any of the investigators faced suspension of research study (in the past 3 years)? Please indicate by checking the appropriate box.

☐ YES _____ (If yes, please state the investigator(s) involved)

☐ NO

SECTION 13: RESPONSIBILITIES OF RESEARCHER(S)

☐ I hereby declare that I will comply with the SSI-IRB requirements (*refer to "SSI-IRB Guidelines"*). Failure to comply will result in legal repercussions (*refer to "Human Biomedical Research Act 2015, Part 5, Section 22"*).

Checklist of attachments to be included for IRB Review: (Please check accordingly)

☐ Curriculum Vitae (max. 2 pages) for each of the listed investigators

☐ Valid CITI or GCP Certification for all listed investigators

☐ Participation Information Sheet*

☐ Participation Informed Consent*

☐ Parent/Guardian Consent & Participant Under 21 years of age**

☐ Participation Dismissal Form, where applicable*

☐ Ethics Approval Letter or Certificate from host Institute[+]

☐ Research Collaboration Agreement with collaborating institutions (signed by Legal Team, PDPA Officer, Head of Research Institute), if applicable

☐ Other supporting documentation, if applicable
(Please indicate: _____)

**Only applicable to research involving human participants*
***Applicable if participants are under 21 years of age*
[+]For those who have answered YES in attainment of prior Ethics Approval in Section 1.

Please submit Application Forms together with accompanying documents to:

SSI – IRB Secretariat
Singapore Sport Institute, Sport Singapore
3 Stadium Drive, Singapore 397630
sport_ssi_research@sport.gov.sg (Email)
6500 5215 (Tel)

SECTION 14: OUTCOME OF REVIEW *(Secretariat Use)*

14. Results of the IRB Review:

☐ Rejected

☐ Approved with no further queries

☐ Approval pending reply from PI on the following queries:

SECTION 15: SUPPORTING DOCUMENTS *(Secretariat Use)*

If IRB approval is pending, please attach supporting documents to detail any correspondence between the IRB and PI.