SINGAPORE SPORTS INSTITUTE INSTITUTIONAL REVIEW BOARD – Recruitment of Human Subjects

1. Introduction

1.1. These guidelines apply to all research, involving human subjects, which is supported by, in collaboration with, or conducted by the Singapore Sports Institute.

1.2. All Human Biomedical research conducted in Singapore is governed by the Human Biomedical Research Act (HBRA) 2015[1]. It is mandatory for any proposed human biomedical research to undergo review and be approved or exempted by an Institutional Review Board (IRB). This is to protect the safety and welfare of research subjects, ensuring that their health and well-being is not compromised, and their privacy and autonomy is respected.

2. Participant Information Sheet

2.1. The participants should be provided with a sheet documenting the objectives of the research study, description of research protocol, and highlight any possible risks or side effects which subjects may encounter during, or after the duration of the research. Also, in the event that the participant should require clarification, the full contact details of the Principal Investigator or research counterparts should be provided.

2.2. The information sheet should also document the procedure and address any implications should they wish to withdraw or terminate his participation in the study.

3. Informed Consent Form

3.1. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

3.2. The consent form may be either of the following:

3.2.1. A written consent form that may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

3.2.2. A short form written consent document presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. The IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form

[1] *Ref: Human Biomedical Research Act 2015*

itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

3.3. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either *(refer to IRB Guidelines 5 – Requirement of consent)*:

3.3.1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

3.3.2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3.4. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

4. Health Declaration Form

4.1. Where applicable, certain research protocols may require subjects to be of a certain health status whereby if not declared; participating in the research study may result in possible harm to the subjects.

4.2. The health declaration form should include a statement in which the subject declares his health status, as best to his knowledge, and re-confirms his agreement to commence with the research protocol.

4.3. This is separate and should not be confused with the Informed Consent Form. The Health Declaration Form should only be signed on the day itself, just before commencement of the research protocol.

5. Participant Withdrawal / Dismissal Form

5.1. The rights for participants to withdraw from the study at any time, without prejudice or consequences, must be upheld at all times. This must be documented via the Withdrawal / dismissal form, to be submitted to the IRB together with the Application Form.

5.2. Where applicable, upon completion of a research protocol, subjects may be asked to declare that they feel physically well enough to be dismissed from the premises. (e.g. venipuncture sites may be inspected to be free from excessive swelling, pain or bleeding.)

6. Recruitment of Subjects

6.1. Children, elderly, mentally-challenged participant, pregnant ladies, neonates and prisoners

Research that involves any one of the above groups of individuals requires additional protection guidelines and considerations. With these populations involved, Office of Human Research Protection (OHRP) Guidelines for the Protection of Human Subjects[2] and National Institute of Health (NIH) Policy Guidance[3] may be referenced.

The above guidelines are written for the purpose of advising applicants on the details required when filling up the SSI IRB Review Application Form. They do not, by any means, represent judging criteria used by the SSI Institutional Review Board or have any impact on the outcome of application and the decisions made by the SSI Institutional Review Board.

[2] OHRP 45 CFR 46.201 (B), 46.301 (C), and 46.401 (D), Rev. Jan 15, 2009.

[3] NIH Policy and Guidelines on the Inclusion of Children as Participants in Research involving Human Subjects, Number 98-03, Mar 6, 1998.