SINGAPORE SPORT INSTITUTE INSTITUTIONAL REVIEW BOARD – Incident Reporting Guidelines

Incident Reporting

The timely collection and assessment of incidents arising from the conduct of research is critical for protecting the safety, well-being, privacy, and autonomy of research participants. In the event of any incident, it is the role of the Principal Investigator (PI) to assess and provide prompt updates, with accurate and complete information to the SSI-IRB Secretariat. Incidents are classified as 1) Serious Adverse Events (SAE), and 2) Suspected Offences or Contraventions (SOC).

Singapore's Human Biomedical Research Act (HBRA) came into force on 1 Nov 2017. As part of the reporting requirements under the HBRA, it is mandatory for PIs to report incidents occurring as a result of the human biomedical research (HBR). The next segment will describe each of the two events (SAE and SOC) and provide guidelines of follow-up procedures after the incident.

1. Serious Adverse Events (SAEs)

Under the HBRA, SAE refers to any unanticipated events, as a result of any HBR, which includes events that:

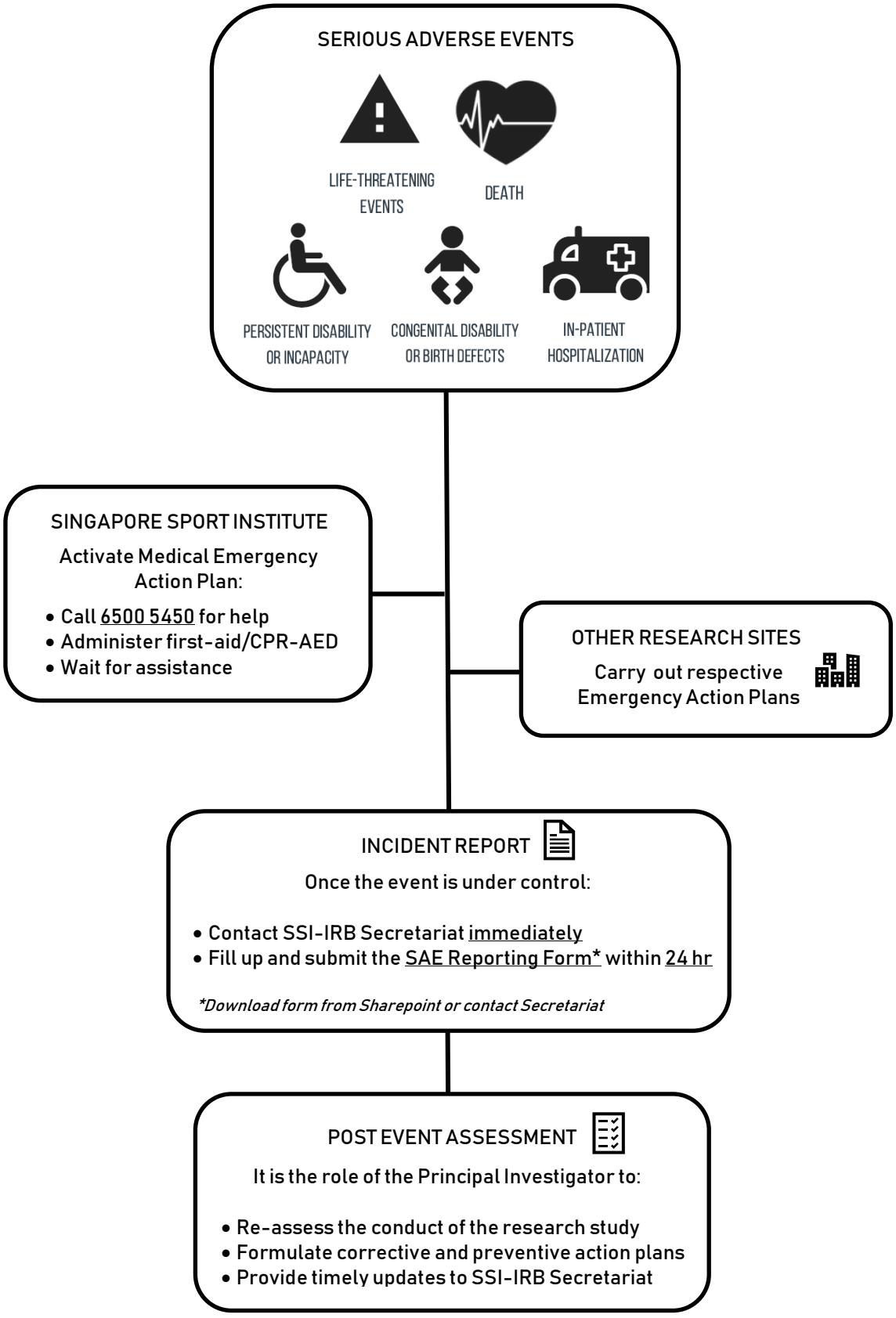
- Results in or contributes to death
- Is life threatening
- Results in or contributes to persistent disability or incapacity
- Requires in-patient hospitalisation
- Contributes to congenital anomaly or birth defects
- Results in the transmission of a communicable disease
- Results in any misidentification or mix-up or any type of tissue, gametes or embryo

1.1. Reporting SAEs

In such unanticipated serious adverse events, the PI should inform the SSI-IRB Secretariat immediately. The SAE Reporting Form should also be filled up and submitted within 24 hours of the event. Thereafter, it is the role of the PI to re-assess the conduct of the research study, formulate corrective and preventive action plans to ensure no reoccurance of the event. Refer to 1.1.1 SAE Reporting Guidelines (For Researchers).

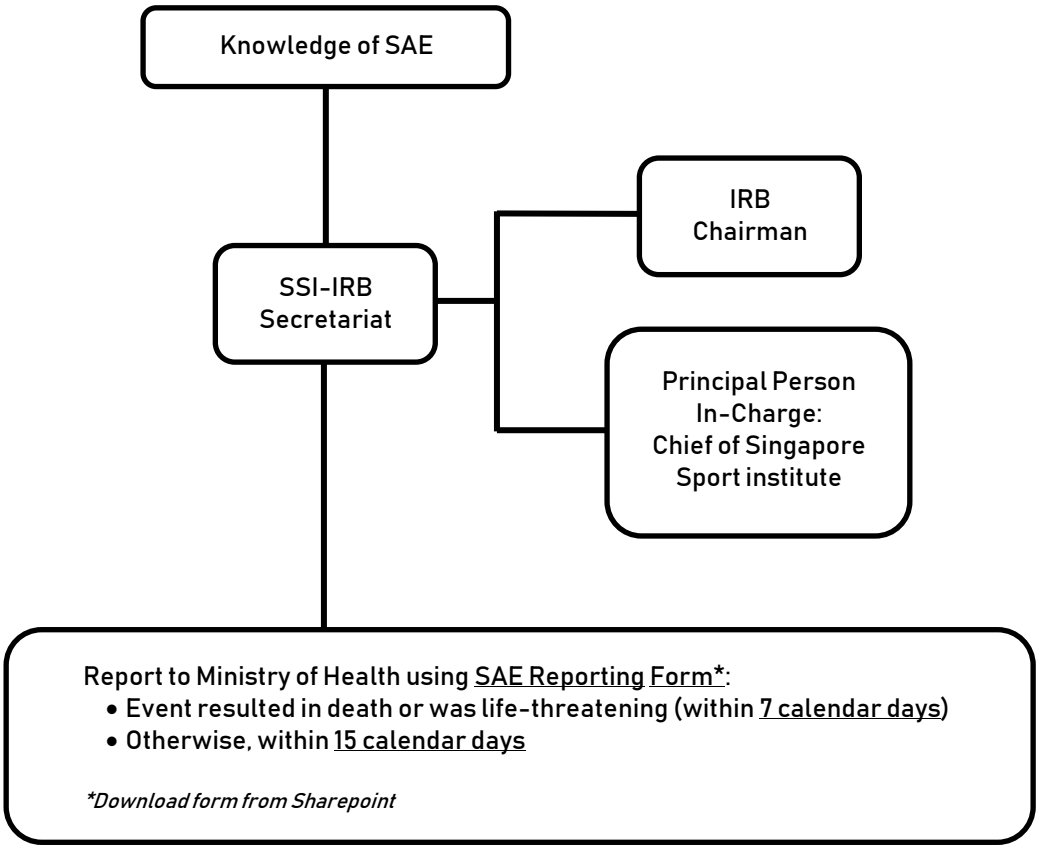
Upon knowledge of the event, the Secretariat should update relevant personnels within SSI-IRB (i.e., Principal Person In-Charge, IRB Chairman, etc.) as soon as possible, and subsequently provide a full report to the Ministry of Health within a stipulated time. Rrefer to 1.1.2. SAE Reporting Guidelines (For SSI-IRB Secretariat).

1.1.1. SAE Reporting Guidelines (For Researchers)



Note: Medical Emergency Action Plan – appended in Annex A as reference

1.1.2. SAE Reporting Guidelines (For SSI-IRB Secretariat)



2. Suspected Offences or Contraventions (SOC)

This refers to offences or breaches committed during the course of a research study. Researchers contravening any part of the HBRA may be guilty of an offence and shall be liable on conviction to the following penalties. Below is a summarised version to guide researchers. For full details on the relevant sections of this legislation, please refer to Singapore Statutes Online.

S/N	List Of Contraventions And Section Reference	Penalties
1	**Duties of researchers** conducting HBR – Section 22 • Proposed research has been reviewed and approved (or exempted) by an IRB; • Appropriate consent obtained from research subject. • Research does not deviate from approved research proposal unless (i) the deviation has been reviewed and approved by IRB, or (ii) is necessary to mitigate an immediate risk of harm to a research subject. • Research is immediately discontinued if IRB has withdrawn its approval for the research • If consent of research subject is withdrawn, the further participation of the research subject or further use of the individually-identifiable biological material or health information of the research subject should be discontinued immediately. • A researcher must ensure that a minor who lacks sufficient understanding and intelligence, or an adult or minor who lacks mental capacity to give consent, must not be a research subject in any biomedical research unless there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of persons to which the minor or adult belongs.	Fine:not exceeding $50,000. Imprisonment:not exceeding 5 years.
2	**Compelling person** to participate in research - Section 26 • Coercion or intimidation to compel another person against that person's will to participate or continue to participate as a research subject.	Fine:not exceeding $ 100,000 Imprisonment: not exceeding 10 years.
3	**Duty to protect** health information and human biological material against loss, unauthorised disclosure, etc. - Section 27 • Every person who has obtained individually-identifiable information or human biological material must take all reasonable steps and safeguards as may be necessary, including rendering information or material non-identifiable, to protect such information or material against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification.	Fine: not exceeding $10,000 Imprisonment: not exceeding 12 months.

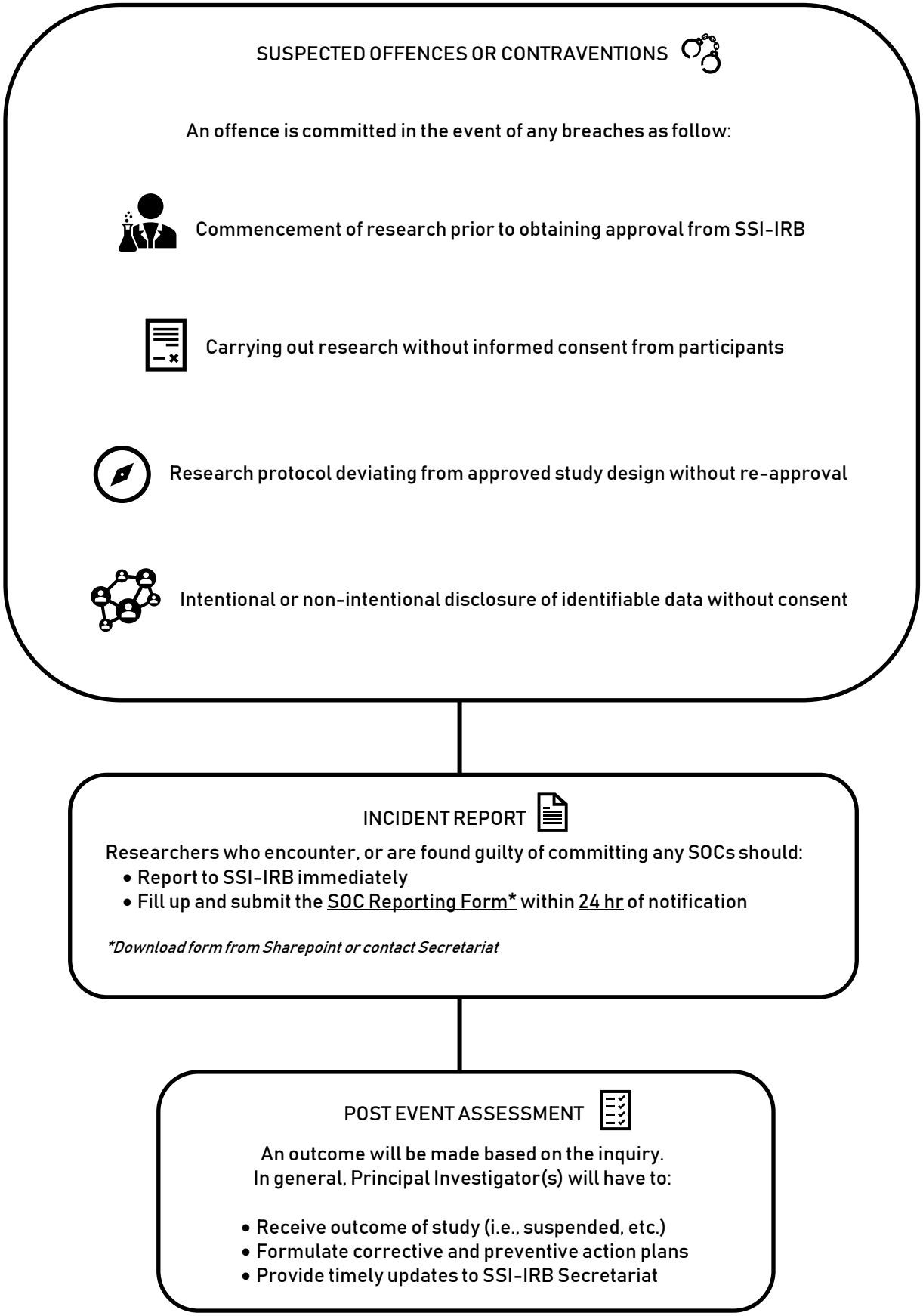
4	**No re-identification** of anonymised information or biological material without consent - Section 28 • No person who is in possession of or in contact with any information or human biological material can take any action to identify the person from whom such information or material was obtained, except with the consent of the research subject.	Fine: not exceeding $20,000 Imprisonment: not exceeding 2 years.
5	**Restrictions on disclosure** of information - Section 29 • Individually-identifiable information obtained from any research subject should not be disclosed, except with the consent of the research subject.	Fine: not exceeding $20,000 Imprisonment: not exceeding 2 years.
6	**Prohibited** human biomedical research - Section 30 • No person can conduct any prohibited human biomedical research specified in the Third Schedule of HBRA.	Fine:not exceeding $100,000 Imprisonment: not exceeding 10 years.
7	**Restricted** human biomedical research - Section 31 • No person can conduct any restricted human biomedical research specified in the Fourth Schedule except: - Prior IBR approval obtained; and - Prior MOH approval obtained.	Fine:not exceeding $100,000 Imprisonment: not exceeding 10 years.

2.1. Reporting SOCs

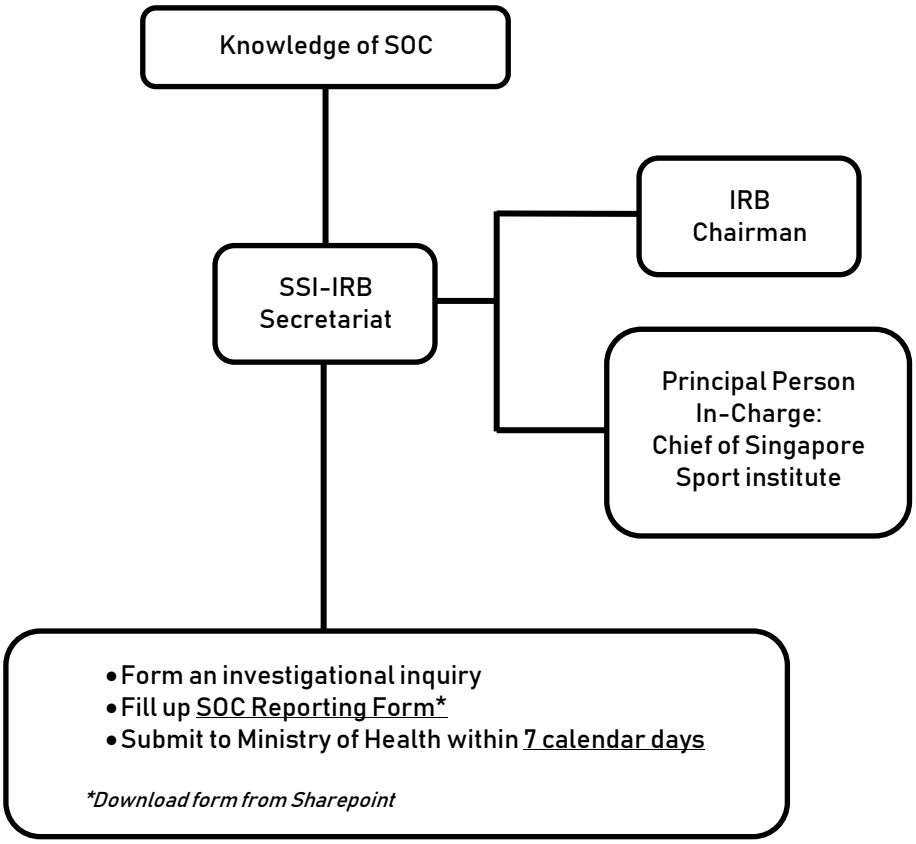
Researchers who encounter, or are found guilty of committing any SOCs should report to the SSI-IRB Secretariat immediately. Refer to 2.1.1 SOC Reporting Guidelines (For Researchers).

The Secretariat will update the relevant personnels within SSI-IRB (i.e., Principal Person In-Charge, IRB Chairman, etc.), form an investigation inquiry, then subsequently notify the Ministry of Health within 7 calendar days after knowing the event. Refer to 2.1.2 SOC Reporting Guidelines (For SSI-IRB Secretariat).

2.1.1. SOC Reporting Guidelines (For Researchers)



2.1.2. SOC Reporting Guidelines (For SSI-IRB Secretariat)



Annex A – Medical Emergency Action Plan

SINGAPORE SPORT INSTITUTE
MEDICAL EMERGENCY ACTION PLAN
STANDARD OPERATING PROCEDURE

INCIDENT DURING OFFICE HOURS

In the event of a Medical Emergency that happens during office hours (e.g., *athlete collapses or is injured during testing or training)* the following steps are to be taken.

Patient Assessment for Responsiveness

Assess for Danger!
Check for Response
Gently tap casualty's shoulder and shout "Hello! Hello! Are you OK?"
Check for A.V.P.U. (Alert, Voice, Pain, Unresponsiveness)
Trapezius Squeeze.

Patient Unresponsive

ACTIVATION PROTOCOL

1. Call SSMC@SSI Counter Staff for help at **6500 5450**
2. Counter Staff to activate the doctors and nurses.
3. Call **995** and details to be given to the Ambulance Operator:
   - Name of responder/caller: *e.g., Paul Tan*
   - Location Scene: *Sport Singapore, SSMC@SSI, Level 1, 3 Stadium Drive, Singapore 397630*
   - Telephone No: *e.g., 6500 5491*
   - Short report of the emergency *e.g., age of patient, sex, complaints, condition – pulse, respiration, help rendered so far e.g., CPR, etc.*
   - Direct ambulance staff to enter through the OCBC arena taxi–stand (taxi stand 129) driveway and the pick-up point is outside the main lobby of SportSG office.
4. Inform SportSG Security at **6500 5555** to coordinate with Sports Hub Emergency (6653 9292) to open the barricade at OCBC arena taxi-stand to allow ambulance to drive in.
5. Doctors and nurses arrive immediately to the scene with emergency bag.
6. Asses the condition of patient and start the resuscitation till arrival of ambulance.
7. Follow up progress of patient with the hospital and submit Incident Report to the Division Head.

MEDICAL PROTOCOL

VERIFY CARDIAC ARREST
(As per BCLS protocol)
Call for Help / AED

Check Airway
⇩
Check Breathing (No)
⇩
Start CPR (30:2) until AED is attached
⇩
Check for contraindications &
⇩
Prepare Chest
⇩
Operate AED

Patient Responsive

1. Call SSMC@SSI Counter Staff for help at **6500 5450**.
2. Counter Staff to activate the doctors and nurses.
3. Doctors and nurses arrive immediately to the scene with emergency bag.
4. Medical team to assess and give immediate treatment.
5. If necessary, call 995 for further medical follow-up in the hospital.

Updated 2 March 2020

Annex A – Medical Emergency Action Plan (Continued)

SINGAPORE SPORT INSTITUTE
MEDICAL EMERGENCY ACTION PLAN
STANDARD OPERATING PROCEDURE

INCIDENT **AFTER OFFICE HOURS**

Need for ambulance after office hours

Inform SportSG Security at **6500 5555**
To inform of incident, location of incident and ambulance has been activated

SportSG Security is to activate Sports Hub Emergency at **6653 9292**
To coordinate with Sports Hub to direct ambulance staff to enter through the OCBC arena taxi– stand (taxi stand I29) driveway and the pick-up point is outside the main lobby of SportSG office.

Respondent is to inform the Division Head of incident, location of incident and ambulance has been activated.

Respondent is to follow up progress of patient with the hospital and submit Incident Report to the Division Head.

Updated 2 March 2020