SINGAPORE SPORT INSTITUTE INSTITUTIONAL REVIEW BOARD – Consent Taking Guidelines

For SSI IRB Secretariat. Retrieved from Ministry of Health – "Guidance on the Requirement of Appropriate Consent for the Conduct of Human Biomedical Research and Handling of Human Tissue" dated 17 May 2019; and "Human Biomedical Research Act 2015", dated 26 Apr 2019

1. Appropriate consent under the HBRA

1.1. These guidelines are for research studies that fall under the category of Human Biomedical Research (HBR). For studies that are non-HBR, please refer to **Section 6: Consent for non-HBR studies**. If unsure, please check with SSI-IRB Secretariat.

1.2. Consent must be obtained in the following forms:

1. In writing (which may be in electronic or other form of documentary evidence),
2. From the research subject or tissue donor personally or their legal proxy,
3. After all information referred to in **Section 2: Elements of Consent** has been provided and explained to the research subject, tissue donor or legal proxy,
4. In the presence of a *witness*.
    a. The witness must be 21 years of age or older; has mental capacity to witness the giving of consent by the research participant; and must **not** be the same individual taking the appropriate consent. The role of the witness is to take reasonable steps to confirm: (1) the identity of the individual giving the appropriate consent, and (2) the consent was given voluntarily without any coercion or intimidation.

If it is not practical for the research team to obtain consent through face-to-face interaction, the research team can consider obtaining consent remotely, including phone calls, email correspondence and e-consent. The consent must be documented in some way, for example, by noting the subject's ID together with the date and time of such consent, to prove that consent has been obtained in cases of dispute.

1.2. Consent does **not** need to be obtained in the presence of a witness if:

1. The research is not interventional;
2. The research is not invasive;
3. The research methodology is interventional **but** involves no more than minimal risk to the research subject, **AND** the research subject is able to read and sign the appropriate consent form.
4. The consent was obtained prior to 1st November 2017, or
5. The human tissue is removed primarily for a therapeutic or diagnostic purpose.

1.4. Research is considered **interventional** if it involves any activities that has a physical, mental or physiological effect (temporary or permanent) on the body of the research subject. Examples of intervention include drawing of blood for the sole purpose of research, or if excess blood is drawn beyond the amount required for clinical or diagnostic use, for research purposes.

1.5. Research is considered **invasive** if it involves any procedure that is incisional (cutting into the tissue of the body. Examples of invasive procedures include finger-prick blood testing.

A study is not considered interventional or invasive if the intervention is carried out primarily for non-research purposes (routine servicing or diagnostic purposes). Similarly, research that comprises solely of a survey and collection of information from the research subjects is treated as not invasive and not interventional.

2. Elements of consent

2.1. For studies with individually-identifiable Health Information (HI) and / or Human Biological Material (HBM), researchers must ensure that the following elements of information have been provided to the research subject (see **Annex A**).

2.2. These elements have been described in the Participant Information Sheet template, and research teams must submit their Information Sheet with SSI-IRB for approval before commencing data collection.

Annex A: Information that needs to be provided for HBR Studies under section 12(1) of the HBRA

Elements of 12(1)	Core or Situational	Explanatory Notes
12(1)(a) the **investigational nature** of the biomedical research	Core	These are essential elements as they have significant bearing on the subject's decision whether to participate or not.
12(1)(b) the **purpose** of the biomedical research	Core	
12(1)(c) the reasonably foreseeable **risks**, discomforts or inconveniences to a living research subject arising from this biomedical research	Core	
12(1)(d) the **benefits** which the research subject may reasonably expect from the biomedical research	Core	
12(1)(h) the extent to which information identifying the research subject will be kept **confidential**	Core	Confidentiality is an important element. This has significant bearing on the

		subject's decision whether to participate.
12(1)(k) whether the participation of the research subject involves info in **individually-identifiable** form	Core	The element is sensitive and it has significant bearing on the subject's decision.
12(1)(n) the research subject's **right to withdraw** his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal as specified in that section	Core	This is an essential element as it has significant bearing on the subject's welfare and decision whether to participate or not.
12(1)(e) where applicable, whether there are any **alternative procedure or treatments** available to the research subject, and the potential benefits and risks of such alternatives	Situational	For interventional research – where alternative procedures or treatments are available, they should be disclosed to the research subject.
12(1)(f) any **compensation and treatment** available to the research subject **in the event of injury arising** from participation in the research	Situational	Not required if there is no intervention.
12(1)(g) any **anticipated expenses** the research subject is likely to incur as a consequence of participating in the biomedical research	Situational	Not applicable if HBR is solely using HBM/HI already collected and there are no anticipated expenses.
12(1)(i) whether individually-identifiable information obtained from the research subject will be **used for future biomedical research**	Situational	If this was not obtained – Researchers are not able to use the identifiable information for future research.
12(1)(j) where applicable, whether **biological material** taken from the research subject will be **destroyed, discarded or stored for future biomedical research**	Situational	If this was not obtained – Researchers are not able to use the biological material for future research.
12(1)(l) the circumstances, if any, under which, the research subject or the person authorised to give consent under this Part will be **contacted for further consent** e.g. SAE, change in proposed research	Situational	Required if the researcher foresees that there will be circumstances under which the research subject will be contacted for further consent.
12(1)(m) whether the research subject would wish to be **re-identified** in the case of an **incidental finding** if the propose biomedical	Situational	If this was not obtained – Researchers cannot re-identify subjects to return

research expressly provided for such re-identification		incidental findings if this consent was not obtained.
12(1)(o) the **person or persons to contact** to obtain further information on the biomedical research and to provide feedback in relation to the biomedical research	Situational	This element does not have significant bearing on the subject's decision whether to participate or not. The subject can contact the research institution if there are further queries.

3. Consent involving Minors

3.1. If the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the research, consent has to be obtained from both the minor and at least one adult parent or legal guardian of the minor.

3.2. The minor's consent (legally known as **assent**) will also have to be obtained. The template can be found in **Page 2** of the SSI-IRB Informed Consent Template (Under 21) Consent and Assent Form.

3.3. The Principal Investigator (PI) should try to the best of his ability to discuss the information sheet with the parent / legal guardian in person. Failing that, it is advised to keep records of the correspondence between the PI and the parent / legal guardians (with time and date recorded).

For example, if the PI wishes to conduct a large-scale study of youth participants but is unable to meet all the parents / legal guardians in person due to time constraints, the PI can drop a phone call to the parent (on speaker), and keep a voice recording of the phone call with clear time and date. The witness can be present in the room with the PI to ensure that the parent understands the information presented clearly and is not coerced into giving consent.

3.4. If the minor does not have sufficient understanding and intelligence, **and** there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without participation of the class of minors to which the minor belongs, consent will be obtained from at least one adult parent or guardian of the minor.

4. Consent-taking Procedure

4.1. Before starting data collection, ensure that your consent form is the most updated version and has been approved by the SSI IRB. For studies with specific purposes (most research studies), use the Informed Consent Form (Specific) template. If the investigator is conducting the activity first and formulating a hypothesis for data analysis afterwards, use the Informed Consent Form (General) template. *SSI-IRB will not condone any data collection without taking consent first. If the scientist proceeds*

with the activity (e.g. servicing) and seek IRB approval afterwards (retrospective submission), all the elements of consent must still be provided to the participant, including witness, if applicable.

4.2. To obtain consent from the participant, a member of the research team conducting the study will have to meet up with the participant in person, with 2 copies of the Information Sheet and Consent Form, and explain the participant information sheet to the participant.

4.3. A witness will be required if the research has interventional and/or invasive elements. (see **Section 2: Elements of Consent**). The witness will need to ensure that the participant's questions are answered to his/her satisfaction, and that the participant gives consent willingly without coercion.

4.4. The investigator will sign both copies of the consent form, then get the participant (and the witness, if applicable) to sign both copies. The investigator will then offer the participant one copy with the information sheet for his reference. The investigator must keep the other copy of the consent form for record-keeping.

4.5. If the participant is a minor: the same procedures will apply, but twice: once with the parent / legal guardian, and a second time with taking the assent of the minor. The research team should take all reasonable means to adhere to meeting both parties face-to-face (see **Section 3.3**).

5. Waiver of requirement of consent, by the SSI IRB

5.1. All studies submitted to the SSI IRB, whether retrospective or prospective, must seek consent from the participant to be considered for ethics approval. The requirement for consent may be waived by the IRB only in very specific cases, if all the following criteria are met:

(1) Where the IRB is satisfied that the research study involves no more than minimal risk to the research subject,
(2) The waiver of parental consent will not adversely affect the rights and welfare of the research subjects; and
(3) The proposed research may not be practicably carried out unless there is such as waiver, and the proposal-
    a. Is designed for conditions, or for a target population which parental or guardian consent is not a reasonable requirement to protect the participants, and an appropriate mechanism for protecting the minors is substituted;
    b. Is of a private and sensitive nature that it is not reasonable to require permission (e.g. adolescents in studies concerning treatment of sexually-transmitted diseases); or

c. Is within the description of such circumstances as may be prescribed.

5.2. SSI IRB Secretariat will assess waiver of requirement of consent on a case-by-case basis. This waiver of consent is only if the rights of the participant are affected by the taking of the consent itself, and cannot be attained for the sake of convenience.

6. Consent for non-HBR studies

6.1 For a study to be considered as non-HBR, it will have to be unable to meet the definition of Human Biological Research, as defined by MOH.

6.2 However, it is SSI IRB's policy to obtain consent with the same procedures outlined above from the participant before the data collection starts. In this case, there is no need for a witness for the obtaining of consent.

7. Consent-Taking Flowchart