SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study coordinators

SingHealth
Defining Tomorrow's Medicine

Issue 7
Jan 2022

In this issue >>>

Alterations of Informed Consent Requirements

1. Waiver of Appropriate Consent (HBRA) >>>

For research regulated under the Human Biomedical Research Act 2015 (HBRA), waiver of requirement for appropriate consent may be granted by CIRB if a research proposal meets the requirements under HBRA Fifth Schedule Part 2.

- HBRA Fifth Schedule Part 2 Section 3: Research involvingHuman Biological Material (HBM) or Health Information (HI) in an individually-identifiable form obtained after 1 November 2017
- HBRA Fifth Schedule Part 2 Section 3a: Research involving HI obtained or compiled before 1 November 2017
- HBRA Fifth Schedule Part 2 Section 3b: Research involving HBM obtained or compiled before 1 November 2017

For research involving HBM/HI in an individually-identifiable form obtained after 1 Nov 2017

- ✓ Cannot reasonably be carried out without the use of HBM/ HI in an individually-identifiable form
- ✓ No more than minimal risk
- ✓ Will not adversely affect the rights and welfare of the research subject
- ✓ Process of obtaining consent involve a disproportionate amount of effort and resources
- ✓ Contribute to the greater public good

For research involving HI obtained or compiled before 1 Nov 2017

- ✓ Cannot reasonably be carried out without the use of the HI in an individually-identifiable form
- ✓ No more than minimal risk
- ✓ Will not adversely affect the rights and welfare of the research subject
- ✓ Process of obtaining consent involve a disproportionate amount of effort and resources

For research involving HBM obtained or compiled before 1 Nov 2017

- ✓ Cannot reasonably be carried out without the use of the HBM in an individually-identifiable form
- ✓ No more than minimal risk
- ✓ Will not adversely affect the rights and welfare of the research subject
- ✓ Reasonable effort has been made to re-contact the person for the purpose of obtaining consent

2. Waiver of Consent (non-HBRA) >>>

For research not regulated under HBRA, waiver of consent maybe granted by CIRB if a research proposal meets the following requirements:

- ✓ No more than minimal risk to the participants
- ✓ Will not adversely affect the rights and welfare of the research subject
- ✓ Whenever appropriate, the participants will be provided with additional pertinent information after participation
- ✓ Cannot practicably be carried out without the waiver
- ✓ The research is not subjected to FDA regulations

3. Waiver of Documentation >>>

Waiver of requirements for approproiate consent to be in writing may be granted by CIRB if a research proposal meets the requirements under HBRA Fifth Schedule Part 1.

- ✓ No more than minimal risk to the research subject and involves no procedures for which written consent is ordinarily required outside of a research context
- ✓ The only record linking the research subject and the research will be the consent form and the principal risk to the research subject is the potential harm resulting from the unauthorised disclosure of confidential information (e.g. research subject's identity and the fact of the subject's participation in the research)

For US-FDA regulated studies, waiver of documentation may be granted only if all the following are true:

- ✓ No more than minimal risk to the subjects.
- ✓ Will not adversely affect the rights and welfare of the research subject
- ✓ Cannot practicably be carried out with the waiver.
- ✓ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The Board may require the Principal Investigator (PI) to submit a written description of the information that may be provided to the participants for review. PI may also provide participants with a written statement regarding the research. This written statement must be submitted to the Board for review and approval.

Do you know?

For request of wavier of documentation, in the CIRB Application Form/Exemption Application Form, the PI should indicate as such:

1. Select "Informed Consent will be taken for all study subjects." in Section F17/J2(V).
2. Select "No" in Section P6 as consent not to be documented in the form of a written and signed Research Participant Information Sheet and Consent Form.

Please note:

Request for wavier of documentation of informed consent is usually applicable only for research involving questionnaire/ survey only. Research involves accessing the participants' medical records will not be applicable to apply for wavier of documentation.

4. Clinical Research & Trials in Emergency Situations >>>

In emergency situations, when prior consent of the participant is not possible, the consent of the participant's Legal Representative (LR), if present should be requested. The written certifications made prior to trial initiation and at the point of enrolment of each participant should be retained on file for verification. The PI should ensure that the participant or the participant's LR is informed about the research as soon as possible and must obtain consent for continued participation in the research. Where the participant has been enrolled into a study and the participant/participant's LR/any family member objects to the participant's continued participation in the study, the participant should be immediately discontinued.

4.1 Clinical Research in Emergency Situations

Emergency Research (ER) refers to human biomedical research (under the scope of HBRA) where life-threatening emergency situations may arise such that appropriate consent may not be obtained before the research subject is:

- Subjected to any intervention or
- After any individually-identifiable HBM is obtained from his or her body or
- After any of his or her individually-identifiable HI is used

Waiver of requirements for approproiate consent for emergency situation may be granted by CIRB if a research proposal meets the requirements under HBRA Fifth Schedule Part 3. Please refer to HBRA Fifth Schedule Part 3 for details on the requirements.

4.2 Clinical Trial in Emergency Situations

Clinical Trial in an Emergency Situation is defined as a clinical trial to determine the safety or efficacy of the investigational therapeutic product being tested in the trial on subjects where:

a. The subjects are facing a life-threatening situation that necessitates intervention.
b. The subjects are unable to consent to being subjects in the trial as a result of their medical conditions.
c. It is not feasible to request consents from the legal representative of the subjects within the window period.

Waiver of requirements for consent for emergency situation may be granted by CIRB if a research proposal meets the requirements under Health Products (Clinical Trials) Regulations 2016 – Sections 8(3) and 17 are met. Please refer to Health Products (Clinical Trials) Regulations 2016 for details on the requirements.

SREC 2021 was successfully held between 23 to 25 Nov 2021 with more than 450 delegates participated in this conference. The conference was jointly organized by SingHealth CIRB, NHG DSRB and NUS CENTRES. It was held on a virtual platform with both overseas and local speakers sharing their insights and experiences.

Takeaway message...

Informed consent should be obtained where possible. In situation where it is not feasible to obtain informed consent, wavier of informed consent may be requested.

If you have any questions, please contact CIRB at irb@singhealth.com.sg