SingHealth
Defining Tomorrow's Medicine

Waiver of Consent for Research regulated by Human Biomedical Research Act (HBRA)

1. Introduction

This document provides guidance to researchers and investigators on the new requirements for waiver of consent as stipulated by HBRA.

Waiver of consent maybe granted by CIRB if a research proposal meets the requirements under HBRA Fifth Schedule Part 2. For details on waiver of requirement for appropriate consent for emergency research, please refer to HBRA Fifth Schedule Part 3.

2. Waiver of Consent Requirements

Please provide justifications and relevant information for request of waiver of consent:

(a) <u>Research involved Human Biological Material or Health Information in an individually-identifiable form obtained after 1 November 2017</u>

Investigators must provide justification in Question Q5 of the CIRB Application Form on how the human biomedical research or health information research would reasonably be considered to contribute to the greater public good to satisfy HBRA Fifth Schedule Part 2, Section 3(d). Waiver would only be granted in rare exception cases.

(b) <u>Research involved Health information obtained or compiled before 1 November 2017</u>

Investigators must specify in Question H6 textbox of the CIRB Application Form the period of data that have been collected for review which is before 1 November 2017 for the research to be qualified for review under HBRA Fifth Schedule Part 2, Section 3A.

(c) <u>Research involved Human Biological Material obtained or compiled before 1 November 2017</u>

Investigators must specify in Question S1(i) of the CIRB Application Form that the existing biological materials were collected before a date which is prior to 1 November 2017 to be qualified for review under HBRA Fifth Schedule Part 2, Section 3B.

3. Section Q of CIRB Application Form – Waiver of Consent

No	Questions	Guidance
1	The study poses no more than minimal risk to research participants. Please justify how your study meets this criterion. (HBRA Fifth Schedule Part 2, Sections 3(b), 3A(c) and 3B(c))	The investigators must provide all the following: - Verification that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life; - Affirmation that the information collected is not sensitive in nature; and - Assurance that the data has been collected and are derived from standard clinically indicated procedures.
2	Waiver of informed consent will not adversely affect the rights and welfare of research participants. Please justify how your study meets this criterion. (HBRA Fifth Schedule Part 2, Sections 3(c), 3A(d) and 3B(d))	The investigators must provide assurance that regardless of being part of the research or not, the information will still be collected as part of patients' clinically indicated procedures or as part of the normal running of business operations. None of the information collected would affect the clinical decisions about the individual's care, and patients are not being deprived of clinical care to which they would normally be entitled to.
3	The study cannot be practically conducted without the waiver of informed consent. Please justify how your study meets this criterion. (HBRA Fifth Schedule Part 2, Sections 3(a), 3(aa), 3A(b), 3A(e), 3B(b), and 3B(e))	The investigators must demonstrate the following to CIRB: - Identifying and contacting thousands of patients / participants, although not impossible, would not be feasible for a collection of information that would not change the care they would already have received. Please use the SingHealth PDPA Impracticability Calculator to demonstrate whether it is impracticable to obtain informed consent from participants. The calculator can be downloaded from the PDPA Research Documents page on Infopedia and should be uploaded under "Other Attachment of the CIRB Application Form". DR/HOD and IR should review the calculator and confirm that it meets the requirements under HBRA Fifth Schedule Part 2, Sections 3(aa) or 3A(e).

No	Questions	Guidance
		- How the study cannot reasonably be carried out without the use of the human biological material or health information in an individually-identifiable form. - Reasonable effort has been made to re-contact the person to which the individually-identifiable human biological material relates for the purpose of obtaining his or her consent for study involving individually-identifiable human biological material obtained or compiled before 1 November 2017.
4	Whenever appropriate, will the research participants be provided with additional pertinent information after participation?	Investigators must provide assurance that the participants will be informed of vital information if there is a means of identifying the participant. Examples where it is not appropriate to provide the information would include: there are no identifiers collected that would enable the investigator to identify the participant, or information cannot be verified due to the experimental nature of the protocol and would be of the patients' best interest not to receive the information.
5	Do you have any additional comments supporting the waiver of informed consent? If yes, Please describe. (HBRA Fifth Schedule Part 2, 3(d))	If the investigators are requesting waiver of consent for research involving human biological materials or health information in an individually-identifiable form obtained after 1 November 2017, justifications have to be provided on how the research would reasonably be considered to contribute to the greater public good.

4. Waiver of Informed Consent granted by CIRB prior to 1 Nov 2017

At the time of renewal of ethics approval, CIRB will review whether the approved study satisfies the requirements under the HBRA Fifth Schedule Part 2. CIRB may request for amendments and informed consent can no longer be waived if the study involves collection of individually-identifiable health information and/or human biological material after 31 October 2017. Informed Consent is required unless the study meets the requirements under HBRA Fifth Schedule Part 2, Section 3.

Contact Us

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