SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study

SingHealth
Defining Tomorrow's Medicine

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Waiver of Documentation of Informed Consent

1. What is Waiver of Documentation of Informed Consent? >>>

- **Informed Consent:** the process of providing participants with information about the research, as well as the documentation that is used to ensure that consent for participation is fully informed. A copy of the signed (whether written or electronic signature) document will be given to the participants.

- **Waiver of Documentation of Consent:** waives the requirement for the investigator to obtain a signed consent form for some or all participants.

  For some research projects, the IRB may approve a request to waive the documentation of informed consent. This means that the study team must provide a research participant with the required information, but the study team is not required to obtain the participant's signature.

  Note: Principal Investigators should consider giving a copy of the research information to the participants even when a signed document is not required.

  It is not appropriate to request a waiver of documentation of informed consent for studies that collect human biological materials.

2. When is Waiver of Documentation Permissible? >>>

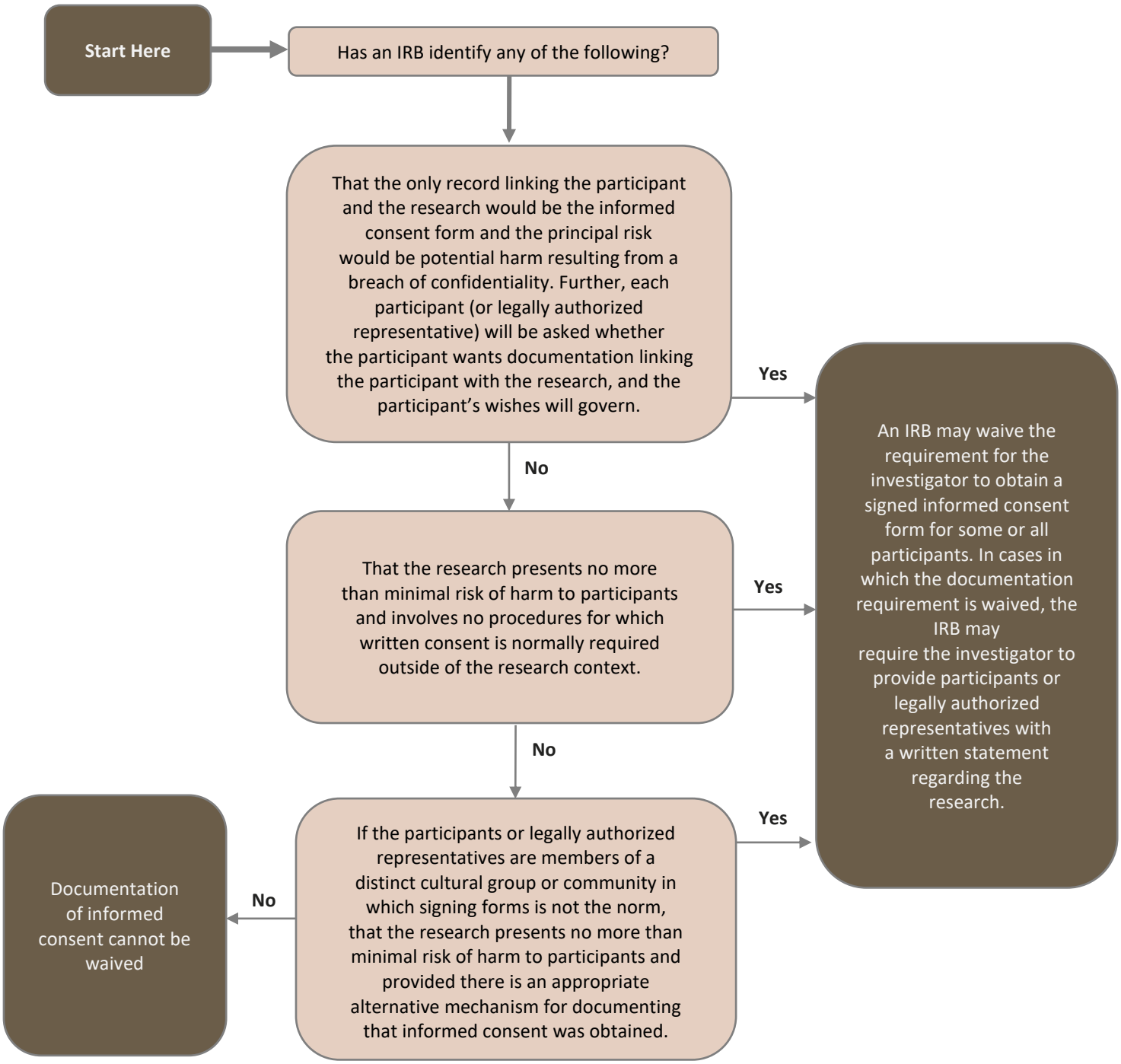
- **For HBRA studies, waiver of documentation can be considered if either condition (i) or (ii) is met:**
- **For non-HBR studies, waiver of documentation is perimissible if any of the conditions below are met, under the Common Rule:**
- **For US-FDA regulated studies, waiver of documentation of consent may be granted only when condition (ii) is met:**

i. The only record linking the research participant and the research will be the consent form and the principal risk to the research participant is the potential harm resulting from the unauthorised disclosure of confidential information. (e.g. research on sensitive topics, such as domestic violence or illegal activities)

ii. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. (e.g. minimal risk studies that involves surveys/ interviews conducted via telephone or online)

iii. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

3. *Waiver of Documentation Decision Tree >>>*



Adapted from www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#cl4

4. Applying for Waiver of Documentation >>>

Some Common Methods for Obtaining Consent under Waiver of Documentation:

Verbal Consent

- May include telephone surveys, telephone interviews, or minimal risk research in-person (e.g. focus group discussion) where verbal consent may be obtained.
- Access to the study information (e.g participant information sheet) should still be given to all participants via email or hard copy.

Information Sheets

- For studies where documentation of consent can be waived, researchers should consider providing a copy of the information sheet to the participants prior to their involvement in the study.
- Studies with minimal risk surveys/ interviews are best serviced by this method of consent.
- The use of information sheets may be coupled with verbal consent.

Online Consent

- Many minimal risk survey research involves the use of online survey platforms such as FormSG, Qualtrics, or any online platform in compliance with institution's IT policy.
- Consent is best conducted using first questions of the survey as the informed consent.
- The full text of the consent can be included with a "I agree" or "I do not agree" checkbox:
  - By clicking "I agree", potential participants will be directed to the rest of the survey.
  - By clicking "I do not agree", the individual cannot move forward and is free to close out the survey.
- Any time consent is obtained with this approach, a print or email option of the survey should be made available to the participant.

How to Submit the Application Form?

CIRB Exemption Application

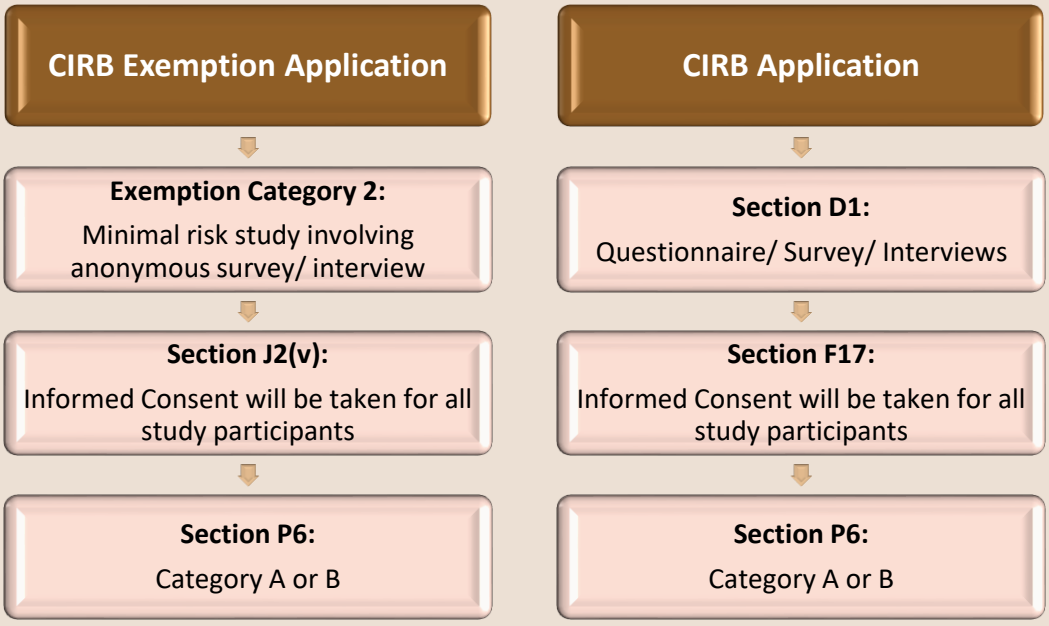
Minimal risk study involving **anonymous survey/ interview** which qualifies for Exemption Category 2.

- Survey form/ questionniare have to be submitted for review (Section F10)
- If online consent will be used, to submit the first question of the survey as informed consent, for the participant to indicate if they agree or disagree (incorporate with survey document, under Section F10)
- If verbal consent or participant information sheet will be obtained or used, to submit the document for review (Section P8)
- Section P6: Select "No" to select the criteria for waiver of documentation

CIRB Application

Minimal risk study involving **face-to-face, phone or teleconferencing platform interview**, using CIRB Application Form and provide the following:

- Interview guide (Section F10)
- Survey form/ questionnaire have to be submitted for review (Section F10)
- Call script (if it involves calling up of participants) (Section P8)
- If verbal consent or participant information sheet will be obtained or used, to submit the document for review (Section P8)
- Section P6: Select "No" to select the criteria for waiver of documentation



4. Applying for Waiver of Documentation (cont'd) >>>

Section P6: Criteria for Waiver of Documentation

Category A	Category B
▪ The only record linking the participant and the research would be the consent document. ▪ The principal risk would be potential harm resulting from a breach of confidentiality. ▪ If the research is subjected to FDA regulations, your study does not qualify for waiver of documentation of consent under Category A. ▪ If the subject will not be asked whether the participant wants documentation linking the participant with the research, your study do not qualify for waiver of documentation of consent under Category A.	▪ The research presents no more than minimal risk of harm to participants. ▪ The research involves no procedures for which written consent is normally required outside of the research context.

Takeaway message...

It is important for all research studies to obtain informed consent. If you have some type of consent process, but will not ask participants to sign a consent form, you should request for a waiver of documentation of consent. However, condition has to be met for such request.

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