

APPENDIX 6: Guideline on the Informed Consent Form

(Also refer to Appendix 11 for Guidance on Risks and Benefits)

1. Consent Form Checklist

Ethically and legally, consent is not considered to be informed unless the investigator(s) discloses all those facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate as a volunteer in a research project.

2. This checklist is for the investigator's own use; it should not be submitted to the REC

This checklist should be used to ensure that ALL of the required elements are included in the study's consent form:

- a. Study Title has been included.
- b. Name(s) of funding agency/agencies (if applicable).
- c. Investigator(s) are listed, and their designation, department & address.

3. Purpose of this Research Project (does the consent document include):

- a. A clear Statement: that the study involves research.
- b. Nature of the study.
- c. Purpose for conducting the research.
- d. Total number of subjects involved.
- e. Investigational products (pharmaceutical/medical device) details with comparator(s)/placebo.

4. Procedures (does the consent document include):

- a. Step-by-step explanation of what will be expected from study participants.
- b. Identification of any procedures that are experimental.
- c. Identification of surgical/invasive procedures with the type of anaesthesia involved.
- d. Identification and purposes of any procedures for genetic testing with details of its regulations.
- e. Identification of subject's bio samples collection and detail of their transportation abroad.
- f. Length and frequency of each study procedure and total time commitment for the subject.
- g. Location of the research.
- h. The instruments / documents that will be used and conditions involved (include an explanation of the instruments in appropriate language).

5. Risks (does the consent document include a description of):

- a. All potential risks described (mental, social, financial, legal, dignity, or physical. The use of survey questions of a sensitive nature may pose emotional distress caused by remembering unpleasant experiences).
- b. Safeguards that are to be employed to reduce or minimize risks.
- c. Safeguards in the genetic testing.
- d. Safeguard in the subject's bio samples being sent abroad.
- e. All the investigational product (pharmaceutical or medical device) side effects, including serious, rare, and/or fatal.

6. Benefits (does the consent document include):



- a. All direct or indirect benefits that may be reasonably expected from the research.
- b. Statement “No promise or guarantee of benefits have been made to encourage you to participate”.

7. Extent of Anonymity and Confidentiality (does the consent document include):

- a. Extent to which subjects will be identifiable
- b. Explanation of how the study will provide the utmost confidentiality or anonymity [confidentiality = individual can be identified directly or through identifiers, but the researchers promise not to divulge that information; anonymity = individuals cannot be identified by anyone, including researchers]
- c. Optional: Statement: “At no time will the researchers release the results of the study to anyone other than individuals working on the project without your written consent”.
- d. Explanation of who will have access to the data.
- e. Statement “It is possible that the REC may view this study’s collected data for auditing purposes. The REC is responsible for the oversight of the protection of human subjects involved in research”.
- f. Description of when data will be destroyed or will be retained for any future (secondary) research purpose, or could be archived at the physician’s record for any future registry development.
- g. Description of when the bio samples will be destroyed or will be kept retained for any further (secondary) research purposes and/or by other investigator.

8. Compensation (does the consent document include):

- a. Subjects informed whether compensated or not for the portion of their time spent in the study.
- b. Amount of compensation.

9. Freedom to Withdraw (does the consent document include):

- a. Statement that participation is voluntary; subjects are free to withdraw from the study at any time without penalty or loss of benefits to which the subjects are otherwise entitled.
- b. Statement that participants are free not to answer any questions or respond to experimental situations that they choose without penalty.
- c. Statement that participants are free not to provide or donate their bio-samples, in case they have concern especially for sending samples abroad for research purposes.
- d. Statement that the participants are free to refuse the genetic testing on their bio-samples.
- e. Statement describing that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

10. Subject’s Responsibilities (does the consent document include):

- a. Statement “I voluntarily agree and consent to participate in this study. I have the following responsibilities:” List of subject’s responsibilities, with the significant limits of subject’s study compliance and adherence, detailed visits, restrictions (if any), not disclosing about the study [to discuss only to the family.

11. Subject’s Permission (does the consent document include):

- a. Statement “I have read the Consent Form and conditions of this project.
- b. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent.
- c. Signature line for the participant (or the responsible guardian, if the participant is not able or legally unfit to give informed consent).



- d. Signature line for an impartial witness (not connected with the research), affirming that the participant was informed & he/she has given consent, either verbally (if illiterate) or in writing.
- e. Contact information of investigators (24-hour/7 days, contact no. of the PI).
- f. Contact information of REC Research Coordinator listed as follows:
- g. "If I should have any questions about the protection of human research participants regarding this study, I may contact the REC office." Current contact numbers of the REC Research coordinator should be listed.
- h. Translator section should be added as one of the signatory options in the Informed Consent form, provided that some patients might need one at the time of consenting.
- i. Structure of Consent Document.
- j. Language of the consent form is directed toward the individual signing the form (avoiding use of jargon, scientific terms, and concepts not readily comprehended by the non-scientist public)
- k. The text and readability of consent form is appropriate for the age, mental capacity and maturity of the individual signing the form.
- l. The consent form does not contain any exculpatory language in which the subject is made to waive or appear to waive any of the subject's rights.
- m. The final draft of the consent document has been reviewed for grammatical and typographical errors.

Please note that:

1. The consent form should not ask patients to waive any of their legal rights, nor should they be asked to release the investigator, sponsor, or hospital from liability for negligence.
2. In cases where persons who are legally incapable of giving informed consent, the investigators nevertheless should (1) provide an appropriate explanation, (2) obtain the participant's assent, and (3) obtain appropriate permission from a legally authorized person.
3. Translator section should be added as one of the signatory options in the Informed Consent form, provided that some patients might need one at the time of consenting.