**CONSENT FORM IV (B)**

Informed Consent form to participate in a clinical trial

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Title: | |  |  |  |
| Study Number: | |  |  |  |
| Subject’s Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Subject’s Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| Date of birth/Age:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |  |  |
|  |  |  | Please initial | |
|  |  |  | Box (Subject) | |
| (i) | I confirm that I have read and understood the information sheet dated | | [ | ] |
|  | \_\_\_\_\_\_\_\_\_\_ for the above study and have had the opportunity | |  |  |
|  | to ask question. |  |  |  |
| (ii) | I understood that my participation in the study is voluntary and that I am | | [ | ] |
|  | free to withdraw at any time’ without giving any reason. | |  |  |
|  | Without my medical care or legal rights being affected. | |  |  |
| (iii) | I understand that the sponsor of the clinical trial, others working on the sponsor | | [ | ] |
|  | ’s behalf’ the Ethics Committee and the regulatory authorities will not need my | |  |  |
|  | permission to look at my health records both in respect of the current study and | |  |  |
|  | any further research that may be conducted in relation to it, even if I withdraw | |  |  |
|  | from the trial. I agree to this access. However, I understand that my identity | |  |  |
|  | will not be revealed in any information released to third parties or published. | |  |  |
| (iv) | I agree not to restrict the use of any data or result that arise from this study | | [ | ] |
|  | Provided such a use only for scientific purpose(s) | |  |  |

1. I agree to take part in the above study.

Signature (or Thumb impression of the subject/legally acceptable Representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_

Signatory’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Investigator’s Name:\_\_\_\_\_\_\_\_\_\_\_

Signature of the Witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_

Signature of the Witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_