#### PART II: Certificate of Consent Informed Consent to Participate in Clinical Trial

Study Title:

Study Number:

Participant’ Initials: Participant’s Name:

Date of Birth /Age:

* 1. I understand that I am being invited to take part in the research study. I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions.
  2. I understand 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.
  3. I understand the risks and potential benefits of this research study that were explained to me. I freely give my consent to take part in research study described in this form.
  4. I understand that the Sponsor of the research study, others working on the Sponsor’s behalf, IEC 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.
  5. I agree not to restrict the use of any data or results that a rise from this study provided such a use is only for scientific purpose(s).
  6. I agree to take part in the above study.

I have read the above information and agreed to participate in this study. I have received a copy of this form.

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| --- | --- |
| Participant's name (print): |  |
| Participant's signature & date: |  |
| Address:  Phone Number:  Qualification (please attach supporting documentation) (if applicable)  Occupation: Student / Self-Employed / Service / Housewife /Others (Please tick as appropriate) and attach supporting documentation (if applicable)  Annual Income of the participant (please attach supporting documentation) (if applicable): |  |

|  |  |
| --- | --- |
| Legal Acceptable Representative name: |  |
| Legal Acceptable Representative signature & date (if applicable): |  |
| Address (capital letters): Phone Nos.: |  |
| Impartial Witness’s name: |  |
| Impartial Witness’s Signature & Date (if applicable): |  |
| Address (capital letters): Phone Nos.: |  |
| Name of PI or Co-PI/Co-I: |  |
| PI or Co-PI/Co-I sign & date: |  |