|  |  |
| --- | --- |
| Independent Ethics CommitteeRamsay Sime Darby Health Care | Checklist of 21 elements in the informed consent form and written subject information |

|  |
| --- |
| Checklist of 21 elements in the informed consent form and written subject information  Reference: ICH-GCP, Malaysian Guidelines for Good Clinical Practice, 3rd edition, 2011  This checklist is a tool to help in determining that the required information is well presented in the Patient Information Sheet and Informed Consent Form. Adherence with this checklist assures compliance with applicable research guideline and regulations. |
| **Study Protocol Title:** |
| **Principal Investigator:** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GCP Informed Consent Elements | Present | Missing | Not applicable |
| 1. | That the trial involves research. |  |  |  |
| 2. | The purpose of the trial. |  |  |  |
| 3. | The trial treatment(s) and the probability for random assignment to each treatment. |  |  |  |
| 4. | The trial procedures to be followed, including all invasive procedures. |  |  |  |
| 5. | The subject’s responsibilities. |  |  |  |
| 6. | Those aspects of the trial that is experimental. |  |  |  |
| 7. | The reasonable foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant. |  |  |  |
| 8. | The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this. |  |  |  |
| 9. | The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks. |  |  |  |
| 10. | The compensation and/or treatment available to the subject, in the event of trial-related injury. |  |  |  |
| 11. | The anticipated prorated payment, if any, to the subject for participating in the trial. |  |  |  |
| 12. | The anticipated expenses, if any, to the subject for participating in the trial |  |  |  |
| 13. | That the subject’s participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |
| 14. | That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject’s legally acceptable representative is authorizing such access. |  |  |  |
| 15. | That record identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential. |  |  |  |
| 16. | That the subject or the subject’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject’s willingness to continue participation in this trial. |  |  |  |
| 17. | The person(s) to contact for further information regarding the trial and the rights of trial subjects (e.g. Representative of Ethics  Committee), and whom to contact in the event of the trial-related injury (e.g. Investigator). |  |  |  |
| 18. | The foreseeable circumstances and/or reasons under which the subject’s participation in the trial may be terminated. |  |  |  |
| 19. | The expected duration of the subject’s participation in the trial. |  |  |  |
| 20. | The approximate number of subjects involved in the trial. |  |  |  |
| 21. | The source of the investigational product that may be culturally unacceptable. |  |  |  |
| Additional guidance | |  |  |  |
| A | If samples of tissue, cells, blood or body fluids are taken, consent must be given to store samples or else you must state that samples will be destroyed at the end of the project. |  |  |  |
| B | Should the subject(s) withdraw, the status of data or biological  specimen(s) collected prior to withdrawal should be disclosed to the subject |  |  |  |
| C | The presence or absence of provision for extended access of study drugs (for research where a study drug(s) is given) |  |  |  |
| D | The language used in PIS and ICF is as non-technical as practical and understandable to the subject or the subject’s legally acceptable representative and the impartial witness, where applicable |  |  |  |
| E | Total amount of blood to be taken for whole study should be  specified and expressed in ordinary everyday measure such as  number of tea-spoon(one tea-spoon is about 5ml) |  |  |  |

Pertinent Format Requirements

**In the Patient Information Sheet, are the following available?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Present | Missing |  |
| 1 | Title of the research project on every page |  |  |  |
| 2 | Protocol Number |  |  |  |
| 3 | Version No. of the PIS on every page |  |  |  |
| 4 | Sponsor’s Name |  |  |  |
| 5 | Name of Principal Investigator and Institution |  |  |  |
| 6 | To mention whether investigational product contain porcine /  bovine ingredients |  |  |  |
| 7 | Page numbers must be expressed on every page |  |  |  |

Source of document: Independent Ethics Committee, RSDHC. Date updated: 2019 January