**Useful points to include in a Participant Information Sheet (PIS)**

NOTE: The amount and type of information that is considered appropriate will vary depending on the type of your study, who your research subjects are, and under what circumstances the PIS may be read. Not all of the following information will be relevant to your study. (1–3)

|  |
| --- |
| **Version number and date**These should be updated whenever you apply changes to the PIS. |
| **Title of the study**The title on the PIS should be the same as that on the research protocol. However, you may add a simpler title if it will be easier for subjects to understand. |
| **Invitation** Invite potential subjects to take time to understand and consider the study properly before they make any decisions. Encourage them to ask questions. |
| **Background and aim** You should explain:* what the study is about
* why it is important
 |
| **Inclusion and exclusion criteria**You may inform subjects: * why they are chosen to participate in the study
* the number of people who are participating
* who should not participate in the study

You **must** state that it is ok to refuse to participate, and there would not be any penalty or loss of benefits to them if they refuse. |
| **Study design and procedures**You should explain:* what type of study you are conducting
* what procedures, tests and/or investigational products are used
* whether samples will be taken, how much and how often
* who will carry out these research procedures
* how long subjects need to be in the study

You should explain words like ‘placebo’, ‘randomisation’ or ‘blinding’.You should state clearly which component of your study is experimental, and which is standard clinical care. |
| **Risks, burdens, discomforts, inconveniences**You **must** inform subjects if there are any risks, burdens, discomforts and/or inconveniences associated with the study. In doing so, you should consider:* the different types of risks (physical, psychological, socio-legal and financial risks)
* risks to subjects’ family and community
* potential cultural and religious sensitivities (for example, warn subjects if there are porcine or bovine ingredients in a drug)
* potential unknown risks (for example, risks to unborn foetuses)

You should also explain:* what measures are taken to minimise each of these risks
* what will happen if harm occurs, whether treatment and/or financial compensations will be given

You **must** state that it is ok for subjects to drop out at any time without giving any reason, and that there would be no penalty nor loss of benefits if they do so. However, you may encourage subjects to inform you, especially if it could be dangerous to withdraw without notice. |
| **Potential benefits**You may inform subjects:* how they may benefit from participating in the study
* how other people may benefit from the results of the study

If there are no direct benefits to the subjects, you should say so.  |
| **Confidentiality of personal data and biological samples**You should inform subjects:* what kind of personal information you will be collecting and storing
* how long they will be stored for
* whether they will be kept confidential
* whether anyone outside of the research team will have access to them (for example, auditors, ethics committee, regulatory authorities)

If data and biological samples will be used for any other research or non-research purposes now or in the future, you should inform subjects:* how their data and samples will be used
* whether they can refuse such usage, but still participate in the current study
 |
| **Notification of new findings or changes to the protocol**Subjects should be notified about any new information that could affect their willingness to continue participating in your study. |
| **Post-study arrangements** You should inform subjects:* whether they can continue receiving any experimental intervention when the study ends, for how long
* whether the final findings of the study will be shared
* whether subjects will be identified in any publication
* how they can find out about the results if they are interested

You should also let subjects know whether they will / will not be notified about:* the results of any tests that they have undergone in the study
* the results of any future tests if their data or samples may be reused or re-analysed
 |
| **Incentives and compensations**You may inform subjects:* whether they will receive financial incentives or compensations for participating, how much and when
* whether they are entitled to any profits generated from the research
* whether there are any expenses that they will have to cover themselves
 |
| **Emphasis on voluntariness**You should re-emphasise that subjects are free to refuse now or change their minds even after they have agreed. You should inform them:* what the other options are if they choose not to participate in this study

You should also inform them if there are situations in which they may be withdrawn by the researchers.  |
| **Source of funding and conflicts of interests**You should inform subjects if the sponsor and/or researchers may have any commercial or substantial personal gains from conducting this study. |
| **Contact information of researchers**Provide at least 2 names and telephone numbers (stating each person’s role) that subjects can contact if they have questions or concerns about your study. |
| **Contact information of the ethics committee**Inform subjects that they can contact the ethics committee directly if they have further concerns. |

**References**

1. National Committee for Clinical Research (NCCR). Malaysian Guideline for Good Clinical Practice Fourth Edition (Mar 2018) [Internet]. Ministry of Health Malaysia; [cited 2019 Jan 8]. Available from: http://www.nccr.gov.my/index.cfm?menuid=6&parentid=17

2. NHS Health Research Authority, UK Medical Research Council. Home - Consent and Participant information sheet preparation guidance. [Internet]. [cited 2019 Jan 15]. Available from: http://www.hra-decisiontools.org.uk/consent/index.html

3. e-CFR (Revised Common Rule) [Internet]. United States Electronic Code of Federal Regulations. Sect. Part 46—Protection of Human Subjects Jul 19, 2018. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html