Fact Sheet: Informed Consent

Before a participant can enrol in a clinical trial, they must be screened for eligibility according to the criteria defined in the trial protocol. After screening, eligible participants should have an informed consent discussion with a sponsor representative. During the informed consent discussion, the participant should learn of the purpose and potential benefits and risks of a study before they decide whether or not they wish to participate.

The process of patient recruitment and informed consent is, as the rest of the medicines development process, governed by regulations and subject to review in order to ensure the rights, safety, and well-being of participants (see Fact Sheet: Informed Consent – Regulations). As a result, the informed consent discussion, the written consent form, and other written information should include explanations according to the Guideline for Good Clinical Practice.

The information provided to a prospective clinical participant should explain:

- That the trial involves research;
- The purpose of the trial;
- The trial treatment(s) and the probability for random assignment to each treatment;
- The trial procedures to be followed, including all invasive procedures;
- The patient's responsibilities;
- Any aspects of the trial that are experimental;
- The reasonably foreseeable risks or inconveniences to the patient and, if applicable, to an embryo, foetus, or nursing infant;
- The reasonably expected benefits. If there is no intended clinical benefit to the patient, the patient should be made aware of this;
- The alternative procedure(s) or course(s) of treatment that may be available to the patient, and their important potential benefits and risks;
- The compensation or treatment available to the patient in the event of trial-related injury;
- The anticipated prorated payment, if any, to the patient for participating in the trial;
- The anticipated expenses, if any, to the patient for participating in the trial.

Additionally, prospective patients must be made aware:

- That the patient's participation in the trial is voluntary and that the patient may refuse to participate or decide to withdraw from the trial at any time without penalty or loss of benefits to which the patient is otherwise entitled;
- That the monitor(s), the auditor(s), the research ethics committees, and the authorities will be granted direct access to the patient's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the patient, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the patient or the patient's legally acceptable representative is authorising such access;
- That records identifying the patient will be kept confidential and, to the extent permitted by the applicable laws or regulations, will not be made publicly available. If the results of the trial are published, the patient's identity will remain confidential;
- The patient or the patient's legal representative will be informed when information relevant to the patient's willingness to continue participation in the trial becomes available;
- Contact details from which to obtain further information regarding the patient's rights, and who to contact in the event of a trial-related injury;
- Foreseeable circumstances or reasons for which the patient's participation in the trial may be terminated;
- The expected duration of the patient's participation in the trial and the approximate number of patients involved.

In the case of vulnerable participants, additional considerations are necessary (see Fact Sheet: Informed Consent – Vulnerable Populations).