Fact Sheet: Informed Consent – Vulnerable populations

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 (see Fact Sheet: Informed Consent for more on these guidelines).

Special considerations are necessary when enrolling participants from vulnerable populations in clinical trials. In terms of informed consent, these considerations include:

- Researchers should sensitively explore the individual's abilities and the nature of their special needs. Information about the trial may need to be presented to individuals in a different format. Individuals need to be given plenty of time to think about the trial and ask any questions that they have.
- Children and their parents/legal guardians should be involved in the informed consent process in proportion to the ability of the child to weigh the benefits and risks of the trial.
- Special care must be taken care to make sure that elderly people do not feel pressured or coerced into taking part in a trial.
- Prisoners should not be used as participants in a trial unless the trial is specifically looking at topics directly related to prison or prisoners.
- Care must be taken to avoid health care staff feeling pressured to take part in a trial. Assumptions should also not be made about their knowledge of the trial and health care staff must be provided with the same detailed information about the trial as other participants.

- Special care must be taken not to overly emphasise the benefits of taking part in a trial to patients who have a rare or incurable disease for which there may be few treatment options.
- Care must be taken to avoid unintentional coercion of individuals in developing countries by offering them incentives, such as free health care, in order to take part in the trial. Local regulations must be taken into account for the location where the trial is going to take place.