

Fact Sheet: Informed Consent – Regulations

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.

Regulations and participant safeguards

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.

- **Scientific Review**

In order to guarantee that subjects are protected during a trial, the study protocol is submitted in a Clinical Trial Application to the national competent authorities who perform the scientific evaluations. They review and monitor clinical trial protocols to ensure the clinical trials are scientifically sound – for instance, if the scientific question being asked will result in an improvement in patient care by the end of the trial. The committee also:

- Assesses whether the methods used to collect data are appropriate;
- Determines whether the right patients will be included in the trial;
- Reviews the people running the trial to make sure they are suitably qualified;
- Some review committees will also ask for input from patients on the proposed trial design.

- **Institutional review – Ethics review**

An Institutional Review Board (IRB) or Independent Ethics Committee (IEC) is there to safeguard the rights, safety, and well-being of all patients in a clinical trial. Special attention is paid to trials that may include vulnerable participants. It also assures that there is no coercion or undue influence on the trial participants and conducts reviews of each ongoing trial at intervals appropriate to the degree of risk to human participants.

- **Clinical Trial Guidelines**

The Clinical Trials Directive harmonises the rules in the EU for the approval of a clinical trial conducted in a member state. As regards national competent

authorities, the details are set out in the *'Commission Detailed guidance on the request to the competent authorities for authorization of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)'*. [Available from: http://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf, 8.12.2015]

These guidelines:

- Standardise designing, signing, conducting, recording, and reporting trials that involve human participants
- Provide public assurance that the rights, safety, and well-being of trial participants are protected
- Establish the guidelines for the written informed consent form – for instance, that the form needs to be written in a non-technical language and should be understandable to the patient or patient's representative.
- Dictate that the patient should be given ample time to inquire about the trial and to decide whether or not to participate.
- State that the consent form must be signed by both the patient or their legal representative and by the trial representative who discussed the trial with the patient.