



Informed Consent

EU NT Training: Joint assessment according to the new clinical trial regulation 536/2014 from the view of ethics committees and national regulatory agencies

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CTR 536/2014, Art.29: Informed Consent

“Informed consent shall be written, dated and signed by the person performing the interview..., and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed.... Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document (or the record) by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical trial.”

CTR 536/2014, Art.29: Informed Consent

- IC has to be signed by the interviewer and the subject or his/her legal representative after having been duly informed.
- Where subject is unable to write other means are permitted with at least one impartial witness present, who has to sign.
- A copy of the IC-document and -material has to be handed out.
- The informed consent shall be documented.
- Adequate time shall be given to consider participation in the CT.

CTR 536/2014, Art.29: Informed Consent

Information provided shall enable to understand

- the nature, objectives, benefits, implications, risks and inconveniences of the clinical trial**
- the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;**

CTR 536/2014, Art.29: Informed Consent

Information provided shall enable to understand

- **the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial;**
and
- **the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued;**

CTR 536/2014, Art.29: Informed Consent

Information provided shall

- be kept comprehensive, concise, clear, relevant, and understandable to a layperson;**
- be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the MSc;**
- include information about the applicable damage compensation system;**
- include the EU trial number and information about the availability of the clinical trial results**

CTR 536/2014, Art.29: Informed Consent

- **In the interview to obtain IC it shall be verified that the subject has understood the information.**
- **The CTR is without prejudice to national law requiring that both the signature of the incapacitated person and the signature of his or her legally designated representative may be required on the informed consent form.**
- **This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical trial.**

Informed Consent Material: Structure

- Trial name and EU number
- Purpose of the trial: disease/indication of the IMP, IMP authorized yes/no, number of pts. already treated;
- Placebo control? Randomisation? Blinding? With explanations;
- Workflow of the trial: all trial related procedures in detail, discontinuation of current treatments, visits, duration of participation, graphical display;
- Potential for benefit if any, direct/indirect;
- Risks: known and potential ones of the IMP with frequencies and severity (incl. relevant findings from preclinical studies) and of all trial-related procedures;
- Reasons for early stop and follow-up measures;

Informed Consent Material: Structure

- **Trial related burdens for subject/family/carer;**
- **Comprehensive and objective presentation of therapeutic alternatives, incl. risk/benefit considerations;**
- **Who must not participate with details, e.g. pregnancy;**
- **Financial issues (see Art.92), compensation in phase I-trials, compensation for expenses;**
- **Damage compensation incl. relevant conditions of insurance;**
- **Information about new findings during the trial and of the results;**
- **Data privacy and data processing, quality control;**
- **Biosamples, results of image methods and genotyping;**
- **Independent contact point;**

Informed Consent Material: Structure

- Subjects' rights incl. to withdraw any time;
- Funding of the trial and potential of the investigators for conflicts of interest.

In addition, the requirements of the EU GDPR and national data privacy laws have to be met.

A couple of templates for informed consent forms are available on the homepage of the Arbeitskreis:

<https://www.ak-med-ethik->

[komm.de/index.php?option=com_content&view=article&id=145&Itemid=154&lang=de](https://www.ak-med-ethik-komm.de/index.php?option=com_content&view=article&id=145&Itemid=154&lang=de)