Your rights as a participant in a clinical trial with medical products

If you are a participant in a clinical trial involving a medicine, it is important that you are aware of your rights. You can read about them on this page.

1. Your participation in a clinical trial is completely voluntary. You are entitled to both written and verbal information about the trial, and you must sign a consent form before you can participate.
2. You have the right to bring a family member, friend or acquaintance to the information session.
3. You have the right to a reflection period before signing the consent form.
4. You can withdraw your consent at any time and withdraw from the trial without giving any reason. This will not affect your right to patient treatment or other rights.
5. Information about you, your health, your blood samples, etc. is subject to confidentiality and must be processed in accordance with data protection legislation [1]. The data controller for the trial must ensure that you are informed of these rules.
6. Your consent to the trial means that the data controller and sponsor may obtain information about your health in the medical record systems when this is necessary for quality control and monitoring of the trial.
7. If the information about your health collected during the trial is later used by the investigator for research or statistical purposes, you cannot object to the processing and sharing of this information.
8. You have the right to opt-out of potential knowledge of new health information that may emerge about you in the trial that is not directly related to the trial.
9. If the trial is conducted under public auspices, you have the right of access to documents relating to the organization of the trial, except for those parts that contain trade secrets or confidential information about other persons.
10. If you are injured during the trial, you can complain according to the rules in the Danish Act on Complaints and Compensation in the Healthcare Sector, see more at www.patienterstatningen.dk
11. When the trial is completed, you have the right to receive information about the results of the trial.
12. The trial coordinator must ensure that an information unit is made available to you from which you can obtain more information about the trial.

Oversættelse af: *Dine rettigheder som forsøgsperson i forsøg med medicin*
Sprog: *Engelsk*

[1] Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation),
Act no. 502 of May 23, 2018 on supplementary provisions to the Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (Data Protection Act)
Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 16, 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC (Text with EEA relevance).

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Oversættelse af: *Dine rettigheder som forsøgsperson i forsøg med medicin*
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