

The rights of a trial subject in a biomedical research project

As a participant in a biomedical research project you should know that:

- your participation in the research project is completely voluntary and can only take place after you have received both written and oral information about the research project and signed the consent form;
- you may at any time orally, in writing or by any other clear notification withdraw your consent to participation and withdraw from the research project. If you withdraw your consent, this will not affect your right to any current or future treatment or any other right you may have;
- you are entitled to bring a member of your family, a friend or an acquaintance with you to the informative interview;
- you are entitled to time to think it through before you sign the consent form;
- strict confidentiality is observed with regard to information about your health, other purely private matters and other confidential information about you disclosed in connection with the research project;
- information about you, including information about tissue and blood samples from you, will be processed according to the provisions specified in the General Data Protection Regulation (GDPR), Danish Health Care Act and the Danish Data Protecting Act . The data controller must inform you about your rights under the data protection rules;
- you will be able to get access to research protocols according to the provisions of the Danish Open Administration Act. This means that you can gain access to all documents concerning the organization of the project apart from the parts containing business secrets or confidential information about others.
- you have the right to complain and compensation can be paid pursuant to the Act on the Right to Complain and Receive Compensation within the Health Service. You can contact Patienterstatningen if any damage occurs. Read more information at www.patienterstatningen.dk .

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Hjemmeside: www.nvk.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
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Hjemmeside:
<https://www.regionh.dk/til-fagfolk/Forskning-og-innovation/Kliniske-test-og-forsoeg/Sider/De-Videnskabsetiske-Komiteer.aspx>

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Den Videnskabsetiske Komité for Region Sjælland
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De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
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The above Appendix is published by the Danish National Committee on Biomedical Research Ethics and can be attached to the written information about the biomedical research project. Questions relating to a specific project must be directed to the principle investigator of the project. General questions regarding the rights of a trial subject can be directed to the ethics committee that has approved the project.

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