# Deltagerinformation

(Information for Participants)

**The information is to appear in a plain language and without medical terms.**

The information must appear in Danish. If you plan to use English-speaking subjects, upi should prepare the information in English (see section 2) as well.

## 1 Deltagerinformation, dansk

(Information for Participants, Danish)

Forsøgets titel: Insert the original or a simplified title

Vi vil spørge, om du vil deltage i et videnskabeligt forsøg, der udføres ved xxxxxx *(name of research group or center)* på Aalborg Universitet.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget. Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.

Du vil blive inviteret til en samtale om forsøget, hvor denne deltagerinformation vil blive uddybet, og hvor du kan stille de spørgsmål, du har om forsøget. Du er velkommen til at tage et familiemedlem, en ven eller en bekendt med til samtalen.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen.

Det er frivilligt at deltage i forsøget. Du kan når som helst og uden at give en grund trække dit samtykke tilbage.

**Formål med forsøget**

(Purpose of the visit)

Insert information about the background and purpose of the experiment.

### Hvem kan deltage i forsøget?

(Who can participate?)

Du kan deltage i forsøget, hvis du ……

Du kan ikke deltage, hvis du bl.a. …….

Mention the most relevant exclusion criteria

### Hvordan foregår forsøget?

The section is to include information of the duration of the experiment, the number of sessions to be attended, the procedure of the experiment and who is performing it, or make a table which illustrates the plan for the experiment. This section also is to describe what happens after the termination of the experiment.

### Biologisk materiale

(Biologic material)

The following information is to be given:

* The type and quantity of material taken out
* The purpose of the research bio-bank
* Whether the material is transferred to other countries (the names of the countries to be stated)
* What is going to happen with the material after termination of the project (is it destroyed, anonymised (i.e. without codes) or stored in a bio-bank for later research)

### Risici, bivirkninger og ulemper

(Risks, side effects and disadvantages)

Please state information about known risks, side effects, complications and inconvenience of the experiment no matter if they are temporary, long-term, frequent or rare.

Please note that if there is a risk of medical radiation exposure, this should also be mentioned.

*Standard text at the end of this section:*

Der kan være risici ved forsøget, som vi endnu ikke kender. Vi beder dig derfor om at fortælle, hvis du oplever problemer med dit helbred, mens forsøget står på. Hvis vi opdager bivirkninger, som vi ikke allerede har fortalt dig om, vil du blive orienteret med det samme, og du vil skulle tage stilling til, om du ønsker at fortsætte i forsøget.

### Nytte ved deltagelse

(Benefit of the experiment)

This section is to include information about the benefit(s) of the experiment – both the personal benefit for the subject and the general benefit of the experiment.

### Udelukkelse fra og afbrydelse af forsøg

(Exclusion from and suspension of experiment)

Information about any circumstances which may lead to the subject being excluded from the experiment against his/her own wish, and under which circumstances the experiment as a whole can be cancelled.

Standard text:

Reagerer du efter forsøgslederens vurdering uventet på forsøgets procedurer, eller viser du dig på anden vis ikke egnet til videre deltagelse i forsøget, kan din deltagelse i forsøget til ethvert tidspunkt afsluttes. Forsøget som helhed vil blive stoppet, hvis det skulle vise sig, at forsøgspersonerne generelt ikke tolererer procedurerne i forsøget eller finder forsøget for udmattende.

### Andre behandlingsmuligheder

(Other treatment possibilities)

If the experiment both has a scientific and a treatment aim, this section is to state information of other treatment methods.

**Persondata**

Vi behandler og opbevarer personoplysninger i overensstemmelse med databeskyttelses­forordningen og databeskyttelsesloven. Under forsøget behandler vi de oplysninger om dig, der er nødvendige for forsøgets udførelse, og efter forsøget gemmer vi dine personoplysninger i overensstemmelse med databeskyttelsesforordningen.

*Text when obtaining information from medical charts*

Med dit samtykke giver du tilladelse til at den forsøgsansvarlige, sponsor og sponsors repræsentanter får direkte adgang til din medicinske journal m.v. (herunder elektronisk journal) under forsøget med henblik på at se oplysninger om dine helbredsforhold, som er nødvendige som led i egenkontrol med forskningsprojektet, herunder kvalitetskontrol og monitorering, som disse er forpligtet til at udføre.

### Oplysninger om økonomiske forhold

(Project economy)

*Forslag til standardtekst*

Forsøget er igangsat af *xxxxx (navn), xxxx (titel), xxxx (affiliation)*, og det finansieres med kr. *xxxx* af *xxxx.*

Ingen af forskerne bag forsøget har økonomiske interesser heri.

* Information of the person(s) initiating the project
* Name of commercial as well as non-commercial financial supporters (foundations, private persons, etc).
* The amount provided by each financial supporter (including the method of disbursement)
* Information about the financial connection of the person responsible for the project to the financial supporters

Insert information about any compensation to the volunteer and tax obligations hereof. The below standard text can be used:

*Forslag til standardtekst*

Der udbetales en kompensation på i alt kr. *xxx* **pr. gang/time** for din deltagelse i forsøget. Beløbet er skattepligtigt og vil derfor blive indrapporteret til Skat som B-indkomst.

Såfremt du vælger at trække sig undervejs i forsøget, udbetales der kompensation for den del af forsøget, som du har deltaget i.

### Adgang til forsøgsresultater

(Access to results)

Forsøgets resultater offentliggøres uanset udfaldet.

Forsøget er godkendt af “Den Videnskabsetiske Komité for Region Nordjylland”, sagsnummer N- xxxxxxxx.

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse. Vi beder dig også om at læse det vedlagte materiale ”Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt”.

Hvis du vil vide mere om forsøget, er du meget velkommen til at kontakte undertegnede.

Med venlig hilsen

Insert name, address, e-mail and phone number of the contact person(s).

# Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forsknings­projekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide at:

* din deltagelse i forskningsprojektet er helt frivillig og kan kun ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen
* du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have
* du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen
* du har ret til betænkningstid, før du underskriver samtykkeerklæringen
* oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt
* behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
* der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshem­meligheder eller fortrolige oplysninger om andre.
* der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade, kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk.

*Dette tillæg udgives af det videnskabsetiske komitésystem og kan vedhæftes den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersoners rettigheder kan rettes til den komité, som har godkendt projektet.*

## 2 Deltagerinformation, engelsk

(Information for Participants, English)

Project title: Insert the original or a simplified title

We would like to enquire if you are interested in participating in a research project which is to be conducted at xxxxxxx *(name of research group or center)* at Aalborg University.

Before you decide to participate in the research project, it is important that you fully understand the procedures of the experiment. Therefore, we ask you kindly to read this information carefully.

We will invite you to participate in an information meeting where we will elaborate the information about the project and where you have the opportunity of asking any questions you may have. You are welcome to bring a family member or a friend to the meeting.

If you decide to participate in the project, we will ask you to sign a declaration of consent. Please remember that you have the right to time for reflection before you sign the declaration of consent.

Participation in the project is voluntary. You can at any time and without stating a reason withdraw your consent.

### Purpose of the Experiment

Insert information about the background and purpose of the experiment.

### Who can participate?

You can participate in the study if you ……

You cannot participate if you, e.g. …………..

Mention the most relevant exclusion criteria

### The Experiment

The section is to include information of the duration of the experiment, the number of sessions to be attended, the procedure of the experiment and who is performing it, or make a table which illustrates the plan for the experiment. This section also is to describe what happens after the termination of the experiment.

### Biological Material

The following information is to be given:

* The type and quantity of material taken out
* The purpose of the research bio-bank
* Whether the material is transferred to other countries (the names of the countries to be stated)
* What is going to happen with the material after termination of the project (is it destroyed, anonymised (i.e. without codes) or stored in a bio-bank for later research)

### Risks, Side Effects and Disadvantages

Please state information about known risks, side effects, complications and inconvenience of the experiment no matter if they are temporary, long-term, frequent or rare. Please also state the safety precautions taken to avoid these.

Please note that if there is a risk of medical radiation exposure, this should also be mentioned.

*Standard text at the end of this section:*

There might be risks in connection with the experiment that we do not know yet. Therefore, we ask you kindly to inform us if you experience any health problems during the experiment. If we discover side effects of which you have not been informed, we will inform you immediately, and in this case we will ask you to re-consider your participation.

### Benefits of the Experiment

This section is to include information about the benefit(s) of the experiment – both the personal benefit for the subject and the general benefit of the experiment.

### Exclusion from and Suspension of Experiment

Information about any circumstances which may lead to the subject being excluded from the experiment against his/her own wish, and under which circumstances the experiment as a whole can be cancelled.

Standard text:

If you, according to the assessment of the investigator, react unexpectedly on the procedures of the project or in any other way are not suitable for continuing in the experiment, your participation in the experiment can be terminated at any time. In general, the experiment will be terminated if it turns out that the subjects in general cannot tolerate the procedures of the project or find the experiment too exhausting.

### Other Treatment Possibilities

If the experiment both has a scientific and a treatment aim, this section is to state information of other treatment methods.

### Personal Data

We process and store personal data in accordance with the Data Protection Regulation and the Data Protection Act. During the experiment, we will process the personal data necessary for the execution of the project, and after termination of the experiment, we will store your personal data in accordance with the Data Protection Regulation.

*Text when obtaining information from medical charts*

With your consent, you allow the principal investigator, sponsor, or sponsor’s representatives direct access to your medical chart etc. (including electronic medical chart) during the experiment. Thus, they will have access the necessary information about your health to conduct the mandatory self-regulation of the experiment, including quality control and monitoring,

### Project Economy

*Proposal for standard text*

The study has been initiated by *xxx (name), xxxx (title) and xxxx (affiliation)*, and it is financed with DKK *xxx* by *xxx*.

None of the researchers have financial interests in the study.

* Information of the person(s) initiating the project
* Name of commercial as well as non-commercial financial supporters (foundations, private persons, etc).
* The amount provided by each financial supporter (including the method of disbursement)
* Information about the financial connection of the person responsible for the project to the financial supporters

Insert information about any compensation to the volunteer and tax obligations hereof.

Proposal for standard text:

You will receive DKK *xxx* per ***experiment session/hour*** as compensation for your participation in the experiment. The amount is liable to tax and will therefore be reported to the Danish tax authorities as B-income.

If you terminate the experiment before completion, you will receive compensation for the time spent.

### Access to Results

The results of the experiment will be published regardless of the outcome.

The experiment has been approved by The North Denmark Region Committee on Health Research Ethics, project number N xxxxxxxx.

We hope that this information has given you sufficient knowledge of the experiment to make a decision about participation. Please also refer to the attached leaflet The Rights of a Trial Subject in a Health Scientific Research Project (”Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt”).

If you require further information about the project, please do not hesitate to contact the undersigned.

Yours faithfully

Insert name, address, e-mail and phone number of the contact person(s).

# The Rights of a Trial Subject in a Health Scientific Research Project

As a participant in a health scientific 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
* processing of information about you, including information about tissue and blood samples from you, will be take place according to the provisions specified in the

Data Protection Regulation and the Data Protection Act. The data controller of the experiment will provide further information about your rights according to the data protection regulations

* 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 planning of the project except for parts containing business secrets or confidential information about others
* you have the right to complain and compensation can be paid pursuant to the Danish Act on the Right to Complain and Receive Compensation within the Health Service. If you suffer an injury, please contact Patienterstatningen (see more on www.patienterstatningen.dk)

*The above Appendix has been published by the research ethics committee system and can be attached to the written information about the health scientific research project. Questions about a specific project should be directed to the principal investigator of the project. General questions should be directed to the regional committee who has approved the project.*