UMC Utrecht

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Information for participation in medical scientific research

Introduction

Dear sir/madam,

We would like to ask your permission for informing you about the medical scientific research that is being done in our department. We need your informed consent to use your medical data for research. You receive this request because you have an appointment at the department of Psychiatry.

1. General information and research goals

You are treated in the Psychiatry department of the University Medical Center Utrecht. Besides providing patient care, we also conduct a great deal of scientific research. The research goals include:

- To find better treatments for psychiatric disorders;
- To learn more about psychiatric disorders, such as causes and risk factors;
- To diagnose psychiatric disorders (at an earlier stage).

We conduct our research in two ways:

1. We research data from patients' medical records. This data has been gathered for the treatment of your psychiatric disorder, and includes data about MRI, blood tests, medication use, and neuropsychological test results. You do not need to do anything else for the research. You will not be informed in detail on the studies for which your data is used.
2. We conduct research that requires some action on your part, especially for the research, such as filling in questionnaires, an MRI-scan or the use of study medication. This is called 'research with active participation'.

2. What consent means

General permission to use your medical data for future clinical scientific research on psychiatric disorders.

3. Possible advantages and disadvantages

You yourself will not benefit from your consent to the use of your medical data for future clinical (scientific) research. However, your consent can eventually contribute to more knowledge on psychiatric disorders and better treatments.
The decision to participate or not participate actively in scientific research will not have any consequences for your treatment at the UMC Utrecht.

4. If you do not wish to be contacted or to withdraw your consent

It is entirely your decision whether or not we are allowed to use your medical data for research. Your consent is voluntary. If you withhold consent, you will receive the same treatment. If you do give consent, you can always change your mind and withdraw your consent.

5. Use of your data

Use of care data

If you give consent to use the data, which has been collected for care purposes, for clinical (scientific) research, this data will be processed anonymously wherever possible. If this is not possible, measures will be taken to protect your privacy, for instance by pseudonymising your data. This means that your data will be processed under a code. This does not involve the use of data that can directly be linked to you (such as name, address, or date of birth).

6. Any questions?

If you have any questions, please contact the coordinator of patient-related research, Marleen Rademaker, via email (OTpsychiatrie@umcutrecht.nl) or by telephone (088 - 755 9425). If you have any complaints, you can discuss them with the coordinator of patient-related research or your doctor. If you would prefer not to, please contact the complaint mediators of the UMC Utrecht, via 088 – 755 6208.

Signing the informed consent form

If you give your consent, please confirm this in writing by signing the enclosed informed consent form. By giving your written consent, you state that you have understood the information. The signatures page will be kept in your electronic patient file. You will receive a copy of this informed consent form.

Many thanks for your time.

Yours sincerely,

Marleen Rademaker
Coordinator of patient-related research

Enclosures:

1. Additional information on data processing
2. Informed consent form
3. ‘Participating in scientific research in the Psychiatry department’ leaflet

Enclosure 1: Additional information on use of your data

Confidentiality of your data

To protect your privacy, your data will receive a code when it is provided for research. Your name and other information that could directly identify you will be omitted. You can only be identified based on this information with the key to the code. The key to the code is stored securely in the local research facility. You can also not be identified on the basis of data in reports. Your personal data is stored in a central database, which is only accessible to the research coordinator. If you decide to participate in a study, your data will also be available to the researcher who will contact you for appointments.

Access to your data for review

Some individuals may gain access to your data at the study site, including the data without a code. This is necessary in order to check that your data is stored properly and reliably in the database. Individuals who can inspect your data: a select section of the research team and the Health and Youth Care Inspectorate. They will keep your data confidential. We ask your consent for this access.

Withdrawal of consent

You can always withdraw your consent for the use of your personal data.

If you do not approve the use of the medical data, which has been collected for care purposes, for research, you can lodge an objection. More information on this can be found on the website of the UMC Utrecht: https://www.umcutrecht.nl/nl/Ziekenhuis/In-het-ziekenhuis/Regels-en-rechten/Gebruik-restmateriaal-medische-gegevens.

More information about your rights concerning the processing of data

For general information about your rights concerning the processing of personal data, please consult the website of the Dutch Data Protection Authority.

If you have any questions or complaints about your rights, we advise you to first contact the coordinator of patient-related research. You can also contact the Data Protection Officer at the UMC Utrecht, via privacy@umcutrecht.nl, or the Dutch Data Protection Authority.

Enclosure 2: Informed consent for scientific research

- I have read the information letter and was able to ask questions. My questions have been answered to my satisfaction. I have had enough time to decide whether or not to participate.
- I know that my consent is voluntary. I also know that I can decide at any time to have my data removed from the database or to withdraw my consent for research using my medical data.
- I know that certain individuals can gain access to all my data for inspection of the database. These individuals are listed in the enclosure in this information letter. I give consent for inspection by these individuals.
- I hereby give consent to use my data, which has been collected for care purposes, for medical scientific research on psychiatric disorders.

  □ **YES** □ **NO**

  This data for research cannot be directly linked to me.

Name of patient*: …… Date: ……..

Signature: ……

**From the age of 16 years, only the patient signs the informed consent.*

Patiëntnummer:

Enclosure 3: Informed consent for scientific research – UMCU COPY

- I have read the information letter and was able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether I would participate.
- I know that my consent is voluntary. I also know that I can decide at any time to have my data removed from the database or to withdraw my consent for research using my medical data.
- I know that certain individuals can gain access to all my data for inspection of the database. These individuals are listed in the enclosure in this information letter. I give consent for inspection by these individuals.
- I hereby give consent to use my data, which has been collected for care purposes, for medical scientific research on psychiatric disorders.
  □ **YES** □ **NO**
  This data for research cannot be directly linked to me.

Name of patient*: …… Date: ……..

Signature: ……

**From the age of 16 years, only the patient signs the informed consent.*