**Concerning this example information sheet (good practice):**

In this research, the following personal data will be collected: nationality, physical and mental health, gender, ethnicity, marital status, demographic data, address and contact details, date of birth.

Several topics from the [standard template](https://www.eur.nl/en/research/research-services/research-quality-integrity/ethical-review/informed-consent#templates) have been merged:

* Purpose of the research, Type of Research Intervention, Participant Selection
* Potential Risks and Discomforts, Potential Benefits
* Privacy, Confidentiality

# Information sheet

|  |  |
| --- | --- |
| **Name of Principal Investigator:** |  |
| **Erasmus University Rotterdam/ specific School:** |  |
| **Name of Funding organisation:** |  |
| **Project Title and Version:** |  |

## Introduction

I am …., working for the Erasmus University Rotterdam. I am doing research on the effects of the deployment of nurses for varying goals. I am going to provide you information and invite you to be part of this research. This consent form may contain words that you do not understand. Please ask me for explanations when anything is unclear.

## The Research

Icon

Description automatically generatedNurses and directing nurses are working at the ward where you have been hospitalized. The latter is a new job function. On top of the daily nursing tasks, directing nurses have a responsibility towards the quality of care on this ward. They help nurses with providing better care under better circumstances. We would like to find out whether patients have a different experience as a consequence of this change.

The research takes place over a period of 3 to 6 months. During that time, we will ask you to complete a questionnaire 4 times: on day 3 of the admission, on the day of discharge and 30 days and 3 months after your discharge from the hospital, independent of whether there will be follow-up care or not.

I invite you to take part in this research, because we think your experience as a patient can add to our knowledge of the influence of the deployment of directing nurses on your health and quality of life.

## Icon Description automatically generatedVoluntary Participation

Your participation in this research is entirely voluntary. Whether you choose to participate or not has no effect on the care you will receive. You may change your mind later and stop participating even if you agreed earlier.

Right to Withdraw (Please note, the text in this section cannot be filled in at will)

You have the right to withdraw your consent to use the data that you have provided at any time except the data that have been anonymized. You do not have to justify your decision to withdraw your consent and there are no consequences for withdrawing your consent.

## Procedure

I am inviting you to take part in this research project. If you accept, you will be asked:

* To grant access to your medical record. In this file the hospital collects data about you and your health, such as age, gender, pain scores, fall prevention, and other complications. Under no circumstances will data be collected about personal stories and relationships. All information will be processed confidentially and will not be accessible to third parties or people who are not working on this research.
* A picture containing text

  Description automatically generatedTo complete several (online) questionnaires. During your stay in the hospital, a nurse will share with you 2 questionnaires and 2 questionnaires will be shared with you by e-mail after discharge from the hospital. You may answer the questionnaires yourself. The submitted information will be kept confidential. Should you need assistance with completing the questionnaires, we can read the questionnaires to you or discuss the questions with you.

## Potential Risks, Discomforts and Benefits

There are no risks or discomforts related to this research. The care you receive when you participate in this research is the same as the care you receive when you do not participate.

There will be no direct benefit to you, but your participation is likely to help us find out more about how different ways of providing nursing care can have an influence on you and other patients. This may help us to provide better nursing care in the future.

## Handling your Data during Research

During this research I will ask you to provide personal data. Personal data is information that can directly or indirectly identify you as an individual, such as nationality, ethnicity, address information, date of birth and gender.Icon

Description automatically generated

Your name and contact details will be taken from the electronic medical record and will be noted on your questionnaires. We do this to be able to connect the data from the electronic medical record to the right questionnaires, so that we cannot mix them up with the data of other participants. Your contact details will be used to send you questionnaires after discharge from the hospital and to share a summary of the results with you after completion of the research project. Once we have done this, we will remove your name and e-mail address from our data.

## Retaining and Sharing your Data

Icon

Description automatically generatedOnly people who are involved in the research and people who maintain the necessary IT systems, will have access to your personal data. Your data will be stored in a secure location for a minimum period of 10 years after publication on the research.

A selection of the data you provide us with may be useful for education and for future research, also in other areas of research. If this is the case, we will make the data – without your personal data – available for this. In addition, we will ask for your consent to re-use your personal data in the certificate of consent. If you do not consent to this, we will only keep these data for integrity purposes.

## Sharing the Results

The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant receives a summary of the results. Furthermore, we will publish the results on a website (include web address) so that interested people may learn from the research.

## Your Privacy Rights and Contact Information (The text below is compulsory\*)

You have the right to request access to your personal data and to request rectification, erasure, restriction, data portability, and to object to the processing of your personal data under certain circumstances.

If you want to invoke your rights or if you have a question concerning privacy in this study, you can contact Erasmus University’s DPO (Data Protection Officer) at fg@eur.nl.

If you would like to lodge a complaint concerning privacy, you can do this with the national supervisory authority in the Netherlands on personal data (Autoriteit Persoonsgegevens).

## Who to Contact?

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Name:

E-mail-address:

Telephone number:

## Certificate of Consent

I have read the Informed Consent Form and I understand what the purpose of the research is and that data will be collected from me. The research has been explained to me clearly and I have been able to ask questions.

By signing this Form, I

* consent to participate in this research;
* confirm that I am at least 18 years old;
* understand that participating in this research is completely voluntary; and
* understand that my data will be anonymised for publication, educational purposes and further research.

See next page.

## A picture containing text Description automatically generated

## Consent

**Consent Special categories of personal data**

I give my consent to the collection, processing, use and storage of my personal data for the purposes of this research including data related to health data derived from my medical record and the answers to the (online) questionnaires.

**Education and further Research**

I hereby consent to having my personal data [age, gender, pain scores, fall prevention, and other complications and the answers to the (online) questionnaires] stored and used for educational purposes and for future research, also in other areas of research than this research.

Name of the participant:

Signature of the participant: Date:

You will be given a copy of the full Informed Consent Form.

This proposal has been reviewed and approved by [name of the local RERC/ IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the RERC/IRB, contact [Add contact details] [or refer to information on the website].