Consent form DENSE-2 study

Breast cancer screening with an MRI examination for women with very dense breast tissue.

We invite you to participate in the DENSE-2 study. This study investigates different ways of breast imaging. You have been invited for an MRI examination. Please read the information below carefully. If you would like to participate in the DENSE-2 study, please complete and sign this form.

After reading the information:

- I have received sufficient information about the purpose and design of the study.
- I have had time to think about participating in this study and ask questions.
- I know that participation in this study is entirely voluntary and that I can withdraw my consent at any time. I do not need to give a reason.
- I know that certain people can see my data. These people are listed in the information brochure.
- I give permission for my GP to be informed of my participation in this study.
- I give permission for the exchange of my data with the hospital so that it can perform the MRI study and share the results with UMC Utrecht. My BSN number will be used in the process to ensure that the hospital is sure they are performing the MRI examination on the right person and the personal data to be processed relates to me. The BSN number will only be used for this purpose. After you receive the results of the MRI examination, the BSN number will be removed from our records. The BSN number will only be stored in the hospital from then on.
- I consent to the exchange of data with:
    - Bevolkingsonderzoek Nederland;
    - Nederlandse Kankerregistratie (Netherlands Cancer Registry)
    - Centraal Bureau voor de Statistiek (CBS) (Statistics Netherlands)
    - Pathologisch-Anatomisch Landelijk Geautomatiseerd Archief (PALGA) (Pathological-Anatomical National Automated Archive)
    - Burgerlijke stand (Dutch Civil Registry)
- I consent to my data being shared and used for scientific research. This concerns the following data:
    - The data provided by me to the study team (by phone and questionnaires)
    - The MRI images and associated medical data
    - Breast images (mammograms) from Bevolkingsonderzoek Nederland and related data;
    - Medical records with the treating doctor(s) if I should be further tested or treated for breast cancer
- I consent to my personal data being saved for 20 years.

Please tick yes or no below

Giving your consent below helps us conduct the study. If you do not agree to the aforementioned information and processing, you will not be able to participate in the study. Whether you consent to the other options or not does not affect your participation in the study or the breast cancer population screening: You can find more explanations on the website (www.dense-2.nl) under 'frequently asked questions'.

	Yes	No
I consent to participate in the study and research and to the processing of my data as described in the information leaflet and previous summary		**NVT**
I consent to the requesting of my data from my health insurance company.		
I consent to the requesting of my data from my pharmacy.		
I consent to be informed by my GP if the MRI scan accidentally finds an abnormality outside the breast that needs further investigation. *I understand that:* ○ *if I do give consent this means that my GP will be informed of this finding in that case.* ○ *if I do not give consent that there are still exceptions in which I am informed. This can happen if an abnormality is found that is life-threatening or could lead to permanent damage without medical intervention. Only if it is in my best interest (or that of my relatives) will I and my GP be informed.*		
I consent to the sharing of my completely anonymised data. This involves sharing with other scientific institutes and companies involved in this study, inside and outside the Netherlands, for scientific research, product development and policy. Your privacy is guaranteed when sharing anonymous data, as stated in the information brochure.		
I consent to the use of residual material for scientific research, as described in the information brochure.		
I consent to be contacted for further scientific research after the end of this study .		

Name of participant: _____

Date of birth: _____ / _____ / _____

I signed this form on date: ____ / _____ / 20_____

Signature:_____

You do not need to fill in this part.

I hereby declare that I have provided this participant with all the available information on the aforementioned study. If information becomes known during the study that could affect the participant's consent, I will inform her in a timely manner.

Name researcher (or researcher's representative): _____

Date: _____ / / _____

Signature: _____