INTRODUCTION

Dear Sir,

We kindly ask you to participate in medical research (see title). You decide whether you want to join. Before you make the decision, it is important to know about the study. Please read this information carefully. Discuss it with your partner, friends or family. There is also an independent person who knows a lot about this study.

You’re currently already a participant in a study of active surveillance. With active surveillance prostate cancer is closely watched instead of using invasive treatment (such as surgery or radiation therapy). With the help of regular blood tests, physical examinations and repeat prostate biopsies, the physician will receive information about possible progression the prostate cancer. Based on this information the physician will assessed whether the prostate cancer is stable or if active treatment should be started because of progression.

The major advantage of active surveillance is that, as long as no treatment is given, no side effects like incontinence (involuntary urine loss) or impotence (inability to get or maintain an erection) may occur. In addition, unnecessary treatment is prevented.

Active surveillance has been used successfully in practice for a while. This does not mean that the current practice cannot be improved. Two important points that could be improved are better selection of men who really have a slow-growing prostate cancer and a better definition of progression of prostate cancer. Currently still too many men are actively treated while this would not have been necessary.

1. WHAT IS THE PURPOSE OF THIS STUDY.

The purpose of this study is to investigate whether using an MRI scan can better select and follow progression of prostate cancer in men under active surveillance. In an MRI scan images are made of the prostate using a magnetic field. The MRI scan can possibly make a better estimate of the aggressiveness of your prostate cancer. This can then be examined by
taking targeted biopsies at places that look suspicious on MRI. In this way a potential aggressive cancer can be treated more rapidly. In addition, unnecessary treatment may be further reduced.

2. HOW WILL THE STUDY BE CONDUCTED.

This study is part of the active surveillance study (PRIAS study) you are already participating in. If you choose to participate in this study some additional examinations are conducted. How many will depend on how long you’ve been on active surveillance in the PRIAS study already.

If you are less than 12 weeks participating in the PRIAS study, an MRI of your prostate will be made 3 months after the start of your participation in the study. Only if the MRI shows abnormalities additional targeted biopsies are taken with a maximum of six. Targeted means that the biopsies are taken from the area in the prostate that was suspicious on MRI. Furthermore, the standard repeat biopsies during active surveillance (year 1, 4, and 7 after diagnosis) will be preceded by an MRI. Additional targeted biopsies are taken at suspicious areas on MRI.

Have you been participant in the study for more than 3 months, then the first MRI will be before your next repeat biopsy according to the protocol (standard at year 1, 4, and 7 after diagnosis).

On the basis of the MRI, additional biopsies (up to 6) could be taken during the repeat biopsies. This means you do not have extra biopsy sessions, but more biopsies are taken during the same session. Based on the results of the standard and targeted biopsies your physician will assess if the cancer shows progression or remains stable. If there is a stable situation, active surveillance can be continued. If there is no stable situation your doctor will advise you to get active treatment.

In the years that no biopsy is scheduled, a combination of the PSA value in the blood and physical examination of the prostate may not give enough information. In that case, your physician will carry out an additional annual MRI. If, based on this MRI, progression of your prostate is suspected, additional targeted prostate biopsy will be taken. If the MRI shows no progression, no biopsies are necessary and you can continue active surveillance.
3. WHAT IS DIFFERENT FROM STANDARD PRACTICE?

Active surveillance is also used outside this study as an approved treatment strategy for low-risk prostate cancer. If you participate in this study, some additional examinations will be done. This includes several MRI scans of your prostate. In total you will receive up to 7 additional MRIs during a 7 years period. Depending on the results of the MRI you will get up to 6 additional biopsies, in addition to the standard number of biopsies (8-12 biopsies).

4. WHAT ARE POSSIBLE ADVANTAGES AND DISADVANTAGES OF PARTICIPATION?

Beforehand, you cannot assume that you have a benefit by participation in this study. It could be that, on the basis of the MRI and the additional biopsies, a better understanding of the aggressiveness of your prostate cancer is possible. This may mean that you will receive treatment in an earlier stage if necessary or that unnecessary treatment will not be performed. In the future, the study may provide useful information for other men with prostate cancer.

Disadvantages of participation are that your will undergo an MRI several times (up to seven times) and based on the MRI your will have additional biopsies. The biopsies can be experienced as painful. During the MRI examination a contrast agent is used. There is a small chance that you will have an allergic reaction to this contrast agent. To prevent this your physician will ask you whether you have had an allergic reaction in the past. During the MRI you will need to lie still in a small tube for approximately half an hour. This can be experienced as claustrophobic by some people.

5. WHAT HAPPENS IF YOU DO NOT WANT TO PARTICIPATE?

If you decide not to participate in this project, you will receive standard care. Please note that this decision will not have any consequences for the quality of care you will receive. Alternative options can be discussed with your physician.

6. CONFIDENTIALITY

Your personal information, which will be gathered for the study can only be accessed by a limited number of persons, and only after you have given a written consent for it. These persons are members of the research team, the medical inspection and members of the
ethical board. Access can be necessary to study the quality and reliability of the research project. The law on protection of personal information and the privacy rules of the hospital will be obeyed.

A unique identification number will substitute personal information. Only that number will be used in analyses and scientific publications. Only those who know which number corresponds to which patient (the study physicians, data managers and your physician) can make the link to you as a person. The data will be stored for 15 years after the research project has ended, but only if you give consent for it.

The board of directors of your hospital has approved this research project after the ethical board has studied and approved it. The international guidelines for this type of research will be obeyed carefully.

7. VOLUNTARY PARTICIPATION

Participation in this project is completely voluntarily. If you do not want to participate, you do not have to explain why. If you give us your consent, but after reconsideration decide that you do not want to participate anymore, it is possible to withdraw your consent at any time, without giving a reason. The research project will be executed by its initial plan, although there are circumstances in which we feel it is necessary to change the initial plan. In that case, modifications will be discussed with you; so you can decide whether you still want to participate. If your personal safety is in danger, your physician will end your participation to this project.
Participant identification number:________

INFORMED CONSENT FORM

"""MRI and active surveillance for prostate cancer"

This form should be stored in the patient file.

I hereby confirm that I have read the patient information form. I understand the information as stated. I have had the opportunity to ask questions, and any questions have been answered to my satisfaction. I have been provided with enough time to think about participation in this study.

I am aware that participation is voluntary and that I can end my participation to it at any time, without the need to provide a reason.

I give consent for access to my medical chart and the research data to competent personnel listed on the patient information form.

I give consent to process the obtained information for purposes described in the patient information form.

I do give consent to retain my data for 15 years after the end of the research project.

I give consent for participation in the above mentioned research project:

Name patient:      Date of birth:

Signature:                     Date : __ - __ - ___

Name researcher:

Signature:                     Date : __ - __ - ___