Patient information folder for the scientific research on the yield of pancreatic cyst surveillance.

Dear Sir/Madam,

Your treating physician has asked you to participate in a clinical research study (the PACYFIC study), conducted by the Erasmus University Medical Centre of Rotterdam, the Netherlands, in cooperation with your own hospital. You were selected as a possible candidate, since you are diagnosed with a pancreatic cyst (fluid filled collection), for which surveillance is warranted.

The decision to participate in this study is entirely voluntary. Before you decide if you want to take part or not, it is important that you fully understand the purpose of the study and the involved procedures and risks. Please, take your time to read the following information carefully. It is also advised to read the brochure with general information about medical scientific research.

Feel free to ask questions now, or at any time during the study, by talking to your treating physician, or by consulting an independent physician (who is not personally involved in the study, but is well informed about the subject). You will find all contact information on page 4 and 5.

1. Aim of the study?

Pancreatic cysts are a common finding. Changes in the appearance of these cysts may be an indication of the development of pancreatic cancer. The risk of a cyst becoming cancer is known to be very small, but exact figures are not available. In the absence of this knowledge, out of caution, international guidelines recommend an intensive, lifelong surveillance strategy. Thus, one hopes to detect pancreatic cancer in an early stage and start treatment as soon as possible.

The present study wants to investigate the actual benefit of this surveillance, as this has never been evaluated before. In addition, we hope to identify risk factors for the development of cancer from a pancreatic cyst. This will help us to choose the best surveillance strategy in the future; providing optimal protection, while causing the least burden for you as a patient.

2. What will be investigated?

This study will investigate the outcome of pancreatic cyst surveillance in a large group of patients during a period of 10 years. We will record how often pancreatic cysts; change, causes symptoms, are operated upon, or become cancer. In addition, we will evaluate blood samples, to look for possible markers to predict the development of cancer. Finally, in patients with a newly diagnosed cyst (discovered in the past 6 months), we will evaluate the burden of for patients undergoing cyst surveillance, by means of a patient questionnaire.

3. How is the study carried-out?

Whether you participate in the study or not, will not affect the way your cyst is followed or treated. In both cases, follow-up will be performed by your own physician, in your own hospital. Cysts will be checked with either a Magnetic

Resonance Imaging (MRI) scan or by Endoscopic Ultrasound (EUS), and by taking blood samples every 6 to 12 months (see appendix 1; Surveillance schedule of pancreatic cysts).

Participation in the study does **not** require any additional hospital visits. Regular cyst follow-up demands two hospital visits. The first visit is used to perform the imaging study and to take the blood sample (1 vial of 6 ml). If you decide to participate in the PACYFIC study, two extra 6 ml vials will be filled. The second visit, several weeks later, consists of an appointment with your treating physician, to discuss your condition and the test results.

We will ask all patients with a newly diagnosed cyst (discovered in the past 6 months), to fill out an online questionnaire. They will be asked to fill out this questionnaire; before the first two follow-up visits, after each follow-up visit (during the first three years of follow-up), and after cyst related events. These questions will concern your experience with pancreatic cyst surveillance and its impact on your daily life. You may find some of these questions confronting or personal. Answering the questionnaire will take about 5 to 15 minutes of your time. Before the first follow-up visit, we will also ask you some questions regarding your background and medical history. You can complete the questionnaire online. A link to the questionnaire will be sent to you by email, if you give us permission.

4. What is expected of you?
There are no special lifestyle rules or limitations, if you decide to participate in this study.

5. How is participation different from regular cyst surveillance?
Participation in the study will only change the blood sampling procedure; instead of a single vial, three vials need to be drawn. In addition, all patients with a newly diagnosed cyst will be asked to fill out an online questionnaire at home. This will be asked; before the first two follow-up visits, after each follow-up visit (during the first three years of follow-up), and after cyst related events.

6. What are the other available surveillance options?
Your own treating physician will decide on the surveillance strategy of your pancreatic cyst. Participating in the PACYFIC study does not affect this process. We will only observe the outcome of this strategy.

7. What are the side effects you can expect?
Since this study does not intervene with cyst management, no side effects are expected for participants. Also, participation will not interfere with any future decisions regarding your health. Your treating physician will remain responsible for all decisions concerning the cyst follow-up, additional diagnostic testing, and treatment of your pancreatic cyst.

8. What are the pro's and con's for participants?
A potential benefit for participants will be to minimize the chance to miss an appointment during pancreatic cyst surveillance. Also, the obtained knowledge from this study will be used to improve pancreatic cyst surveillance in the future and prevent unnecessary hospital visits.

The burden for participants will be to fill out a questionnaire during the first three years of follow-up. This will only be asked of patients with a newly diagnosed cyst. In addition, two extra blood samples will be obtained, during the regular vena-puncture procedure.

9. What happens if I do not want to participate in this study?
Participation in this study is entirely voluntary. You have the right not to take part at all or to leave the study at any time, without an explanation. Declining to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with your treating physician.

10. Are you insured?
As participants will not be exposed to additional risks, the medical ethical committee of the Erasmus University Medical Center in Rotterdam has decided that an additional insurance is not necessary.

11. Will you be informed if new insights concerning the study become available?
The study procedures will be carried out as accurate and well controlled as possible. It will be frequently evaluated whether new significant insights become available. These insights will be shared and discussed with you. You can always decide to withdraw from the study.

12. What happens with your data and body tissue?
Normally, only your treating physician and his/her team will have access to your medical files. If you take part in this study, several individuals, involved in the study, will be allowed to look at your data. These being;

- the investigators and members of the research team
- members of the Medical Ethical Committee that approved this study
- authorized members of the Health Care Inspection
- the safety committee of this study

In the general brochure on medical scientific research it is explained that the investigators will collect and handle your medical data in a confidential manner. This means that they may review your medical records and use this information for study purposes. The investigators will store your data in a coded manner; study documents will contain a number instead of your name. Only the study coordinator has access to a list that links this code to your personal information. All research data will be handled according to the Dutch Data Protection Act (in Dutch: Wet Bescherming Persoonsgegevens). Study results will always be presented without using your name or other personal information. Thus, your identity will never be disclosed.

When the study is terminated, the collected data and body tissue (blood and, if obtained, cyst fluid and tissue) will be preserved for 15 years, after which they will be destroyed. This is necessary to allow verification of the study results. Your data files will not be used for other research projects without your permission. Of course, stored data will be handled with the same confidentiality, as described above. Will you allow us to store your data and body tissue? You can make your choice known on the supplied consent form (appendix 1). Off course we will respect your decision.

In addition, we would like to use your body tissue for other research regarding pancreatic cysts. Therefore, we kindly ask your permission. If you don't want us to use your body tissue, we will also respect that. On the informed consent form (appendix 1.), which is attached to this patient information folder, you can specify your choice. We may want to contact you in the future for additional research projects. For this too, we will ask your permission on the consent form.

In the informed consent form (appendix 2), we will also ask you for your e-mail address. This address will only be used to send you a link to fill out the patient questionnaire online. Your e-mail address will be stored in a safe place, which separately from the other research data.

13. Are there extra costs or is there a financial compensation for participants of the study?
You will not be compensated financially for your participation. For this study there are no extra costs or additional hospital visits.

14. Which Medical Ethical Committee approved the ASPRO study?
The Medical Ethical Committee of the Erasmus University Medical Center in Rotterdam, the Netherlands approved the implementation of the ASPRO study. You can find more information on the approval in the brochure on general medical research with humans (see appendix 3.)

15. Is there anything else you would like to know
You will be given enough time to decide if you would want to participate in the PACYFIC study (at least 48 hours until 7 days). If you have any questions about the study, feel free to contact the principal investigator at your hospital: Dr. …… ,Gastroenterologist.

Telephone: ……
E-mail: ……..

If you have doubts whether you should participate in the PACYFIC study or if you have questions you rather not discuss with our researchers, you can contact an independent physician. This person is not involved in the study, however capable of answering your questions;
Dr. ……..,……..(specialism) at the Department of …… of the ……..
(hospital name), ……(country).
Phone number: ……., e-mail:……

Also, you can contact the coordinating investigator of the Erasmus Medical Center in the Netherlands:

Drs. P.A. van Riet
E-mail: pacyfic@erasmusmc.nl
Website: www.pacyfic.net

If you have any complaints about the study or your treatment, you can contact the independent hospital complaints committee of the ……..(hospital name and city/country) by phone: ……..(phone number).

If you decide to participate in this study after careful consideration, we kindly ask you to sign the informed consent form (appendix 2.) together with the principal investigator or his/her representative.

Yours sincerely,

The PACYFIC research team

Appendices

1. Pancreatic cyst surveillance schedule
2. Informed consent form
3. General brochure on medical research with humans
4. Patient insurance policy

Appendix 1: Surveillance schedule of pancreatic cysts.

Frequency:	**1st year**:	Every 6 to 12 months
	Year 2 to 10:	Yearly
Location:	Your own hospital	
Performed by:	Your own treating physician	

Each follow-up moment consists of;

1. Hospital visit I

- MRI (Magnetic Resonance Imaging) or EUS (Endoscopic Ultrasound)

- Blood sample (1 sample of 6 ml + **2 extra samples of 6 ml***)

2. Hospital visit II

- Evaluate your condition and symptoms

- Discuss test results of hospital visit I

3. Fill out online patient questionnaire at home*

- Only for patients with a cyst discovered in the past 6 months.

- Before the first two follow-up visits, after each follow-up visit (during the first three years of follow-up), and after cyst related events.

*** Bold and underlined text; additional procedures for participants of the PACYFIC study.**

Appendix 2: Informed consent form for the scientific research on the yield of surveillance of cyst lesions of the pancreas

I have read and understood the foregoing patient information folder for participants of the PACYFIC study. I have been given the opportunity to ask questions about this study and I have had all my questions answered to my satisfaction. I have had sufficient time to consider my participation in this trial properly.

I understand that my participation in this trial is voluntary and that I can withdraw at any time, without being penalized or questioned on why I have withdrawn.

I consent to the viewing of my medical file by authorized persons as was written in the patient information folder.

I consent to the use of my medical data and body tissue for all purposes which are mentioned in the patient information folder.

I give permission to send me the patient questionnaire by e-mail. My e-mail address will be invisible for unauthorized persons and will only be used to send me the patient questionnaires mentioned earlier.

Please write down your e-mail address here: _____

I do/ do not* give permission to store my medical data, which will be collected during this study, for 15 years after the end of the trail.

I do/ do not* give permission to store my body tissue, which will be collected during this study, for 15 years after the end of the trail.

I do/do not* give permission to use my body tissue, which will be collected during the study, for other research regarding pancreatic cysts.

I do/ do not* give permission to contact me for additional research in the future.

I voluntarily agree to participate in this study.

Name participant: ……..

Signature: …… Date: __ / __ / __

** Please, delete what is not applicable.*

This form has to be filled out by the study investigator:

Undersigned declares to have informed the above mentioned person and to have answered all the questions about this trial to the best of his/her ability

If significant new insights that might influence the consent of the participant become available during the study period, I will inform him/her as soon as possible.

Name investigator (or it's representative): ……

Signature: …… Date: __ / __ / __

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Signature: …… Date: __ / __ / __

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Signature: …… Date: __ / __ / __