Information letter OncoLifeS

Lung oncology understanding mutations in NSCLC

Introduction

Recently or in the past, you have (possibly) been diagnosed with a tumor for which you receive treatment. You have been asked to participate in medical scientific research performed at the University Medical Center Groningen (UMCG) in the Netherlands. The program in which this research is embedded is called 'OncoLifeS'. Medical scientific research of tumors is necessary to improve the quality of care and the outcome of treatments.

OncoLifeS

OncoLifeS is a data-biobank in which data and biological specimens (such as blood, urine, saliva, feces, bone marrow, abdominal fluid, thoracic fluid and tumor tissue) are stored from people with a (possible) cancer diagnosis and of people with an increased risk of cancer. This data, biological specimens and other derivatives (including DNA) can give researchers the opportunity to conduct better research into the prevention and treatment of cancer.

The purpose of OncoLifeS is to answer questions such as how certain forms of cancer develop, how they can be treated, which preventive measures work, how cancer can be diagnosed early and what factors increase the risk of cancer and what effect cancer and the treatment has on a patients daily life. The researchers also hope to answer the question why some patients respond well to treatment and other patients do not respond well to treatment. The ultimate goal is to improve both short and long term outcomes of cancer treatment and to improve the quality of life of patients after diagnosis.

In this information letter, you can read how you can participate in OncoLifeS. Please read this information carefully. In addition to this written information, your physician or a researcher from the UMCG will also inform you in person. If you do not understand something, please ask your physician or a researcher from the UMCG. It is important that all of your questions are answered before deciding whether or not to participate in OncoLifeS.

How can you participate in OncoLifeS?
You can participate in OncoLifeS by providing researchers with:

- Your medical data
  In order to properly investigate your clinical profile (type of tumor), OncoLifeS needs the medical data from you medical file. This concerns data such as the diagnosis, the characteristics of the tumor, the treatment and the results of the treatment. In addition, the details of the follow-up check-ups after your treatment are also important. Therefore, we are not only interested in data that is currently known, but also in your medical data that will be collected in the future.

- Your biological specimens:
  ☐ *Blood*
  Blood is often drawn before the start of your treatment. During this blood collection, we ask you if we can withdraw extra blood for the purpose of OncoLifeS. Depending on the type of tumor, this will be 4 to 6 extra tubes of blood (40 to 60ml). Therefore, you will not have to go through an extra venipuncture. You may also be asked to provide extra blood for OncoLifeS during your treatment. This will then be 1 or 6 extra tubes of blood (10 to 60 ml) at a time. You will not have to go through an extra venipuncture for this either.
  ☐ *Urine*
  Depending on the type of tumor you have, you may be asked to submit a single portion of urine. You will receive special collection material for this.
  ☐ *Bone marrow*
  Depending on the type of tumor you have, bone marrow research can be conducted. During bone marrow biopsy and aspiration, extra bone marrow can be collected. You will not undergo an additional biopsy for this. Bone marrow biopsy and aspiration only takes place if necessary for the treatment.
  ☐ *Stool*
  Before starting and during the treatment, you may be asked to submit a small amount of stool several times (a total of four times). You will receive special collection material with instructions for this. You will also be asked to keep a record of how often you have bowel movements in a so-called bowel diary during the first four courses of treatment. If you object to the submission of feces, you can refrain from this. You can still participate in OncoLifeS.
  ☐ *Tissue*
  This concerns tissue that has been taken from you for diagnosis (biopsy) or tissue that has been removed during an operation or endoscopy. During an endoscopy, extra tissue can be taken, during an operation there will be no extra tissue removal from you. After the pathologist has examined the tissue, some of the tissue will be saved for OncoLifeS or used for cell cultures.
  ☐ *Abdominal fluid*
  Depending on the type of tumor you have, abdominal fluid (also called ascites) may be collected. The abdominal fluid will only be collected if this is necessary for your treatment. Abdominal fluid remaining after clinical usage will be stored for OncoLifeS.
  ☐ *Chest cavity fluid*
  Depending on the type of tumor you have, chest cavity fluid/ fluid behind the lungs (also called pleural fluid) may be collected. Collection takes place by means of a puncture. Pleural effusion will only be taken if this is necessary for your treatment. Pleural fluid remaining after clinical usage will be stored for OncoLifeS.

Biological specimens is generally collected only once. We may ask you to provide extra blood, urine, feces, saliva, abdominal fluid or bone marrow, for example because your biological specimens is at risk of running out in the data bank. The additional collection will take place (if possible) during a regular visit to the outpatient clinic.
During your treatment, blood, urine, saliva or stool will often be collected prior to your hospital visit. Additionally, tissue, abdominal fluid, chest cavity fluid and bone marrow may be collected. Sometimes, not all material is needed

for your diagnosis or treatment. We ask you if we may use this remaining material to conduct scientific research later.

- Additional information
  If necessary for the scientific research that we do within OncoLifeS, we would like to request data from your general practitioner, your pharmacy and any medical specialists in another hospital. We would also like to request biological specimens that is available in another hospital, that is necessary for scientific research within OncoLifeS. By requesting this, the researchers can gain more insight into the outcomes of your current treatment, you medication use and the long-term effects of your treatment. To conduct additional research, OncoLifeS wants to link research data to registrations, this concerns, for example, national cancer registries, other population-based cohort studies.

- Questionnaires
  Researchers from OncoLifeS may ask you to complete 5 a 6 questionnaires. At the start of your participation in OncoLifeS you will be invited to complete a (digital) questionnaire about lifestyle and the effect of your condition on your quality of life. It takes about 30 minutes to complete. After 3, 6, 12, 18 and / or 24 months, you will receive another invitation to complete a (digital) questionnaire. Completing this takes approximately 10 to 20 minutes.

How does OncoLifeS handle your privacy?
When participating in OncoLifeS, it is necessary to collect and store your personal data. This is done under the strict rules of privacy legislation as determined in the General Data Protection Regulation (GDPR). This concerns information such as your name, address, date of birth and information about your health. The use and storage of this data is necessary to answer future scientific questions. You will be asked to give permission for this. When using your data, identifiable data, such as your name, address and place of residence, will be replaced by a code. Your medical data and biological specimens will also only be issued to researchers in encrypted form. The OncoLifeS administrator is the only person who can find out which person is behind the encrypted code. The administrator will only use this in your interest.
OncoLifeS emphasizes that your medical data and biological specimens are collected and stored according to strict UMCG guidelines. For research purposes, it may be necessary to send your data and biological specimens to a country outside the EU. The EU rules for the protection of your personal data do not apply here. However, your privacy will be protected on an equivalent level.

Retention period
Your coded medical data and your stored biological specimens will be kept for an indefinite period of time. In this way, it can be used in the future for new research that fits within the objectives of OncoLifeS.

What are your risks of participating in OncoLifeS?
There are no risks associated with the collection of your coded medical data, because the data from your medical file is used for this. The extra blood for OncoLifeS is collected during a scheduled blood draw at the outpatient clinic, and does not involve any risks. Also, the collection of urine does not involve any risks. Tumor tissue collected during an operation or endoscopy will first be examined by a pathologist. After that examination, it will be stored for the purpose of OncoLifeS. If your tumor tissue is requested at another hospital, sufficient material will remain available to be able to answer possible medical questions related to your diagnosis or treatment in the future.

Who conducts research with your specimen material and data?
The researchers and doctors of the UMCG carry out the medical scientific research. The research can also be carried out in collaboration with other institutions or companies, both nationally and internationally.

What happens with the results of the research?
You participation in OncoLifeS is unlikely to be of direct benefit to you. We expect that the results of research will improve the prevention, control, diagnosis or treatment of cancer in the future. The results of the research are published in scientific journals.

Incidental findings
During research, it may happen that (incidental) findings occur that may be relevant to your health or treatment. You can indicate whether you want to be informed about this via your physician (medical specialist) or general practitioner. As a patient you cannot derive any rights from this option.

Is participating in OncoLifeS voluntary?
Your participation in OncoLifeS is completely voluntary. You do not need to state a reason if you do not want to participate. It will not affect your treatment or care if you decide not to participate. You give your consent for an indefinite period of time, and your consent will continue after your death. You remain free to stop your cooperation without giving a reason.

Does you participation in OncoLifeS entail expenses and fees?
Your participation in OncoLifeS does not bring any additional costs for you. You will not receive any reimbursement for participating in this study.

What to do if you want to participate in OncoLifeS?
If you would like to cooperate, we ask you to fill in the "Permission OncoLifeS" form. This confirms your intention to participate in OncoLifeS. The attending physician or nurse practitioner from the UMCG will also sign the "OncoLifeS Consent" form, confirming that he / she or your own physician has informed you about the study, that he / she has handed over the information letter with attachment (s) and that he / she is willing to answer your questions.

Important additional information
If you have any questions after reading this information, please contact your physician or one of the undersigned (the head of the department where you are being treated and / or the OncoLifeS administrator from the UMCG).

If you would like to consult with someone who is well informed about OncoLifeS, but is not directly involved, you can contact Mrs. A.J. Berendsen. She can be reached via telephone number +31 6 203 266 53. Ms. Berendsen is a general practitioner and affiliated with the UMCG.

If you are not satisfied with the implementation of OncoLifeS and / or have a complaint, you can contact your physician or one of the undersigned (the head of the department where you are being treated and / or the administrator of OncoLifeS from the UMCG).

You can also discuss your dissatisfaction with an employee "Patient Information and Complaint Support" of the UMCG, via telephone number +3150 361 3300. You will receive advise on how to deal with this.

More information?
More general information about OncoLifeS can be found at www.OncoLifeS.nl, or you can send an email to oncolifes@epi.umcg.nl.

Dr. A.J. van der Wekken Chief department lung oncology +3150 361 5643	Fenneke Zwierenga Physician researcher, lung oncology +3150 3617841	Prof. dr. G.H. de Bock, Administrator OncoLifeS +3150 361 0739

Contact address:

UMCG
Department lung oncology
Huispostcode DA12
Antwoordnummer 332
9700VB Groningen, the Netherlands

Attachments: Consent form OncoLifeS
Consent form OncoLifeS (copy) for your own administration
Withdrawal of consent form OncoLifeS

umcg

Consent form OncoLifeS

Patients name:
Birth date:
Name hospital:
City name hospital:
Country:

I am well informed about the objectives of the data-biobank OncoLifeS and how I can contribute to scientific research by voluntarily providing my coded medical data and biological specimens.

I have read and understood the study information, or it has been read to me. I have been able to ask questions and my questions have been answered to my satisfaction. I have had enough time to think carefully about my participation.

I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions. I can withdraw from the study at any time, without having to give a reason. I am also aware that this has no negative consequences for my medical treatment.

I consent for the collection and provision of my coded personal data, medical data, biological specimens and data that can be retrieved from this, including for example DNA, for research as described in the patient information letter.

I consent to preserve my encrypted personal data, medical data and biological specimens for an indefinite period of time for future research that fits within the objectives of OncoLifeS.

I consent to be approached with the request to donate extra material (blood, feces, saliva, bone marrow, abdominal fluid, chest cavity fluid and/or urine). I can decide whether or not to agree to this request.

I consent to link the coded data of my general practitioner, my pharmacy and my treating medical specialists for a better insight into my current medication use and the long-term consequences of my illness and treatment.

I consent to the retrieval of my bodily material stored in hospitals where I am being treated. After the study, the bodily material will be returned so that it is always available to answer additional questions if necessary.

I consent to associate my encrypted data with other registrations in the future, as long as they relate to OncoLifeS objectives. This concerns, for example, national cancer registries, other population-based cohort studies.

I consent to the conduction of research in which my (medical) data and biological specimens will be used by the UMCG in collaboration with other institutions and commercial companies at national and international level.

I consent to be informed through my physician (my medical specialist) or general practitioner about (incidental) findings which may be relevant to my health and my treatment. I cannot derive any right from this option.

I consent that OncoLifeS may request my data in the future from the applicable population register.

Name patient: _____	Name of physician:
Email: _____	
Date:_____	Date:
Signature: _____	Signature:

Questions

For questions, please contact:

Dr. A.J. van der Wekken Chief department lung oncology +3150 361 5643	Fenneke Zwierenga Physician researcher, lung oncology +3150 3617841	Prof. dr. G.H. de Bock, Administrator OncoLifeS +3150 361 0739

Withdrawal of consent form OncoLifeS

O I wish to withdraw my consent to OncoLifeS

I hereby declare that I am withdrawing my participation in OncoLifeS. I understand that encrypted medical data and specimen material collected as part of OncoLifeS and already processed in an investigation cannot be retrieved or destroyed. This bodily material and these medical data remain coded and available to the person conducting the research.

This withdrawal regards:

- that I will not receive any further information about OncoLifeS;
- that my coded data will no longer be linked to another registration;
- that my (address) data will not be requested from the registry office;
- that I will no longer be informed about (incidental) findings.

You have declared that you do not wish to continue to participate in OncoLifeS. Would you like to indicate which of the following two answers applies to you?

O I agree that my encrypted data and my biological specimens collected so far for OncoLifeS will remain available for future research consistent with the purpose of OncoLifeS.

O I do not agree that my encrypted data and my biological specimens collected so far for OncoLifeS will remain available for future research consistent with the purpose of OncoLifeS.
I assume that all biological specimens stored for the study will be destroyed within 8 weeks and that other materials will be returned to the original assessors.

Patients name:_____

Birth date:_____

Name hospital:_____

City hospital:_____

Country:_____

Signature:_____

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You can return this form to:

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umcg

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Email: _____	
Date:_____	Date:
Signature: _____	Signature:

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