OncoLifeS

Medical scientific research toward better care for people with cancer

What is OncoLifeS?

OncoLifeS is a data-biobank that collects data and human body materials from patients diagnosed (or possibly diagnosed) with cancer or at increased risk of cancer. It also collects information about quality of life. This collection supports cancer research.

Why should you participate?

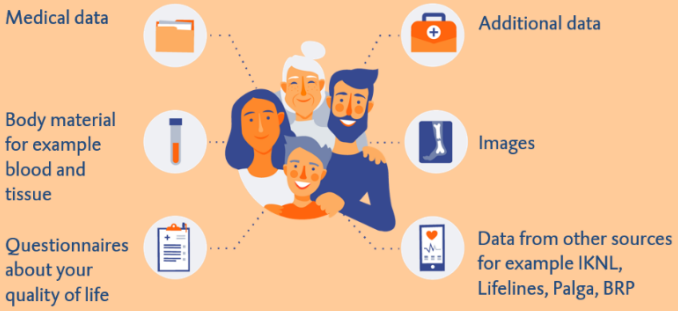
Research on cancer and other diseases is important. It improves the quality of care and treatment.

Goals of OncoLifeS are:

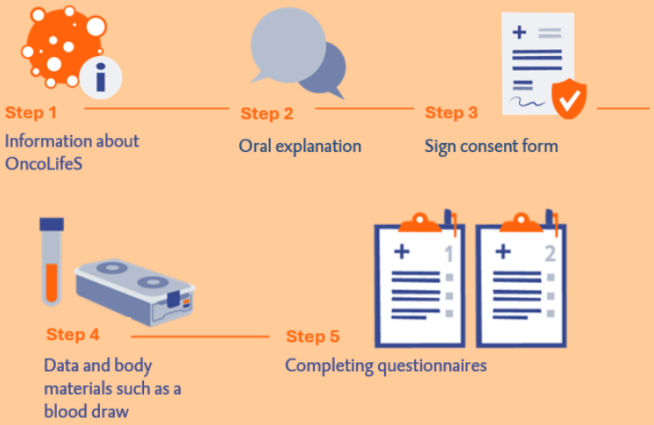
- increase our understanding of how cancer occurs to reduce the risk of getting cancer (prevention).
- improve cancer care.

Participation is completely voluntary. You decide whether to participate. You can withdraw your consent at any time. Withdrawing your consent will not affect your medical treatment.

What information and materials does OncoLifeS collect?



What can you expect if you participate?



Who are the researchers?

Medical scientific research is conducted by researchers and physicians at UMCG and participating hospitals.

The research may also be conducted in cooperation with other institutions or companies, both in the Netherlands and abroad.

Your data and body material will be replaced with a code. This way, researchers will not know that this belong to you.

Other information you need to know

Before you decide to participate in OncoLifeS, it is important that you read the information letter. If you want to participate sign the consent form.

If you want even more general information about OncoLifeS scan the QR code or go to: https://www.umcg.nl/-/oncolifes

You can also email us at:
oncolifes@epi.umcg.nl

OncoLifeS
Living well as a cancer survivor

umcg

Information letter OncoLifeS

You are receiving this information letter because you have been diagnosed with a (possible) tumor or a hematological disorder, either recently or in the past. You are being treated or supervised at the University Medical Center Groningen (UMCG). Your clinician will ask you if you want to participate in the OncoLifeS medical research project.

Tumor
A tumor is a mass. It can be benign or malignant. A malignant tumor is cancer. A benign tumor is not cancer. A benign tumor can very occasionally become cancer. On kanker.nl you can read more about this.

Hematological disorder
A hematologic disorder is a disease of the bone marrow, blood, or lymph nodes. It can be benign or malignant. A malignant hematologic disorder is cancer. A benign hematologic condition is not cancer. You can read more about this at hematologiegroningen.nl and kanker.nl.

The following topics will be covered in this information letter:

1. What is OncoLifeS?
2. Why should you participate?
3. What can you expect if you participate?
4. What information and materials does OncoLifeS collect?
5. Other information you need to know.

It is a lot of information. Please read the information carefully. In addition to this information letter, you will also be informed verbally about this study.

Before you decide to participate in the study, it is important that all your questions are answered. You can make your decision with the information you read in this information letter. In addition, we recommend that you:

- Ask questions to your clinician who is giving you this information.
- Talk to your partner, family, or friends about this study.

If you decide to participate in the study, your consent is required. You do this by signing the consent form. You can find this form in the Appendix of this information letter.

1 What is OncoLifeS ?

OncoLifeS is a data-biobank and was set up by the University Medical Center Groningen (UMCG). This was authorized by the Board of Directors of the UMCG after a positive recommendation from the METc. The METc is a committee that checks whether the data-biobank meets all laws and regulations and medical-ethical conditions. The research conducted by OncoLifeS is called medical scientific research.

OncoLifeS collects data and human body material from:

- patients with a (possible) diagnosis of cancer,
- people at increased risk of developing cancer.

Data on the quality of life of patients with cancer is also collected and preserved.

Data-biobank
A data-biobank is a collection of body material and associated data. This is kept for medical scientific research. You can read more about this at https://www.umcg.nl/-/medische-gegevens-en-lichaamsmateriaal.

Quality of life
This research is performed to better understand the impact of cancer. The focus lies on the impact of the disease on a physical, psychological, and social level.

Medical scientific research
The purpose of medical scientific research is to advance medical science. Research attempts to answer a question in the field of health and disease. For example, to understand how a disease occurs and how to treat it.

2. Why should you participate?

2.1 Goals of OncoLifeS

Research into cancer and other diseases is important. It improves the quality of care and treatment. OncoLifeS has two goals: cancer prevention and improving cancer care. These are short-term and long-term goals.

Cancer prevention
Increase our understanding of how cancer occurs, to reduce the risk of getting cancer.

Improving cancer care
By improving the:

- treatment of cancer.
- cancer survival rate.
- quality of life for patients with cancer and their loved ones.

To achieve these two goals, it is important to answer the following questions about cancer:

- How does it arise?
- How can we treat it?
- How can we prevent it?
- How can we diagnose it earlier?
- What are risk factors?
- How is quality of life perceived?
- Why is treatment effective in one person and not in another?

OncoLifeS collects and stores data and human body material. Information is extracted from this. This information is used to answer the above questions. For example, researchers extract DNA from the body material. The information is also used to make comparisons with other diseases. You can read exactly what is collected and stored in the section, " What information and materials does OncoLifeS collect?"

Researchers
Medical scientific research is conducted by researchers and physicians at UMCG and participating hospitals. Research may also be conducted in cooperation with other institutions or companies, both in the Netherlands and abroad.

DNA
DNA is the material in our cells that contains the instructions for how our body grows, works, and looks. In cancer cells, there are changes in the DNA that cause those cells, for example, to stop dividing and grow uninhibitedly.

2.2 Voluntary participation

Participation in OncoLifeS is completely voluntary. If you wish to participate in the study, you will sign the consent form. You then give your consent indefinitely. Your consent remains valid even after your death. You may stop the study at any time. You do not have to give a reason for this. This will not change your treatment or supervision at the UMCG in any way. If you want to stop, you can sign the form to withdraw your consent.

If you do not want to participate, you do not have to give a reason. Again, this will not change your treatment or counseling in the UMCG in any way.

2.3 Privacy

When participating in OncoLifeS, your data and body material are collected and stored. This is done according to the strict rules of privacy legislation as set out in the General Data Protection Regulation (GDPR). This includes data such as your name, address, date of birth, and information about your health. The use and retention of this information is necessary to answer future scientific questions.

Data such as your name, address and place of residence will be replaced with a code. Your medical data and body material are also given a code. This is called coding. Only the administrator of OncoLifeS can find out who the person behind the code number is. The administrator will do this only in your best interest.

OncoLifeS emphasizes that your medical information and body material are collected and stored according to strict UMCG guidelines. Your coded data and body material may be sent to another EEA country or outside the EEA if this is required by research.
Within the EEA, your data and body material are protected by European privacy laws. Outside the EEA, these rules do not apply. However, your privacy will be protected at an equivalent level.

EER
The EEA stands for European Economic Area. The EEA consists of the countries of the European Union (EU) and Liechtenstein, Iceland, and Norway.

2.4 Monitoring

Monitors, auditors and supervisory authorities can check to see if the study is being conducted properly and reliably as agreed. They also have access to the data without a code. They keep your data confidential.

Monitor
A monitor checks if the study is executed according to the plan and if all the rules are being followed.

Auditor
An auditor checks that medical research is conducted fairly and according to the rules.

Supervisory authorities
Supervisory authorities check whether rules and laws are followed. For example, the Dutch Health Care and Youth Inspectorate.

2.5 Risks

There are no risks associated with the collection of your data. The data that is collected comes from your medical record and is stored in encrypted form. There are also no risks associated with the collection of your body materials, such as: urine, stool, blood, or tissue. Additional blood will be collected for OncoLifeS during a scheduled blood draw at the outpatient clinic. You can read exactly what is collected and stored in the section: "What information and materials does OncoLifeS collect?"

2.6 Cost, reimbursement and benefit

Your participation does not incur any additional costs. You will not be reimbursed for participating in the study.

Your participation in OncoLifeS is unlikely to provide any direct benefit to you. The information helps researchers answer the questions. The answers are published in scientific journals. The results provide new knowledge. This can help improve care and treatment.

Accidental findings may be made while examining your records. These may be important to your health and/or treatment. They may also be important to your family members. You will be informed about this through your clinician or your family doctor. As a patient you cannot derive any rights from this possibility.

Accidental findings
While examining your data and body material, very occasionally something may be found by chance. This is called a chance finding or accidental finding.

3 What can you expect if you participate?

Step 1: Information about OncoLifeS
You will receive information about OncoLifeS. You have read the information in this letter.

Step 2: Verbal explanation
You have talked to your clinician about the study. You understand what the study entails. Your questions have been answered.

Step 3: Sign consent form
If you decide to participate in the study, fill out the "Consent OncoLifeS" form during your next outpatient visit. You can find this form in the Appendix of this information letter. By signing this form, you confirm your participation in the OncoLifeS study. Your clinician will also sign this form. By doing so, your clinician confirms that he/she has informed you about the study. He/she also confirms that you have received this information letter and that your questions have been answered.

Step 4: Data and body materials such as a blood draw
Blood will be drawn before the start of your treatment and possibly during treatment. You will not be given an additional blood draw for this. It will be combined with your standard outpatient appointment.

In addition to blood sampling, other data and body material may be collected. The section: " What information and materials does OncoLifeS collect?" describes what is collected and stored from you.

Step 5: Completing questionnaires
At the start of the study and after 3, 6, 12, 18 and/or 24 months, you will be sent a questionnaire (digital). This will be used to survey your quality of life.

You may also be asked to complete additional questionnaires or questions outside of these times. You can decide at that time whether or not you want to do so.

4 What information and materials does OncoLifeS collect?

After you give your consent in step 3, collection and storage of your data and body material will begin in step 4. Your coded personal data, medical data and body material will be kept forever. This way, the information can also be used for new research that fits within the goals of OncoLifeS. Your coded data may be linked to other sources, such as the Central Bureau of Statistics, if it fits within the two goals of OncoLifeS.

	What will be collected and stored?	Explanation
A	Body material	Depending on your disease and proposed treatment, different types of body material will be collected and stored. This is combined with the times when body material is already collected as part of your treatment. So, for example, you will not be given an additional puncture. The body material collected may also be used to culture cells for research. As part of your treatment, body material such as: blood, urine, stool, and tissue will be collected. Sometimes, not all material is needed for your treatment. OncoLifeS would like to collect this remaining material for medical scientific research and store it in the data biobank. If insufficient body material remains for the data biobank, you may be asked to donate additional body material. This will take place, if possible, during a normal outpatient visit.
	Blood Four to six tubes of blood are taken. This is approximately 40 to 60 ml. You may also be asked to give additional blood during your treatment. This will take place during a normal outpatient visit. **Tissue** This is tissue that has been taken from you for diagnostics. For example, this tissue was obtained through a biopsy, or during surgery. Additional tissue may be collected during a scopy. In surgery, no additional tissue collection takes place. After the pathologist examines the tissue, a portion will be stored for OncoLifeS. Tumor tissue and other tissue will be collected and stored only after the diagnosis has been made by the pathologist. This will not affect your diagnosis or your treatment. It may be necessary to request cell or tissue material from you at another hospital. Upon completion of the examination, the material will be returned to this hospital. Tissue will always remain available for future use in treatment. **Stool sample** You may be asked to submit a small amount of stool samples (a total of 4 times). This will be at the start of the study and during treatment. You will be given special collection material for this purpose with instructions. If you object to this, you may waive it. You will also be asked to fill out a stool diary. **Urine** You may be asked to submit urine once. You will be given special collection material for this purpose. **Bone marrow** Depending on your disease, your bone marrow may need to be examined. During this examination, additional bone marrow may be collected for OncoLifeS.	

	Abdominal fluid Depending on your disease, it may be necessary to take abdominal fluid. This abdominal fluid is called ascites. If ascites remains, it will be collected and stored by OncoLifeS. **Chest cavity fluid** Depending on your disease, chest cavity fluid/ fluid behind the lungs may need to be collected. This is called pleural fluid and is removed through a puncture. If pleural fluid remains, it will be collected and stored by OncoLifeS. **Exhaled air** Depending on your disease, you may be asked to blow into a special tube before and during your treatment. This tube contains measuring instruments that record breath data. The breathalyzer test is not mandatory. It takes place in the pulmonary function department when you are still in the hospital for a check-up or treatment. **Bile** Depending on your disease, bile may need to be taken. If bile is left over, it will be collected and stored by OncoLifeS.	
B	Medical data	• Relevant medical information from your medical record. • Information about your tumor. • Information about your treatment. • Results of your treatments. • Information about other diseases or their absence. • Information about follow-up checks after your treatment.
	Additional data	Additional data are important to understand your treatment(s) and medication use. Therefore, relevant data can be requested from, for example: • your general practitioner, • your pharmacy, • other practitioners / medical specialists / hospitals.
D	Data from other sources	Linkage with for example: • Central Bureau of Statistics (CBS) Statistical information about Dutch society • Integraal Kankercentrum Nederland / Integral Cancer Center (IKNL) Independent cancer institute for oncological and palliative care in the Netherlands • Lifelines Large-scale research in the Northern Netherlands region • Pathologisch-Anatomisch Landelijk Geautomatiseerd Archief / Pathological-Anatomical National Automated Archive (Palga) Palga collects anonymous results of pathological research in the Netherlands • Basisregistratie Personen / Basic Registration of Persons (BRP) Former Gemeentelijke Basis Administratie / Municipal Personal Records Database (GBA) Information from these sources is used for comparison. This gives the researchers more insight into your disease. Information from the BRP is used, for example, to send digital questionnaires about your quality of life.

E	Images	Results and images of relevant tests, where your disease has been visualized. For example: • MRI • CT scan • PET scan • Pathology
F	Questionnaires about your quality of life	You will be asked to complete 5 to 7 questionnaires. The questionnaires are about the effect of your disease and treatment on your quality of life. You will also be asked about your lifestyle and physical activity. You will receive the questionnaires: • At the start of your participation in OncoLifeS, • 3, 6, 12, 18 and/or 24 months after starting OncoLifeS research, • Additionally if required for research purposes. This may include additional questions. You will preferably receive the questionnaires digitally. The first time filling out the questionnaires will take about 30 minutes. After that it will take between 10 and 20 minutes.

5 Other information you need to know

5.1 Who can I ask my questions to?

If you have any questions after reading this information letter, please ask your clinician. You can also ask your questions to the undersigned. This is the head of the department where you are under treatment and/or the administrator of OncoLifeS.

Mw. J. Nagel Coördinator OncoLifeS +3150 361 3576	of	Prof. dr. G.H. de Bock Beheerder OncoLifeS +3150 361 0739

You can also consult with an independent physician. This doctor knows a lot about OncoLifeS research, but is not directly involved.

Dr. S.W.M.C. Accord-Maass can be reached by email s.w.m.c.maass@umcg.nl or by phone at +316 836 065 16

General information about OncoLifeS can be found at https://www.umcg.nl/-/oncolifes. You can also send an e-mail to oncolifes@epi.umcg.nl.

General information about research involving humans and about the use of medical data and bodily materials can be found at:

- https://www.umcg.nl/-/medische-gegevens-en-lichaamsmateriaal
- www.rijksoverheid.nl/mensenonderzoek

5.2 I have a comment and/or complaint

If you are not satisfied with the performance of OncoLifeS and/or you have a complaint about the OncoLifeS study, please report it. Please contact your practitioner or the undersigned.
You can also discuss your complaint with an employee of "Patient Information and Complaint Resolution." You can reach them at telephone number: (050) 361 3300. This staff member will advise you on how to proceed.

Mw. J. Nagel Coördinator OncoLifeS +3150 361 3576	of	Prof. dr. G.H. de Bock Beheerder OncoLifeS +3150 361 0739

5.3 Contact information

UMCG
OncoLifeS
Huispostcode FA40
Business reply number 332
GRONINGEN 9700 VB, the Netherlands

5.4 QR codes websites patient information letter

Kanker.nl

Hematologie Groningen.nl

https://www.umcg.nl/-/oncolifes

www.rijksoverheid.nl/mensenonderzoek

https://www.umcg.nl/-/medische-gegevens-en-lichaamsmateriaal

5.5 Appendices

1. Form Withdrawal of Consent OncoLifeS
2. Form Consent OncoLifeS (copy for your own administration)
3. Form Consent OncoLifeS

Form Withdrawal of Consent OncoLifeS

O I declare that I do not wish to continue participating in OncoLifeS.

I hereby give notice that I withdraw my participation in OncoLifeS. I understand that the coded medical data and body material collected as part of OncoLifeS and already included in an ongoing study cannot be retrieved or destroyed. This body material and medical data will remain encrypted and available to the person conducting the study.

This withdrawal means:

- that I will not receive any further information about OncoLifeS;
- that my coded data will no longer be linked to other records;
- that my (address) data will not be requested from the civil registry;
- that I will no longer be informed about (coincidence) findings.

Above, you have indicated that you do not wish to continue participating in OncoLifeS. Please indicate below which of the two answers applies to you.

O I agree that my coded data and my body material collected to date for OncoLifeS will remain available for future research that fits within the purpose of OncoLifeS.

O I do not agree that my coded data and my body material collected to date for OncoLifeS study remain available for future research that fits within the objective of OncoLifeS.
I assume that body material retained for the study will be destroyed within 8 weeks and other materials will be returned to the original reviewers.

Patients name: Date of birth: Name hospital: City hospital: Country: Signature:

Questions:
For questions, please contact:

Mw. J. Nagel Coördinator OncoLifeS +3150 361 3576	of	Prof. dr. G.H. de Bock Beheerder OncoLifeS +3150 361 0739

Send this form to:

UMCG
Administration [name of department]
Outpatient clinic [name of department], Postcode [department]
Business reply number 332
GRONINGEN 9700 VB, the Netherlands

OncoLifeS
Living well as a cancer survivor

umcg

Patients name:

Birth date:

Name hospital:

City name hospital:

Country:

Form Consent OncoLifeS

I am well informed about the objectives of the OncoLifeS data biobank and how I can participate in scientific research by making my coded medical data and body materials available.

I have received and read the information letter about this and have been given sufficient opportunity to ask questions about it. I have had sufficient time to think about it and to consider my participation carefully.

I know that my participation is completely voluntary and that I can withdraw my consent at any time without having to give a reason. I also know that it will not adversely affect my medical treatment.

I consent for the collection and availability of my coded personal data, medical data, body material and data that may be extracted from it including, for example, DNA, for research as described in the patient information letter.

I give permission to keep my coded personal data, medical data, including radiology and pathology images and body material, carefully and indefinitely, for future research that fits within the objectives of OncoLifeS.

I give permission to be contacted for asking me to donate additional material (blood, stool, saliva, bone marrow, abdominal fluid and/or urine) or to complete additional questionnaires. At that time, I may decide whether or not to agree to this request.

I consent to the linking of the coded data of my general practitioner, my pharmacy, and the medical specialists where I am under treatment, so that better insight can be gained into my current medication use and the long-term consequences of my illness and treatment.

I consent to the retrieval of my body material kept at the hospitals where I am undergoing treatment. The material will be returned after completion of the study so that material will always be available to answer additional care questions, if necessary.

I give permission to have my coded data linked to other registrations in the future, provided they relate to the objectives of OncoLifeS. This concerns, for example, registrations of CBS (Central Bureau of Statistics), Palga (Pathological-Anatomical National Automated Archive), IKNL (the Integral Cancer Center Netherlands) and of Lifelines (large-scale research in the Northern Netherlands region, if you are a Lifelines participant).

I give permission to use my (medical) data and body material to conduct research in which researchers from the UMCG and other participating hospitals collaborate with other institutions and commercial both domestic and foreign companies.

I give permission to be informed via my clinician (my medical specialist) or general practitioner about (accidental) findings that may be relevant to my health and my treatment. I cannot derive any rights from this possibility.

I give OncoLifeS permission to request my details from the civil registry BRP (Basic Registration of Persons) in the future.

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

Questions

For Questions, please contact:

Mw. J. Nagel Coördinator OncoLifeS +3150 361 3576	of	Prof. dr. G.H. de Bock Beheerder OncoLifeS +3150 361 073