INFORMATION TO RESEARCH PARTICIPANT

You are hereby asked to participate in U-CAN. This question is directed to patients who either have a confirmed tumor disease or are undergoing investigation where a tumor disease not yet has been confirmed. If investigations are still ongoing, this inquiry does not mean that a tumor disease has been confirmed in your case.

THE U-CAN PROJECT

Intensive research and increased knowledge has over the past decades in many cases led to new treatments and better survival for cancer patients within several different types of cancer. Despite this progress, tumor diseases are still a serious health problem in Sweden and in the world. Cancer research is often dependent on samples collected from patients. To conduct good studies, well-characterized and systematically collected patient samples are needed, which can be utilized by many different research groups. The U-CAN project was initiated through financial support from the Swedish Government, and supports the collection of samples and information from patients with confirmed or suspected tumor diseases at the Akademiska Hospital in Uppsala, with the aim of making this resource available for future cancer research.

Researchers also need to analyze samples from patients without a cancer diagnosis for comparative studies, since it otherwise is difficult to evaluate whether samples from cancer patients differ in any way. Therefore, if investigations would show that you do not have a tumor disease, your samples, patient record and survey answers could still be of great value for cancer research. Samples that may already have been obtained from you prior to this consent, could for the same reasons also be useful for research. In addition, U-CAN also collects comparative materials from healthy volunteers, patients without a tumor disease and from patients with chronic bone marrow diseases.

We therefore ask if we for future research studies can have your consent to:

- Take and save extra blood samples
- Take and save other diagnosis-relevant sample types
- Save tissue samples from biopsies or surgery, e.g. from tumor and adjacent normal tissue
- Collect information, e.g. from surveys and the patient record
- Collect results from X-ray or laboratory investigations
- Collect samples and information from follow-up visits
- Use samples and information that may have been saved prior to the time of this consent

HOW WILL THE SAMPLES BE HANDLED?

Your samples will be stored in a biobank, meaning that they are protected by the Swedish Biobanks in Medical Care Act (SFS 2002:297) that regulate the way in which your samples may be stored and used. Samples taken within Uppsala County are saved in Uppsala biobank (IVO 827) for which Uppsala County Council (Region Uppsala) and Uppsala University have joint responsibility. Samples taken in other counties are normally saved in local biobanks. Your samples may only be used in the way you have consented to. You have the right to terminate your participation or to withdraw your consent regarding storage of your samples. To terminate or to withdraw your consent, please contact the responsible physician for your diagnosis within U-CAN (see list on page 4).

HOW WILL THE SAMPLES BE USED?

Your samples will be used for future, not yet specified, research projects that first must have been approved by the Swedish Ethical Review Authority (SERA), which upon review of the research project proposals will decide if you need to provide a new consent. The research could for instance be aimed at investigating factors and compounds that impact tumor growth and/or studies on how tumor cells respond to treatment. The studies could also include investigations of changes in DNA and RNA (genes) with the aim of improved diagnostics and treatment, and may involve sequencing the whole

genome in your sample. Certain research projects may involve sending coded samples abroad[1] for analysis, or provision of samples to companies for e.g. the development of novel diagnostic methods and/or anti-cancer drugs. The sequence of the genome (DNA and/or RNA) in your sample could be made available for researchers in open or closed databases. Your samples could also be used for isolating cell populations, for cell culturing and/or for the establishment of so called cell lines from either tumor and/or normal cells, which means that living cells from your sample are grown in a laboratory for research purposes. In all these types of research projects coded samples are used and your identity will therefore not be revealed to the sample receiver. Research data that may have implications for your care or treatment will under normal circumstances not be communicated to your healthcare provider. However, within certain research projects this may be possible if it has been approved beforehand by the SERA.

GATHERING OF INFORMATION

Within different research projects relevant information about you will be gathered from e.g. your patient record, laboratory data systems and quality registries provided that it has been approved by the SERA beforehand. The information will be collected within a research registry that is used for further analyses. All information will be coded when entered into the research registry so that it cannot be traced to you as an individual without access to a code key. The code key is stored separately from the research registry on servers inside Region Uppsala's fire walls. All research results will be presented as statistics and will therefore not be traceable to you individually. If you choose to terminate your participation in U-CAN, no more personal information will be gathered but we retain the right to keep and use the information that has been already collected along with any potential research data already generated from your samples.

PERSONAL INFORMATION

According to GDPR (2016/679 2 chap 6.1e) the legal basis for processing your data is because it "is necessary for (…) a task carried out in the public interest" (i.e. research). Your information will be kept indefinitely. The Hospital board of Region Uppsala is responsible for the data. You may upon written request obtain an excerpt of your personal information once a year free of charge. If you have questions or want to obtain an excerpt, you should contact Gunilla Enblad (see page 4). Any incorrect personal information will be corrected upon notification. The Data protection officer is contacted through Region Uppsala. If you are unsatisfied with how your personal information is handled you have the right to file a complaint with The Swedish Authority for Privacy Protection.

PARTICIPATION

Your participation in U-CAN is completely voluntary and you participate by signing the consent form below. If you do not want to participate, simply ignore the consent form. You can at any time terminate your participation or withdraw your consent without the need for an explanation. If you terminate no more samples or information will be collected from you, although U-CAN retain the right to use already collected samples and data. If you want to withdraw your consent, your samples will also be anonymized and/or destroyed and your data will be excluded from further U-CAN research. To decline, terminate or withdraw your consent to U-CAN will not in any way affect your care or treatment. However, any research data that has been already published, or genomic information that has been made available in open databases cannot be destroyed. No remuneration will emanate from participation in U-CAN or from potential commercialization of research findings.

CONTACT WITH U-CAN

See footer. For questions concerning your care or treatment, we refer you to your physician.

[1] According to The Data Protection Act, coded biobank samples can be sent to all EU/EES countries and to countries considered having a sufficient level of protection. For other countries, e.g. Canada and the USA, other rules apply. For more information, see The Swedish Authority for Privacy Protection website (www.imy.se).

INFORMED CONSENT

NB! Participation in U-CAN requires an active signing of this consent.

I have been verbally informed about U-CAN and have reviewed the written information. I understand that participation is voluntary and that I can terminate my participation whenever I choose without further explanation, and that termination will not in any way affect my care or treatment.

- I consent to participate in the collection of samples and information for research purposes within the U-CAN framework and according to the information provided above. I give my permission to store my samples in a biobank.
- I consent to the use of my samples and survey answers in future, not yet specified, research projects which must have been approved by the Swedish Ethical Review Authority (SERA). I may be asked to provide additional consent if SERA so decides.
- I consent to the use of my personal information to generate computer-based research registries. I understand that this include collecting relevant information from my patient records and/or from other registries, provided that this has been approved by SERA.
- I consent to my coded samples being provided to companies and/or being sent abroad for analysis, provided that this has been approved by SERA.
- I consent to my samples being used for isolating cells, for cell culturing and/or for establishing cell lines for research purposes, provided that this has been approved by SERA.
- I consent to the genome sequence (DNA and/or RNA) of my samples being made available for researchers in open or closed databases, provided that this has been approved by SERA.
- I understand that research data obtained from my samples will under normal circumstances not be used for my care and treatment, except within specific research projects where the results are still traceable to me personally and where this procedure has been approved beforehand by SERA.

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Personal number: ☐☐☐☐☐☐-☐☐☐☐

Texted name: _____

Place and date: _____

Signature: _____

The consent is prepared as 2 originals, the research participant keeps one and the other is archived in the patient record.

CONTACT INFORMATION

UPPSALA /U-CAN

RESP. PERSONAL INFORMATION	U-CAN PROGRAMDIRECTOR	DATA PROTECTION OFFICER
Gunilla Enblad	Tobias Sjöblom	Region Uppsala, Box 602
Professor, Chief physician	Professor	751 25 Uppsala
Onkology clinic, Uppsala	Uppsala university	dataskyddsombud@regionuppsala.se

GÄVLE HOSPITAL 026-15 40 00 (switchboard)

LUNG CANCER	GYNECOLOGICAL CANCER	COLORECTAL CANCER	LYMPHOMA
Johan Isaksson Chief physician	Hanna Rapp Chief physician	Sepher Doroudian Specialist physician	Amal Abu Sabaa Physician
Eva Brandén Chief physician	Isabell Sjöberg Nurse	Thorbjörn Sakari Läkare, Sektionschef	Carola Nylen Nilsson Chief physician
Hirsh Koyi Chief physician	Annette Henriksson Nurse	Catherine Theuer Nurse	
			HEMATOLOGY
Sandra Person Nurse	Ngoc Huynh Nurse		Helena Gustavsson Chief physician
Malin Wallström Nurse			Malin Månsson Leinonen Nurse

KARLSTAD HOSPITAL 010-83 150 00 (switchboard)

LYMPHOMA
Karin Hallén Chief physician
Karin Törnkvist Nurse

VÄSTERÅS HOSPITAL 021-17 30 00 (switchboard)

HEMATOLOGY
Josefin Hidman Specialist physician
Elisabet Danielsson Nurse

FALU HOSPITAL 023-49 20 00 (switchboard)

LUNG CANCER	HEMATOLOGY
Pierre Sobrino Chief physician	Max Flogegård Chief physician
Gabriel Lundberg Chief physician	Monica Holst Nurse
Anders Birkehag Sjuksköterska	
Johan Isaksson Chief physician	

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.....

Personal number: ☐☐☐☐☐☐-☐☐☐☐

Texted name: _____

Place and date: _____

Signature: _____

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COPY FOR HOSPITAL RECORDS