INFORMATION TO RESEARCH PARTICIPANT: CONSENTING TO U-CAN AS A CANCER-FREE VOLUNTEER

You are hereby asked to participate in U-CAN. The purpose is to collect samples from you and other volunteers in order to serve as reference material in research based on samples from cancer patients.

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, U-CAN also collects comparative samples from healthy volunteers and from patients without a tumor disease for this purpose. Information about e.g. your life style and/or your disease history will be collected from surveys and from your patient records in order to better compare the results of your samples with the results from samples analyzed from cancer patients.

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

- at one singe occasion take and save extra blood samples
- (potentially) take and save other diagnosis-relevant sample types
- for research purposes collect information from e.g. surveys and your patient records
- for research purposes 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 withdraw your consent regarding storage of your samples, in which case all your samples will be destroyed or anonymized.

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 survey answers or patient records provided that it has been approved by the SERA beforehand. The purpose for collecting this information is to better compare the results of your samples against those from cancer patients. 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. Region Uppsala is responsible for the registries and the information from your patient records.

PERSONAL INFORMATION

Responsible for your personal data is Region Uppsala. Contact person for personal data is Gunilla Enblad. According to GDPR (2016/679 2 chap 6.1e) you may obtain an excerpt of your personal information once a year free of charge and to have potential errors corrected. You may also ask that information should be deleted, or that the use of your data should be limited. 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 Data Protection Authority.

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 withdraw your consent without the need for an explanation, whereby your samples will be anonymized and/or destroyed and your data will be excluded from further U-CAN research. To decline or withdraw your consent to U-CAN will not in any way affect you negatively. 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

On the U-CAN homepage **www.u-can.uu.se** you can find more information about the project.

GENERAL CONTACT INFORMATION

AKADEMISKA HOSPITAL	RESP. PERSONAL INFORMATION	DATA PROTECTION OFFICER	U-CAN PROGRAM DIRECTOR
Region Uppsala	Gunilla Enblad	Data Protection Officer	Tobias Sjöblom
Akademiska sjukhuset	Professor, Chief physician	Region Uppsala, Box 602	Professor
751 85 Uppsala	Oncology clinic	751 25 Uppsala	Uppsala universitet
Phone: 018-611 00 00 (switchboard)	gunilla.enblad@akademiska.se	dataskyddsombud@regionuppsala.se	tobias.sjoblom@igp.uu.se

[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 Data Protection Authority (www.datainspektionen.se).

INFORMED CONSENT: CANCER-FREE VOLUNTEER

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.

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COPY FOR HOSPITAL RECORDS