Letterhead of the institution

Request to participate in medical research:

Gynaecological Oncology (GO) Quality Cohort: Centralization and assessment of Quality of Care in Gynecological Oncology during the Highly Specialized Medicine (HSM) process

Dear madame,

We are asking you here whether you would be willing to participate in future research projects in the field of gynecological cancer based on your routine health-related data and samples, which will be collected within this registry.

The data registry is carried out by the European Society of Gynecologic Oncology (ESGO) and the gynecologic oncologists (specialists in female abdominal cancer) of the Swiss Society of Gynecology and Obstetrics (Swiss-AGO). Your data are collected within this registry and will be used for the quality purposes specified by the cantons on the basis of Art. 39 KVG.

Apart from this, the data could also give rise to interesting questions for research into the treatment of patients with gynecological cancer in Switzerland and Europe.

How can you contribute to research?

By signing the declaration of consent, you are making your clinical data and leftover samples related to your gynecological cancer available for research purposes. Data and samples include those that have been collected and will be collected during your hospital stay. Your consent is voluntary. It remains valid indefinitely or until withdrawn. You are entitled to withdraw your consent at any time without having to justify your decision. After withdrawal, your data and samples will not be available for new projects. Data already integrated in further use projects will still be used/analyzed. Your decision has no effect on your medical treatment. Please contact your treating physician if you would like to withdraw your participation.

How are your health-related data and samples protected?

Data will be collected coded in this registry and protected in accordance with the applicable legal requirements. Coded means that all personal information such as your name or date of birth is replaced by a code. The key showing which code belongs to which person is kept safe at your local hospital. Only authorised employees from your hospital, e.g. physicians, have access to your uncoded data and samples. People who do not have the code are not able to identify you. In case of anonymisation, the link between the biological material and/or associated data and the participant is definitely removed so that no specific participant can be reidentified.

Your samples are routinely stored in the pathology of your hospital that contain structured collections of samples under safety regulations.

Who may use your health-related data and samples?

Data and samples may be used by authorised researchers for research projects in collaboration with Swiss-AGO and ESGO, in Switzerland and abroad. For research abroad, it must be ensured that at least the same data protection conditions are followed as in Switzerland. The projects may include genetic analyses for research purposes. Research projects relying on your data and samples have to be authorised by the relevant ethics committee.

Will you be informed about research results?

Research carried out with your samples and data will generally not reveal any individual information for your health. In rare cases, research results might be relevant or significant to your own health and clinical action might be possible. In these cases you might be informed. Please tell your treating physician if you do not want to be informed. On the ESGO website (esgo.org) you can find information on subsequent studies as soon as they are published.

Will there be any costs or financial benefit?

There are no additional costs generated. The law excludes commercialisation of data and samples. Thus, no financial benefits will be generated for you or the hospital.

If you have any questions or would like additional information, please contact us at the address below or visit our website at esgo.org

Declaration of consent for the use of health-related data and samples for research purposes

I herewith agree that my health-related data and samples collected during health care (ambulant or as an inpatient) related to ovarian cancer will be made available for research purposes

BASEC-Number:	AO_2024-00051
Title of the data registry (scientific and lay language):	Centralization and assessment of Quality of Care in Gynecological Oncology during the Highly Specialized Medicine process.
Responsible institutions (project leaders with address):	ESGO: Prof. Dr. Nicole Concin President of the ESGG Chair Steering Committee of ESGO Database Medical Universities of Vienna & Innsbruck 1090 Vienna & 6020 Innsbruck Swiss-AGO: Prof. Dr. Viola Heinzelmann-Schwarz, President Swiss-AGO and Swiss GO Trial Group University Hospital Basel Spitalstrasse 21 4031 Basel
Place of conduct:	
Head of the registry at the place of study: Surname and first name in block capitals:	
Participant: Surname and first name in block capitals: Date of birth:	

I understand

- the explanations about the further use of my health-related data and samples for research purposes.
- that my personal data are protected.
- that my coded data and samples may be used in national and international projects within the public and private sectors.
- that projects may include genetic analyses of my samples for research purposes.
- that I may be recontacted in case of individually significant findings, if any.
- that my decision is voluntary and has no effect on my treatment.
- that my decision is not limited in time.

- that I may withdraw my consent at any time without having to justify my decision. I know what will happen to the material and data collected up to that point if I withdraw my consent.

Place, date	Signature of participant

Confirmation of the investigator: I hereby confirm that I have explained to this participant the nature, significance and scope of future use of data and samples for research purposes.

Place, date	Surname and first name of the investigator in block capitals Signature of the investigator