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Centre universitaire de médecine générale et santé publique · Lausanne

Dépistage du cancer du côlon
Canton de Vaud

Study information document

Study title: Colon cancer screening study (PRESENT)

Simplified title: PRESENT study

Dear Sir/Madam

We would like to introduce you to the PRESENT study and invite you to participate. The PRESENT study is testing a new way of communicating information about colon cancer screening. You will receive information about how to get screened in the form of a brochure. This could help you make an informed decision about colon cancer screening.

Such research is called a **clinical study**. Your participation in this study is voluntary. Study documents are also available in French. You can ask questions to the study's research team. Just send us a message or give us a call (our contact details are on the next page).

If you wish to participate, please sign the **declaration of consent** at the end of this document. Your signature confirms that you have read and understood the information. If anything is unclear, please do not hesitate to ask the research team for clarification.

This information and consent form consists of four parts:

Part 1 **Summary of important information**
Part 2 **Detailed information about the study**
Part 3 **Data protection and insurance coverage**
Part 4 **Declaration of consent**

In **Part 1**, you will find general information about the study. In **Part 2**, we explain the objectives and conduct of the study. **Part 3** contains information on data protection and insurance coverage. By signing the consent form at the end of the document, **Part 4**, you confirm that you have understood all of the information and agree to participate.

This study is being carried out by the University Centre for Primary Care and Public Health (**Unisanté**). This institution is referred to as the **Promoter**. The Promoter assumes responsibility, management and financing of the study.

Here is the contact information, if you have any questions:

Research team contacts:

Name:	Carolina Mejia Perez
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Phone:	079 556 38 46
Email :	etude-colon@unisante.ch

Contacts for the Vaud screening program:

Name:	Romain Freund
Address:	Route de la Corniche 21, 1010 Lausanne
Phone:	0848 990 990
E-mail:	depistage.colon@unisante.ch

Part 1: Summary of important information

1. Why are we conducting this study?

Colon cancer screening is strongly recommended for people aged between 50 and 69, as the risk of developing this disease increases significantly with age. For colon cancer screening, your canton offers a choice of two tests: a colonoscopy (a test performed by a specialist) or a FIT (a stool blood test that you can perform at home).

In this study, we compare two ways of informing people about screening. To do this, we have prepared information brochures. Our aim is to see which brochure gives the best information and helps people make an informed choice about colon cancer screening. We also want to understand whether this new way of communicating information is as effective in finding early-stage cancers as the method used today. Find out more in **Chapter 4**.

2. What do you have to do if you want to take part?

If you agree to take part in this study, we will ask you to read and sign the declaration of consent (your agreement to participate) and fill in a questionnaire (takes 10 to 20 minutes). A few weeks later, you'll receive an information brochure about colon cancer screening. You will be asked to read this brochure carefully before deciding whether to undergo screening. You may also receive your personalized colon cancer risk. Figure 2 on page 6 explains the steps involved in the study. Find out more about the study process in **Chapter 5**.

Screening is covered by your health insurance with no deductible. You will pay 10% of the cost of the test. Screening is voluntary, and you can decide not to do it.

* * * * *

You are completely free to participate in this study. If you don't want to take part, you don't need to give any explanation. Refusing to participate will not impact your future participation in the colon cancer screening program**. If you wish to be screened outside this study**, please wait for the standard screening invitation which will be sent to you in a few weeks. If you have any questions, you can also contact the research team.

If you agree to take part in this study, we first ask you to sign the declaration of consent. You will then be asked to complete a questionnaire. This information form, the consent form and the questionnaire are also available in paper format. To receive a printed version, please contact the research team (see page 2 for contact details).

3. What are the benefits and risks of participating?

Benefits

Your participation is not intended to bring you any direct benefit. However, the information you receive may help you better understand the benefits of screening and choose the right test for you. In addition, your participation will contribute to improving the cantonal colon cancer screening program. Thank you.

Risks

Information about colon cancer may make you feel anxious. Don't hesitate to talk to your GP or contact the research team if you feel anxious.

You will find more information on risks **in Chapter 6**.

Part 2: Detailed information on the study

4. Aims and conduct of the study

4.1 Objective: why are we doing this study?

Most colon cancers appear after the age of 50. Small lumps may appear in the colon: these are called polyps. Polyps in the colon and rectum are common. Most polyps are harmless, but some can develop into cancer. The polyps most likely to develop into cancer are called adenomas. Screening can detect adenomas and early cancers when treatment is simpler and more effective.

Your canton's colon cancer screening program currently offers two tests:

- FIT, which looks for invisible blood in the stool/poo, and
- Colonoscopy, which uses a tube with a camera to examine the intestine directly.

Both tests can detect adenomas and early-stage cancers. Of course, each test has its advantages and disadvantages.

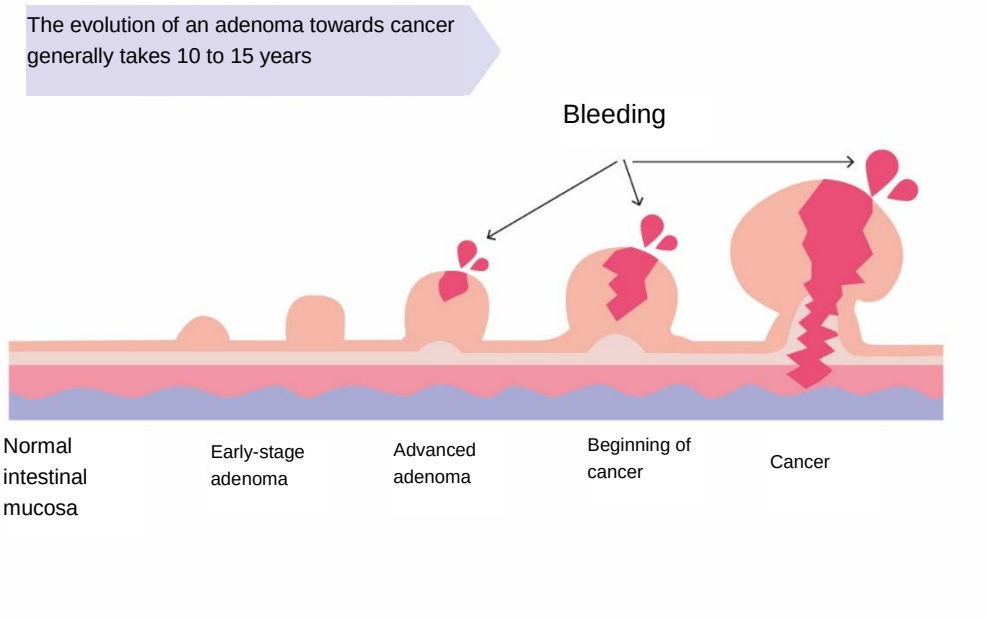

Figure 1: Evolution of a polyp towards cancer.

This study has two **main objectives**:

- Check whether our new colon cancer screening information brochure helps people make an informed decision about screening.
- Check whether screening using the new brochure is as effective (i.e. whether it finds as many cancers and adenomas) as using the current brochure.

4.2 How does the study work?

In our study, participants are randomized into three groups. This separation is important to obtain reliable results. Each group will receive an information brochure about colon cancer:

- **Groups 1 and 2** (intervention groups) receive our new brochure,
- **Group 3** (control group) receives the brochure currently used by the screening program in your canton.

This is a "single-blind" study, which means that participants don't know which group they've been assigned to. This option is chosen so that participants have as little influence as possible on the results of the study. This allows us to objectively evaluate the effectiveness and safety of the method we are testing.
Our study will take place in six Swiss cantons: Geneva, Vaud, Fribourg, Bern, Basel-Stadt and Basel-Landschaft. We aim to include 8,000 people. A similar study was carried out in the canton of Vaud between 2021 and 2022. Most participants were satisfied with the brochure and the organization of the study. If you would like to know more about the results of this study, please do not hesitate to contact us.

We are conducting this study in accordance with Swiss law (law on human research and data protection law). We are also complying with all international requirements. The ethics commissions of the cantons of Vaud, Geneva, Bern and Basel have authorized this study. The study is financed by the Swiss National Science Foundation.

A description of the study can also be found on the website of the Swiss Federal Office of Public Health at www.kofam.ch, under the registration number HumRes.

5. Course of the study

5.1 What do you have to do if you participate in the study?

Participation in the study is voluntary and lasts until May 2029. Figure 2 explains how the study works. Please follow the instructions given by the research team.

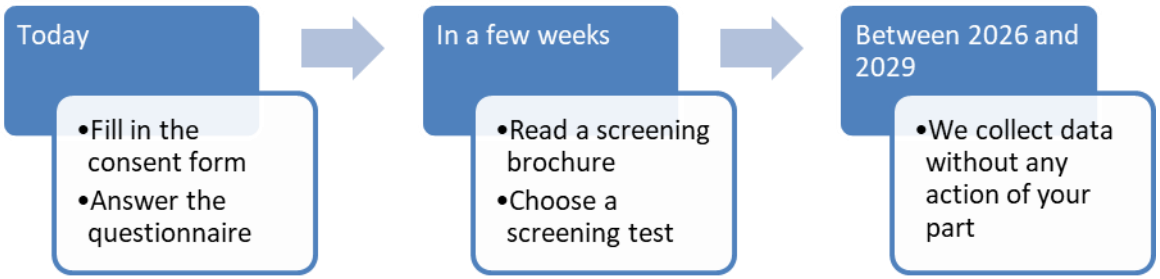

Figure 2. Study schedule.

5.2 What happens during the 3 years of the study?

To begin with, we ask you to complete our questionnaire. It will take about 10 to 20 minutes. Your answers will enable us to :

- Check whether we can include you in the study. For example, we cannot include people who are already up to date with colon cancer screening.
- Collect certain information about your lifestyle, gender, age, level of education, etc., which we need to analyze the data. This data will be coded, i.e. all identifying data (name, date of birth, etc.) will be replaced by a unique code for each participant (for more details, see **Chapter 9**) and will be accessible only to members of the research team.

A few weeks later, you'll receive an information brochure about colon cancer screening. This brochure will provide you with information on the screening tests available in your canton and how to obtain the tests.

The screening test is paid for by your health insurance with no deductible. You will pay 10% of the cost of the test (see **Chapter 7** for more details).

To know whether you have been screened, we work with the screening program in your canton. The program will inform us if you have been screened and what were the results. This means we'll know whether your FIT is positive or negative, or whether any polyps were found during your colonoscopy. This information will be handled in accordance with Swiss data protection regulations. For more information on how your data is protected, please read **Chapter 9**.

To carry out our study, we need data relating to your screening history. We will ask the screening program in your canton to send us this data, if they have it.

As the FIT must be repeated every two years, people who have taken a FIT or who have not taken any test will receive another invitation for screening. We will also contact a subset of people to complete an additional questionnaire or for a telephone interview. You are free to accept or decline.

Colon cancer develops slowly over several years. This is why we would like to follow the participants in your canton's Tumor Registry until May 2045 (for an additional 15 years after the end of the study). We will ask the Tumor Registry to inform us whether the participants in this study had a cancer or adenoma. We will then compare the number of cancers and adenomas in people who received our new brochure with those who received the usual brochure. This will enable us to assess the safety of the method we are proposing.

In order to automate the search for information in the Tumor registry, we would like to collect your AVS number.

You can take part in this study even if you don't want the research team to follow you in the Tumor Registry.

5.3 When does participation in the study end?

The study runs from September 2025 to May 2029. You can stop participating at any time before this date (**see Chapter 5.4**). You do not need to justify your decision. If you wish to stop participating, please inform the research team.

If you stop taking part in the study, your medical care and colon cancer screening will remain unchanged (**see Chapter 5.4**).

If you stop taking part in the study, we will still be able to analyze the data collected up to that point. Your data will remain coded (**see Chapter 9**).

5.4 What happens if you don't want to take part?

If you do not participate in this study, the colon cancer screening program in your canton will send you a standard invitation for screening in about two months.

6. Risks associated with this study

6.1 What are the risks associated with this study?

One potential side effect of participating in this study is an increase in anxiety linked to information about colon cancer. If you are feeling anxious, talk to your GP or contact the research team (see page 2).

Screening is a very good way to reduce your risk of colon cancer.

7. Funding and compensation

You will receive no compensation for your participation in this study.

The costs associated with screening are the same as if you were to undergo screening outside the study. The majority of screening costs are covered by your health insurance with no deductible. If you decide to have a FIT, you will pay around CHF 5. If you opt for a colonoscopy, you will pay between 80 and 160 CHF. The price of a colonoscopy depends on the complexity of the examination. For example, if the doctor finds polyps, he or she has to remove them and send them to a laboratory for analysis, which involves additional costs. Costs that are not covered outside the deductible include a consultation with your doctor if your FIT is positive, laxatives to prepare your colon for the colonoscopy and anesthesia during the colonoscopy.

8. Study results

Your personal results are communicated directly to you. If you take a FIT, you and your GP will receive the results by mail within 8 days. If you opt for a colonoscopy, the specialist who examines your intestine will inform you directly of the results at the end of the examination.

In addition to personal results, the study will produce global results that are derived from the data of all participating individuals. These include, for example, new insights into the effectiveness of this new information brochure (see **Chapter 4.1**). These results do not directly impact you or your health. If you wish, the research team will provide you with a summary of the overall results at the end of the study. In addition, the results will be published in plain language after the study is completed (in December 2030).

Part 3: Data protection and insurance coverage

9. Data protection

We will protect your data (e.g. your answers to the questionnaire). Swiss law imposes strict rules for data protection.

Swiss data protection legislation gives you the right to access, rectify and receive data that has been collected, processed and transmitted within the framework of the study. In exceptional cases, due to other legal or regulatory requirements, these rights cannot always be guaranteed. **If you have any questions in this regard, please contact the research team.**

9.1 Data and sample coding

Every study produces data like answers to questionnaires or screening test results. These data are recorded in coded form, usually electronically. Coding means that personal information that can directly identify you is kept separate from other data, in the form of the identification list (see box below). The identification list identifies each person with a unique code. Your name, date of birth or address are not stored with the other collected data.

Example of non-coded data

First and last name	Date of birth	Address	FIT date	FIT results
Olivier Küffer	24.01.1970	Avenue Wendt 15, 1203 Geneva	18.10.2025	Negative
Olivia Sandala	15.06.1968	Avenue de Berne 123, 1011 Lausanne	05.12.2025	Positive

Example of coded data

Identification list

First and last name	Date of birth	Address	Personal code
Olivier Küffer	24.01.1970	Avenue Wendt 15, 1203 Geneva	10GE524
Olivia Sandala	15.06.1968	Avenue de Berne 123, 1011 Lausanne	12VA125

Participant data

Personal code	FIT date	FIT results
10GE524	18.10.2025	Negative
12VA125	05.12.2025	Positive

The participant identification list remains at Unisanté and the University of Basel, with whom we collaborate to conduct this study, and will be archived separately from the research data for 20 years. Only the person in charge of this study and some members of the research team have access to these lists. Specific exceptions are noted in **Chapter 9.5**.

Our colleagues at the Erasmus University Medical Center (Rotterdam, Netherlands) will be carrying out a study to estimate the cost-effectiveness of this new approach to screening. To enable this study, we are sharing some of the data we collect. Your data will always remain encrypted and protected. Researchers at Erasmus University will never have access to the identification list.

9.2 Data security during the study

Unisanté is responsible for the security of your data. It ensures compliance with laws, such as data protection laws.

In this study, your data will be recorded and transmitted electronically. The data is recorded and stored securely at Unisanté. Although Unisanté takes all measures to protect the data of study participants, we cannot exclude a small risk of data theft.

9.3 Data security after study completion

Once the study is over, Unisanté will continue to ensure the security of your data. By law, all study documents, such as questionnaires, must be kept for at least 20 years. During this

period, study data remains coded. Data collected for this study may not be reused for other research without your consent (**see Chapter 9.4**).

Once the study is complete, the results will be published in scientific journals. The published articles contain the results of statistical analyses (e.g. averages or percentages). Your personal data will never be mentioned.

9.4 Re-use and transfer of your data for other studies

The data collected in this study is valuable for future research. It may be reused and/or shared with other studies (including those abroad).

A separate informed consent form is required for the reuse and/or transfer of your data. Without your written consent, your data will not be transferred. Please read the additional declaration of consent at the end of this document carefully. Please sign the consent if you agree to share your data for further research. You can participate in the study and carry out the screening, even if you refuse to share your data.

9.5 Right to access data during inspections

This study may be reviewed by the relevant ethics commission. Unisanté must also carry out checks to guarantee the quality of the study and its results.

For these checks, specially trained persons have access to your personal data. In this context, the people carrying out the checks may have access to the identification list. Persons carrying out checks are bound by professional secrecy.

As a participant, you have the right to view your data at any time.

10. Insurance coverage

You are covered if you suffer any injury as a result of the study. In the event of a health problem related to the intervention method tested in this study (our information brochure), you are entitled to coverage under Unisanté's liability insurance. The procedure is regulated by law. If you believe you have suffered an injury because of the study, please contact the person in charge of the study (Dr. Kevin Selby).

If you have a health problem related to the use of a treatment method that has already been authorized (e.g. complications related to colonoscopy), the liability rules are the same as for treatment outside the study. In such a situation, the liability insurance of the hospital or doctor who performed the treatment covers the costs/compensation.

Part 4: Declaration of consent

This declaration of consent consists of three separate parts:

- Declaration of consent to participate in the PRESENT study;
- Declaration of consent for the research team to collect your data from the Tumor Registry in your canton;
- Declaration of consent for the re-use and transfer in coded form of data from this study for other research.

Please read this document carefully. If you have any questions or need clarification, please do not hesitate to ask.

Your signature on the **PRESENT consent form is required** to participate in this study.

Declaration of consent for participation in the PRESENT study

BASEC number	2025-00727
Study title	Colon cancer screening study (PRESENT)
Simplified title	PRESENT study
Responsible institution (Promoter and address)	Unisanté Route de la Corniche, 1010 Lausanne
Locations	Colon cancer screening program in the canton of Vaud
Physician-investigator responsible for this study	Dr. Kevin Selby
Physician in charge of the colon cancer screening program in the canton of Vaud	Dr Romain Freund
Participant Surname and first name in capital letters Date of birth	Your first and last name _____ _____ Your date of birth _____

- I have received written information about the study.
- The study information document clearly explains the purpose, conduct and risks of the study.
- I am participating voluntarily in the study.
- I have had enough time to make my decision. I can keep the written information (download the completed form).
- I understand and agree that the screening program in my canton will send the research team information on the screening tests I have undergone and the results of these tests.
- I can stop participating at any time; I don't need to explain my decision. Even if I stop participating in the study, I can get access to colon cancer screening with the test of my choice. The data collected up to that point will remain stored and can be analyzed as part of the study. My data will remain coded.
- Specialists from Unisanté or the relevant ethics commission may view my uncoded data for control purposes. All of these people are obliged to respect professional secrecy.
- I know that Unisanté has insurance. Unisanté's liability insurance can cover any damage caused by the intervention method tested in this study.

Place, date _____ _____	Participant's first and last name in capital letters _____ Signature of participant _____

Optional declaration of consent for the research team to collect your data from the Tumor registry of your canton

This declaration concerns the collection of data from the Tumor registry of your canton. **This declaration is optional. You can participate in the study and refuse to have your data collected from the Tumor Registry.**

BASEC number	2025-00727
Study title	Colon cancer screening study (PRESENT)
Simplified title	PRESENT study
Participant First and last name in capital letters Date of birth	Your first and last name _____ _____ Your date of birth _____

- I agree that the Tumor Registry may share information about my colon cancer or adenoma diagnosis with the research team, if available. This follow-up will take place between 2025 and 2045.

- I am making my own decision and can change it whenever I wish. I can simply inform the research team of my decision. I don't have to justify my decision.

- If I decide to stop participating, no information from the Tumor Registry will be shared with the research team.

Place, date _____ _____	Last name and first name of participant in capital letters _____ Signature of participant _____

Optional declaration of consent for the re-use and/or transfer of data in coded form

This declaration concerns the reuse and/or transfer of data. **This declaration is optional. You can participate in the study and refuse the reuse and/or transfer of your data.**

“Re-use” means that your data may be kept after your participation in the study and used in coded form for other studies. For example, your answers to the questionnaire may be analyzed with other data sources, or new analyses may be carried out with these data.

"Transfer" means that your data may be transmitted to other researchers or research institutions in coded form for further studies. These other researchers or research institutions may be located abroad. It is Unisanté's responsibility to ensure that this country has an adequate level of data protection, comparable to that of Switzerland.

BASEC number	2025-00727
Study title	Colon cancer screening study (PRESENT)
Simplified title	PRESENT study
Participant First and last name in capital letters Date of birth	Your first and last name _____ _____ Your date of birth _____

- I authorize the reuse and transfer in coded form of my data collected during this study for further research (also abroad).
- I understand that the data is coded and that the identification list is stored securely.
- The data can be analyzed in Switzerland and abroad and stored in a database in Switzerland or abroad. Research institutions abroad must comply with the same data protection standards as those in Switzerland.
- I am deciding for myself whether to reuse and/or transfer data in encrypted form, and I can change my decision at any time. I can simply inform the research team of my decision. I do not have to justify my decision.
- If I decide to stop participating, my data will remain coded.

Location, date _____ _____	Participant's first and last name in capital letters _____ Signature of participant _____