Official Protocol Title:	Sensitivity of Fecal Immunochemical Test (FIT) for Colorectal Cancer
	(CRC) Screening (FITBACK)
NCT number:	NCT ID not yet assigned
Unique Protocol ID:	FITBACK (29BRC21.0147)
Document Date:	19/10/2021

Appendixes

Appendix 1



REGISTRE DES TUMEURS DIGESTIVES DU FINISTERE

Patient Information Note

What is the purpose of a cancer registry*?

In order to better understand the epidemiology of cancers (geographical distribution of cases, favourable factors) and to better fight against this disease, cancer registries have been set up in several French departments. Thanks to a permanent and exhaustive census, the registries contribute to the surveillance of cancers and to the progress of research in this field. The French cancer registries are grouped within the Francim network.

What information is collected and for what purposes?

To carry out their missions of observation and surveillance of cancers, evaluation and research, the registries collect identification data (patient identity, address) and medical data (date of diagnosis, characteristics of cancers/tumors, type of treatment, evolution of the disease). This information is transmitted to them by the health establishments and physicians involved in the diagnosis and management of the disease (hospitals and clinics, anatomical pathology and biology laboratories, treating physicians and specialists) and other organizations such as the health insurance company, the CRCDC29**; the registry also has access to information from the Cancer Communication Document (CCD). These data make it possible to know the type and frequency of cancers in the population and their evolution over time. They are essential for improving knowledge of the causes of cancer and evaluating the quality of care.

Legal basis and controller of your personal data

The personal data collected by the registers are subject to computer processing which is carried out under the responsibility of the legal entity of the structure to which it is attached. This processing is necessary for the execution of the public service mission of the registers. This mission is at the heart of the cancer control policy, which the public authorities have affirmed as a national public health priority (Articles L. 1413-3 and L. 1413-6 of the Public Health Code). The registries are authorized by the Commission Nationale de l'Informatique et des Libertés (CNIL) and are qualified by the Comité d'Évaluation of the registries.

How is your data protected and how long is it kept?

The data collected are covered by medical secrecy and are strictly confidential. Only authorized registry personnel have access to personal data and data processing is carried out in a manner that respects confidentiality. Registry data of historical, scientific and statistical interest are kept for as long as the registry carries out its tasks in order to meet its objectives, in accordance with the applicable regulations and laws and under strict security procedures. Only fully anonymized data are published.

Who are the data recipients?

Some data are sent to other public health organizations (Institut National du Cancer [INCa], Santé publique France [SpF], International Agency for Research on Cancer [IARC]) to allow, for example, geographic comparisons of cancers in France and in the world.

What are your rights and how can you exercise them?

In accordance with the General Data Protection Regulation 2016/679 (RGPD) you have various rights on the information concerning you: right of access, rectification, opposition, limitation of the processing of your data, in particular in order to verify its accuracy and, if necessary, to rectify it, complete it or update it. You can exercise these rights through the doctor who follows you or directly with the DPO by mail at the following address:

Email address: DPORegistreFinistere@ageris-group.com

Registry website : http://registre-tumeurs-29.fr

If, after contacting the DPO, you feel that your rights have not been respected, you can submit a complaint to the CNIL online https://www.cnil.fr or by mail.

For more information on registries: You can consult the National Cancer Institute website at: http://lesdonnees.e-cancer.fr/Themes/Les-registres-de-cancers

List of departments covered by a cancer registry: 08, 14, 16, 17, 21, 25, 29, 33, 34, 38, 44, 50, 51, 59 (Lille proximity zone), 61, 67, 68, 69, 71, 79, 80, 85, 86, 87, 90, 971, 972, 973, 974, 987, 988.

- * more generally, cancer registries are required to register tumours whether they are cancerous (malignant), non-cancerous (benign) or precancerous
- ** CRCDC29 : departmental branch of the Centre Régional de Coordination du Dépistage des Cancers

Appendix 2



Data protection

Personal data management policy of the Centre Régional de Coordination des Dépistages des Cancers de Bretagne

Article 1. Responsibility

The CRCDC Bretagne is responsible for the processing of personal data that it implements directly or indirectly in France and abroad. It therefore complies with French laws and European regulations applicable, in particular with the Data Protection Act and the General Data Protection Regulation (GDPR).

In accordance with legal requirements, it undertakes to complete all formalities necessary for the implementation of personal data processing, whether these concern its patients or its employees or service providers.

Article 2. Determination of the purposes of the data collection

The CRCDC BRETAGNE collects the personal data of individuals who meet the criteria defined by the cancers screening:

- BREAST,
- COLORECTAL
- UTERINE CERVIX

The CRCDC BRETAGNE legitimately processes the data of persons concerned by the screening of a CANCER.

The processed data are kept until the end of the follow-up, decided by the person himself or his doctor. At the end of this period, the data are deleted or archived in an anonymous form.

They are used for the following purposes:

- Creation of files of the persons concerned for the purpose of inviting them to the screening operations,
- · Extraction of identity data for sending invitations and mailings, carrying out follow-up operations on these people,
- Management of contacts with relevant health professionals, evaluation of screening programs.

These data are exclusively intended for use by the professionals authorized by the CRCDC BRETAGNE centers.

They may be transmitted anonymously to public structures such as :

- Santé Publique France
- <u>L'Institut National du Cancer</u>

This data concerns the following information about people:

Civil status, identity, identification data

Birth name, Use name, First name(s), Sex, Date of birth, Address, Telephone number, E-mail address

Health data: previous examinations and medical history, if applicable, if the persons concerned agree, their reason(s) for refusing to participate in the screening operations, results and reports of the examinations, imaging films, dates of sending of the results and information on the effective medical care allowing to verify the entry in a care channel of the persons concerned.

The CRCDC BRETAGNE undertakes to process this data in a manner compatible with the purposes set out above. Further processing for archival purposes in the public interest, for scientific or historical research purposes or for statistical purposes is not considered, in accordance with Article 89 of the GDPR, paragraph 1, as incompatible with these purposes (purpose limitation); Article: 6, 26 of the GDPR.

The CRCDC BRETAGNE may also be required to carry out studies and research on these data in the public interest. For this purpose, it undertakes to do so according to the reference methodologies defined by the CNIL or to request authorization from the latter. The person in charge of processing personal data is:

CENTRE RÉGIONAL DE COORDINATION DES DÉPISTAGES DES CANCERS DE BRETAGNE

Headquarter: CRCDC BRETAGNE
7, rue Armand Herpin Lacroix
35000 RENNES
Phone: 02 99 30 40 10