ULB Center of Human Genetics
www.ulbgenetics.be

HEREDITARY ONCOGENETICS

Date of sample collection	Doctor's stamp	Doctor's signature
Write in black pen please		Copy to :

Laboratoire de Génétique
Hôpital Erasme
808, route de Lennik
1070 Anderlecht
tel : 02/555 41 45

PATIENT

Patient Identifier

Last Name : _____

First Name : _____

Date of Birth : _____ / _____ / _____ Sex : □ M □ F

Street : _____ N°_____ Box _____

Postal code : _____ Municipality : _____

Mutual insurance Nº: _____/_____

National Social Security Nº: _____

Request No. Label	Request No. Label
ERASME	ERASME

Indications Cliniques

☐ Isolated case ☐ duo ☐ trio ☐ other : _____

☐ Therapeutic (theranostic) aim : _____

☐ Suspicion of genetic condition : _____

☐ Family segregation – carrier testing : _____

☐ Familial genetic anomaly affected patient : _____

Index case must be specified : _____

☐ Presymptomatic test : □ 1/2 □ 2/2

Two independent requests, only after genetic counseling

Index case must be specified : _____

☐ Confirmation of a genetic anomaly : _____

Types of Samples and Analyses

Gene panel analyses to investigate hereditary cancer predisposition through exome sequencing

E□ Hereditary cancers[1,3]

=> specific form required*

□ Breast/ovarian □ Prostate
□ Pancreas □ Colorectal
□ Melanoma □ Endocrine**

□ Other (to be specified)**:

_____

** TAT 6 months

Gene panel analysis for therapeutic purposes with a PARP inhibitor

E□ Cancer [1]

□ Metastatic breast cancer
□ Breast cancer prior to adjuvant treatment meeting the required criteria***
□ Ovarian cancer (non-mucinous)
□ Pancreatic cancer (adenocarcinoma)
□ Metastatic prostate cancer

*** Required criteria:
Received anthracycline- AND taxane-based chemotherapy and considered "high risk"
(check the criteria present, one criterion is sufficient) :

If Luminal: □ Tumour size >2 cm or □ 4+ invaded lymph nodes

If triple negative: □ Lack of complete response to chemotherapy

If another "high risk" criterion, specify : _____

I informed the patient that, in case a pathogenic variant is identified, genetic counseling will be arranged.

Subcontracted Analysis

E□ Subcontracted analysis: □ DNA □ Blood

Belgian laboratory : _____

Foreign laboratory[1] : _____

Indication : _____

Gene(s) : _____

Polygenic Risk Score

Reserved for the CUPS study

E□ PRS [1,3] □ Eligible, declined the study

REDCap ID : _____

Ethnicity : _____

=> Genetic counseling mandatory

Others

E□ DNA storage E□ Long reads storage *

E□ Long reads */!\ Blood draw at the beginning of the week

E□ Other indication : _____

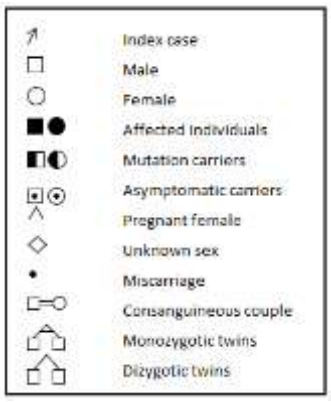
Gene(s) : _____

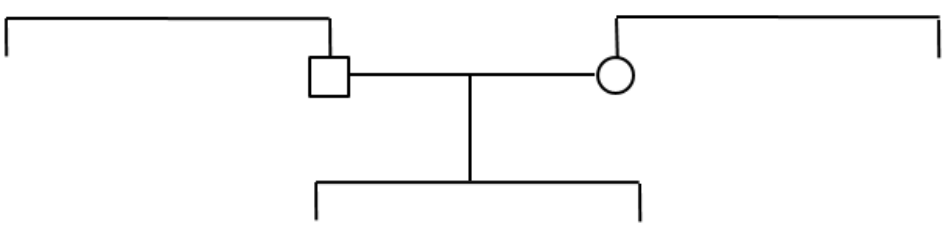
Mutation(s) : _____

1 MANDATORY consent 2 RECOMMENDED consent 3 Clinical signs and pedigree MANDATORY 4 ACCREDITED analysis

Family history

For each affected and/or sampled individual, indicate: name, first name, date of birth.
Specify the relationship and the phenotype of the individuals concerned.





E □ = EDTA *http://ulbgenetics.be/documents-utiles/#prescription

Insurance / Mutual Fund

Have you verified that your patient has health insurance or obtained approval for genetic analysis from a private insurance company ?
If the patient does not have insurance, did they mention that they agreed to pay after being informed of the high costs (up to €1700 per analysis) ?

Informed Consent for Genetic Analysis

PATIENT

Patient Identifier

Last Name: _____ First Name: _____ Date of Birth: _____ / _____ / _____

Presence of a translator: □ yes □ no Last Name: _____ First Name: _____

I have **received the necessary clinical information** from the healthcare professional and/or have read the corresponding information leaflet.
I confirm that I have been **properly informed about the objectives and type(s) of analysis** selected above, which will be carried out in relation to the aforementioned condition.
I understand that **variants of unknown clinical significance** may be identified in one or more genes, which may not allow a formal and definitive conclusion about their pathogenic role (requiring reassessment at a later stage).
I have had the time and opportunity to ask questions and **I am satisfied with the answers and explanations** I have received.

CLINICAL CONSENT	**YES**	**NO**
1. Do you consent to being informed of incidental findings of other medically useful and actionable conditions ?		
2. Do you consent to the re-analysis of data within the diagnostic framework ?		

I understand that **sharing medical and genetic data** with experts/scientific collaborators (via recognized databases) is crucial to improving our knowledge of the links between genetic variations, human biology mechanisms, and the occurrence of diseases. I am informed that such sharing and expert evaluation may lead to better diagnosis for myself or others, improved healthcare in general, and enhanced prevention and therapeutic options. I understand that data sharing and research are always undertaken in a pseudonymized manner in accordance with Belgian, European, and international regulatory and legal frameworks*.

I understand that **I retain the right to change or withdraw my consent at any time**, and that once the child reaches adulthood, they may modify the choices made by their parents on their behalf. Modification and/or withdrawal of my consent will have no negative consequences on the performance of the selected test above, nor on the non-genetic medical care of the person concerned by this consent, but may alter the genetic information that could have been transmitted after the date of my change. I understand that my withdrawal cannot apply to results and information obtained and/or transmitted before the date of my withdrawal request.

I understand that my participation in research is voluntary and will not provide me with any financial benefits.

RESEARCH CONSENT	**YES**	**NO**
3. Do you consent to the storage in the GenB3 biobank of DNA/RNA/tissue samples taken ?		
4. Do you consent to the re-analysis and sharing of data within a research framework and to the possible publication of results ?		

The cost of genetic analyses is covered by INAMI in most situations. If you are not covered by a mutual insurance, an insurance company, a social service, or an officially recognized association willing to cover the costs, these (which may amount to up to 1700 euros per person depending on the analysis) will, by default, be charged to you. **It is therefore very important**, before any genetic test, to check with your prescribing physician/geneticist that the tests are clinically justified and represent a minimal or acceptable financial burden for you.

To be completed by the patient or legal representative	
	Patient or legal representative * (*cross out unnecessary mentions)
Last Name	
First Name	
Date	
Signature	

To be completed by the healthcare professional	
I confirm that I have informed and answered to the best of my ability regarding the possible results and limitations of the tests performed.	
Last Name	
First Name	
Date	
Signature and stamp	

This version of the consent documents has been adapted and approved by the Erasme-ULB Ethics Committee.

***Requests, consents and information documents :** http://ulbgenetics.be/documents-utiles/#prescription
***Declaration of Helsinki :** https://www.wma.net/fr/policies-post/declaration-dhelsinki-de-lamm-principes-ethiques-applicables-a-la-recherche-medicale-impliquant-des-etres-humains/
***Respect for privacy :** https://www.autoriteprotectiondonnees.be/reglement-general-sur-la-protection-des-donnees-citoyen