OncoDNA
THE CANCER THERANOSTIC COMPANY

OFFICIAL DOCUMENT

Informed Consent Form OncoDEEP

The purpose of this informed consent form (the **"Informed Consent Form"** or **"ICF"**) is to provide you with clear and precise information regarding **OncoDEEP®** test on your tumor tissue provided by OncoDNA ("Tests", as further described in this ICF), in order for you to freely give your consent to the performance of these test in the context of molecular characterization of your tumor.

The content of this ICF must be presented and explained to you in its entirety by your doctor or the medical personnel in charge of your medical file. You must be provided with a complete copy of this ICF. Do not hesitate to ask them all the questions you might have. Take as long as you need to think about it. You can also speak about the relevant Test with your family and friends or with your family doctor before making your decision. The decision to accept the Test is entirely yours.

Your participation must be completely voluntary and if you choose to refuse to have any Test performed on your Samples, whether or not the Test has been (strongly) recommended by your doctor, such decision will not affect either your relationship with your doctor or the quality of your medical care.

[1] **While this ICF contains all necessary information in relation to the processing of your Personal Data, you may find the Privacy Policy applicable to OncoSHARE at www.oncoshare.com/legaldocs/oncoshare-privacypolicy.pdf.**

1. WHAT IS THE PURPOSE OF THE TEST?

When a cancer develops, some modifications of the DNA of the tumor appear leading to a dysfunction of those cells and therefore induce cancer. Since it might affect different genes and different parts of those genes, each tumor has a unique bundle of those modifications. This unique bundle will lead to different responses to treatments against cancer.

OncoDEEP® : aims at analyzing the molecular profile of your tumor from a tumor tissue in order to identify those modifications. In addition, it analyses several markers also related to the tumor progression. Thanks to this unique characterization of your tumor, it might be possible to identify treatments that could lead to clinical benefit (meaning a partial or total reduction of your cancer or the stabilization of your disease).

The Test is conceived and developed by OncoDNA SA – Rue Louis Breguet 1, 6041 Charleroi, Belgium, registered with the Crossroads bank for enterprises under company number 0501.631.837 – (**"OncoDNA"**).

The Test will be accompanied by **"Theranostic Report"** generated by OncoDNA containing personalized treatment options, taking into account your tumor's molecular characteristics.

2. WHAT ARE THE IMPLICATIONS OF THE TESTS FOR YOU?

The molecular characterization of your tumor by **OncoDEEP®** require your signature of this ICF.

When consenting to this test (or part thereof) via this ICF, you agree that a sample from one of the biopsies you have undergone be processed through **OncoDEEP®** and to have those Samples sent to OncoDNA for the performance of the test.

The information related to the results of the **OncoDEEP®** as performed on your Samples, including without limitation, the genetic characteristics of your tumor DNA (sequencing raw files and sequencing data resulting from the Test(s)) ("Results") and other Health Data as defined in section 4, will not be communicated directly to you. The Report will be exclusively communicated to your doctor, who will solely determine whether to take such Report into account for his/her therapeutic decision. In addition, your doctor will exclusively evaluate whether the Report is of interest for you and, therefore, whether it is opportune (or, in some cases, mandatory under applicable law) to disclose such Report to you.

3. WHAT IS THE TESTS PROCEDURE? WHAT WILL HAPPEN TO THE SAMPLES SENT TO ONCODNA?

TEST REQUEST ON OncoSHARE®

OncoDNA is the developer and owner of the platform **OncoSHARE®** (www.oncoshare.com), an online platform where doctors, patients and interested third parties may seek, collect and share information on cancer and oncology. Without limiting the generality of the foregoing, **OncoSHARE®** offers the following services to doctors: shipment box request, analyses ordering, process follow-up, data analysis and data sharing. In addition, on the basis of (i) the Results and your other relevant Personal Data (as defined in section 4), in particular your Health Data as defined in section 4 – combined with (ii) OncoDNA's know-how and medical research results, OncoDNA will generate (a) Report(s). The Report(s) will be communicated to the requesting doctor exclusively.

When you consent to one or more Tests (or part thereof) by signing or otherwise consenting to this ICF, your doctor – who registered with **OncoSHARE®** – will submit a request to OncoDNA for the analysis of your Samples, via **OncoSHARE®**.

EXECUTION OF THE TEST(S)

Your collected Samples will be marked by the medical or pathology laboratory personnel with a unique identifier that is linked to your medical file. There will be no information on the Samples which could allow you to be identified directly.

The coded Samples will then be sent to OncoDNA's service provider, BIO.be SA ("BIO") – having its registered offices at Avenue Georges Lemaitre 25, 6041 Charleroi and registered with the Crossroads bank for enterprises under company number 0861.738.595, or any other selected service provider. The Tests will then be executed on behalf of BIO by BIO's mother company, the Institute of Pathology and Genetics ASBL ("IPG"), having its registered offices at Avenue Georges Lemaitre 25, 6041 Charleroi, registered with the Crossroads bank for enterprises under company number 0408.333.871. IPG is a specialist in anatomical pathology, clinical genetics and molecular and cell biology medical diagnosis. The genetic analysis of the tumor and/or the monitoring of biomarkers in your Samples will be performed by IPG, on behalf of BIO, the latter acting as the subcontractor of OncoDNA. The Results will be inserted by IPG in OncoDNA's database in a pseudonymised form (with the unique identifier), without disclosing your identity. BIO and IPG will not be able to link your Personal Data to you.
As soon as the data are available, they will be sent to OncoDNA. OncoDNA will then integrate and interpret all those findings in order to build the final report sent to your doctor.
Only your doctor and OncoDNA will be able to link the attributed identifier to your medical file.

REMAINING SAMPLES

Upon specific request, any slide made from the tumor tissue and any remaining part (**"Remaining Samples"**) may be returned to your doctor upon request made through **OncoSHARE®** or by sending an email at support@oncodna.com. In case the Test is ordered through an official distributor, the Remaining Samples may either be kept by OncoDNA or returned directly by OncoDNA, as part of the monthly samples batch, to OncoDNA's official distributor in charge of dispatching each sample to the hospital for storage or disposal (if any), based on the applicable local protocol.

4. HOW IS YOUR PRIVACY PROTECTED?

Who's the data controller?

The data controller responsible of the processing of your personal data is :
OncoDNA SA – Rue Louis Breguet 1, 6041 Charleroi, Belgium, registered with the crossroads bank for enterprises under company number 0501.631.837
Contact : **dpo@oncodna.com**

For which purpose do we process your personal data?

By signing or otherwise consenting to this ICF, you agree to the processing of the personal data related to you identified below (the **"Personal Data"**) for the purpose of performing the Test(s) chosen in the Declaration of Consent at the end of this ICF, generating the Reports, communicating the Reports to your doctor and realizing a follow-up of your treatment. As explained hereunder, you also have the possibility to consent that part of your Remaining Samples is used by OncoDNA or third parties for purely scientific research purposes.

What is the legal ground for processing your personal data ?

OncoDNA relies on your explicit consent to process your personal data, as foreseen by Article 6.1.a) and 9, §2, a) of the GDPR. You have the right to revoke your consent in writing at any time. Upon receipt of the written revocation, OncoDNA will (i) stop using or disclosing your Personal Data, except to the extent that OncoDNA has already taken action in reliance on the consent, and (ii) stop providing the Service, without prejudice to payment obligations as the case may be. To exercise this right, please send an email to **support@oncodna.com** or contact the Data Protection Officer, Nathalie Poupaert (**n.poupaert@oncodna.com**) together with a copy of your identity card or other identification document.

Which data will be processed?

The following categories of Personal Data will be collected and processed:

IF YOU ARE REGISTERED WITH OncoSHARE®:

- Personal Data relating to you as provided by you or generated by OncoDNA during the registration procedure to **OncoSHARE®** and the creation of your user-account or when updating the latter (**"Account Data"**): first and last names, username, interface language (optional), title (optional), gender (optional), email address, postal address (optional), birthdate (optional), patient unique number, password, access rights and log files;

IF YOU ARE NOT REGISTERED WITH OncoSHARE®, THE FOLLOWING PERSONAL DATA ARE COMMUNICATED BY YOUR DOCTOR:

- first and last names, patient unique number, as well as gender, birthdate, postal address, email address or phone number, depending of the available information.

IN ANY CASE:

- Personal Data relating to your health (**"Health Data"**):
- Diagnosis, cancer stage, primary site, diagnosis date, current site of metastases, collection date, previous systemic therapies, current therapy, relevant comorbidities, concomitant medications, biomarkers already tested, indication of possible change of doctor treatment decision on the basis of the Report, list of drugs given, indication of possible reaction to the treatment as well as any other relevant information with respect to (the treatment of) your condition;
- Clinical data post treatments (follow up), i.e. data relative to treatment, dosage, protocol, answer status ("complete response", "partial response", "progression disease", "stable disease"...), that could help to improve the predictive value of our data base to benefit for future patients;
- Reports;
- Results;

- Personal Data related to your use of the **OncoSHARE®** chat/forum: messages posted/sent, date and time of messages posted/sent.
- Identification and contact information related to your doctor.

You expressly agree to the processing by OncoDNA of your Health Data as listed above in this section 4 without the supervision of a health professional, for the purpose of performing the Tests and generating the Reports.

How long will the data be processed?

Your Account Data – if any – will be kept for as long as you remain registered with **OncoSHARE®** and will otherwise be suppressed within twelve (12) months from the deactivation of your **OncoSHARE®** user-account. The raw data generated by **OncoDEEP®** will be kept for 5 years, any other data will be incorporated in our database in a fully anonymized way without being deleted.

How do we protect your privacy?

Except with respect to your Account Data (if any), no Personal Data – including your Health Data – will be kept in a manner that enables your direct identification by anyone other than your doctor and OncoDNA.

Who will have access to your personal data?

As part of the service available to your doctor on **OncoSHARE®**, the latter may choose to disclose or share, through **OncoSHARE®**, any generated Report in relation to your Tests, to (i) you and/ or (ii) medical doctor specialized or not in the diagnosis and treatment of cancer collaborating with OncoDNA and the distributors of OncoDNA working with your medical doctor if required by the latter (the **"Expert Advisors"**), for advising purposes or in case the doctor has peculiar questions pertaining to such Expert Advisors' specialties with respect to your condition. In addition, the doctor may disclose anonymized Reports to other doctors registered with **OncoSHARE®**, to discuss and exchange medical expertise/opinion about a specific case.

Can we use your data or the remaining part of your sample for other purposes, such a research and development of our Tests?

You have the option to agree to the collection and processing of your Personal Data (including Health Data) and the remaining part of your sample by OncoDNA for the purpose of its integration in the existing OncoDNA database and further research program, so that OncoDNA may continue to improve upon its service delivery and provide more accurate and tailor-made services and Reports to other (future) cancer patients. In this respect, please note that the option to request a Test and receive a Report has been made possible by other cancer patients before you, who have consented to their data being included in the OncoDNA database and having it (re)used for the continued delivery of Reports to other fellow cancer patients. **You are entitled to revoke or withdraw your consent – if any - at any time, free of charge and without having to provide any justification.**

Subject to section 7, OncoDNA will not (a) collect, process and use your Personal Data and remaining part of your sample for other purposes than those indicated in this section 4 or (b) transfer your Personal Data or the remaining part of your sample to third parties, except the transfers (i) authorized or required under applicable law or (ii) as mentioned in this section 4 or elsewhere in this ICF. You also consent to the transfer of your Personal Data in the event OncoDNA sells or transfers all or a portion of its business or assets to a third party.

How do we protect your personal data in case of transfer of data outside of the European Economic Area?

To the extent that this involves the transfer of Personal Data to countries outside of the European Economic Area in countries not considered by the European Commission as ensuring an adequate level of personal data protection, OncoDNA shall ensure, by contractual means, that security measures are put in place in accordance with applicable laws relating to the protection of personal data *(as set out under section 8)*.

5. WHAT ARE THE FORESEEABLE BENEFITS LINKED TO TESTS? WHAT IS THE NATURE OF THE REPORT?

Your doctor will have access to the Reports which can be kept in your medical file.

However, OncoDNA draws your attention to the fact that the Reports do not constitute and are not intended to replace independent medical judgment and advice. The Reports merely constitute one element among all applicable information concerning the patient's condition (such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences) to assist doctors in the determination or adaptation of your medical treatment. Your doctor solely and exclusively decides whether (and to what extent) to take into consideration the Reports with respect to your treatment.

Consequently, OncoDNA assumes no liability whatsoever as to the possible consequences of the decision of your doctor to follow or not the (content of) the Reports. By signing or otherwise consenting to this ICF, you expressly declare and acknowledge having understood and agreed to OncoDNA's exclusion of liability as stated in this section 5.

6. WHAT IS THE PRICE OF THE TESTS?

The Tests may only be ordered by your doctor, directly or through the intermediary of an OncoDNA official distributor, on **OncoSHARE®**. In consideration of the performance of the Tests, you (or your doctor, acting on your behalf) will be required to pay the Tests price, the amount of which depends on the type of Test chosen (the **"Price"**).

Subject to other instructions communicated by OncoDNA and in accordance with the **OncoSHARE®** General Terms and Conditions (available on oncoshare.com), any payment must be made by credit card or wire transfer.

In case your doctor pays the Price to OncoDNA or an official distributor, such Price will be invoiced to you afterwards.

By signing or otherwise consenting to this ICF, you acknowledge and agree (i) that the Tests constitute a payable service and (ii) to pay the Price, (a) either indirectly to your doctor, hospital or medical institution or (b) directly to OncoDNA or the official distributor.

No Guarantee of Reimbursement: OncoDNA makes no promises or guarantees that a healthcare provider, insurer or other third party payor, whether private or governmental, will reimburse you for the cost of the Tests.

7. CAN YOUR SAMPLES, REMAINING SAMPLES AND PERSONAL DATA BE USED IN THE FRAMEWORK OF RESEARCH STUDIES/CLINICAL TRIALS?

OncoDNA may conduct internal research studies and may participate to research studies and/or clinical trials with third parties. In such context, OncoDNA may process and disclose selected Personal Data – including Health Data – to accredited research centers/institutes and competent authorities for biomedical researches purposes. Your separate written informed consent might be required according to the applicable law.

Subject to very strict conditions required by law, OncoDNA might also use or send to third parties, for purely scientific research purposes, part of your Remaining Samples that is not necessary for your diagnostic and might therefore be destroyed. In accordance with the applicable law, OncoDNA shall in this circumstance keep a sufficient part of the Remaining Sample in order to establish, ameliorate or complete your diagnostic or treatment. If you refuse that part of your Remaining Samples is used by OncoDNA or third parties for purely scientific research purposes, please inform OncoDNA using the contact details described under section 9.

You are entitled to revoke your consent – if any - at any time, free of charge and without having to provide any justification.

8. WHAT IS THE APPLICABLE LEGISLATION ?

OncoDNA shall provide the Tests and related services as described in this ICF in compliance, where applicable, with the following legislation:

- The EC Data Protection Directive (Directive 95/46/EC), as transposed into national law by the relevant EU Member States, and as this will be replaced by the General Data Protection Regulation (Regulation 2016/679) («GDPR») on 25 May 2018, as this regulation may be amended, repealed, replaced or updated from time to time; and
- Belgian Law of 22 August 2002 relating to patient rights, as modified;
- Belgian Law of 5 July 1994 relating to blood and blood derivatives of human origin, as modified;
- Belgian Law of 7 May 2004 concerning experiments on the human person, as modified;
- Belgian Law of 19 December 2008 on obtaining and using human body material intended for human medical applications or for scientific research purposes, and its implementing Royal Decrees, as modified.

9. YOUR RIGHTS

In accordance with the Article 15 to 20 of GDPR, you have the right to:

- Access to your personal data, as collected and processed by OncoDNA;
- Request the rectification or erasure of personal data relating to you;
- Request the restriction of processing concerning you or object to processing;
- Data portability, namely the right to receive the personal data concerning you, which you have provided to a controller, in a structured, commonly used and machine-readable format and the right to transmit those data to another controller;
- Request that OncoDNA provide you a copy of the personal data undergoing processing. For any further copies requested, OncoDNA may charge a reasonable fee based on administrative costs.

To exercise these rights, please send an email to support@oncodna.com or contact the Data Protection Officer, Nathalie Poupaert (dpo@oncodna.com) or at the postal address of OncoDNA SA (Rue Louis Breguet 1, 6041 Charleroi, Belgium), together with a copy of your identity card or other identification document.

Moreover, you have the right to lodge a complaint before the Supervisory Authority, i.e. the Belgian Data Protection Authority, either by postal means at Rue de la Presse 35, 1000 Brussels, or by email at commission@privacycommission.be or by telephone at +32 2 274 48 00.