OFFICIAL DOCUMENT

Informed consent form

The purpose of this **informed consent form** (**« ICF »**) is to provide you with detailed information about OncoDNA's range of molecular profiling solutions: **OncoDEEP**, **OncoSTRAT**, **OncoSELECT** and the **Monitoring Solution** (**« Test »**) so that you can freely consent to its performance. This ICF must be completed, signed and returned to OncoDNA prior to the Test being performed. The content of this ICF shall be presented to you and explained by your medical doctor or the staff in charge of your medical file. Feel free to ask any questions you may have and take the time to think about it before making your decision. A copy of this ICF must be given to you. Your decision must be voluntary and thoughtful. If you choose to refuse to have the Test performed, even if it has been (strongly) advised by your medical doctor, this decision will no way impact the quality of your care, going forward.

This page must be separated from the rest of this ICF and be sent to OncoDNA.
The following pages must be kept by you or your medical doctor.

I, undersigned (FIRST NAME and FAMILY NAME in capital letters) : .....

and/or barcode of the collection kit : .....

Confirm that:

1. I have read this ICF relating to the selected Test (or that is has been read to me) (last updated on October 2nd, 2020).
2. I had the chance to ask appropriate questions and to receive satisfactory answers from my medical doctor or the medical team in charge of my medical file to understand the entire content of this ICF.
3. I have been given sufficient time to understand the content and hereby provide my informed consent.
4. I have understood the following:
   a. My samples and personal data will be sent by my medical doctor to OncoDNA;
   b. My samples and personal data will be processed by OncoDNA, Bio.be, IPG or any other service provider, previously evaluated and selected by OncoDNA, as described in Section 2;
   c. I can withdraw my consent at any time and free of charge, as mentioned in Section 7;
   d. The performance of the Test may lead to the detection of genetic anomalies likely to be inherited. In this case, my medical doctor will be informed by OncoDNA to recommend me, as well as my family, the corresponding genetic counseling;
   e. The content of my Report - written in English - will be communicated and explained to me by my medical doctor in a consultation;
   f. OncoDNA assumes no liabilities for the possible consequences relating to your medical doctor's decision to follow or not follow the therapeutic recommendations in the Report, as described in Section 3.

In addition:

MANDATORY: please, check the appropriate box for the 7 following finalities:

1. I authorize the processing of my Samples and personal data (identified in Section 4) by OncoDNA, without the supervision of a health professional and as defined by the applicable law. **YES - NO**

2. I authorize my medical doctor to send my Samples to OncoDNA so that the selected Test is carried out. **YES - NO**

3. When the Test Report has identified a treatment that is still under development, I authorize OncoDNA to contact my medical doctor to put him/her in contact with pharmaceutical companies and/or centers that carry out clinical trials to assess the relevance of my participation in these trials. **YES - NO**

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4. In order to continue to improve the quality and accuracy of the Tests and Reports for future patients, I authorize my medical doctor to provide to OncoDNA with his/her therapeutic decision and post-treatment clinical data once the test is completed. **YES - NO**

5. In order to provide increasingly accurate and personalized services and Reports, I authorize OncoDNA to integrate, in an anonymous way, my Analysis Results and post treatment clinical data into its database. *In this respect, please note that this database has already been enriched with data from previous patients who have consented to its integration and reuse to improve the Tests and Reports for the future patients.* **YES - NO**

6. In order to continue to improve the quality and accuracy of the Tests and Reports for future patients, I authorize OncoDNA and/or its partners to use my pseudonymized Residual Samples for scientific purposes and/or to participate to clinical trials. **YES - NO**

7. In order to allow the approval of the OncoDNA's Tests and services according to the regulatory and/or normative requirements of third countries, I authorize OncoDNA to use my pseudonymized Residual Samples for validation purposes specific to the territory concerned. **YES - NO**

Date (dd/mm/yyyy) : .....

Patient's signature : .....

WITNESS (A WITNESS IS REQUIRED SOLELY IF THE PATIENT OR HIS/HER LEGAL REPRESENTATIVE IS PHYSICALLY OR LEGALLY INCAPABLE OF GIVING CONSENT)

I confirm that I have no connection to OncoDNA and that the information contained in this ICF has been provided to the subject appropriately.

Name of the witness : .....

(FIRST NAME and FAMILY NAME in capital letters)

Date (dd/mm/yyyy) : .....

Signature of the witness : .....

HOW TO RETURN THIS FORM TO ONCODNA?

OPTION 1	IN THE COLLECTION KIT TOGETHER WITH THE SAMPLE
OPTION 2	BY E-MAIL AT PATIENTCONSENT@ONCODNA.COM
OPTION 3	BY SMS/MMS AT 0032 499 89 01 55

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1. BASIC INFORMATION ON THE TESTS

When a cancer develops, some modifications of the DNA and proteins appear leading to a dysfunction of the cells, which induces cancer. Each cancer type and each patient present a unique set of modifications that induces a different response to the existing cancer treatment. The Tests aim to identifies these modifications from a **sample of tumor tissue and/or blood sample** (**« Sample »**) to provide the medical doctor with personalized recommendations on the treatment decision for the patient. These recommendations are presented in a **report** (**« Report »**).

OncoDEEP identifies the modifications of the DNA and proteins from a Sample of tumor tissue. In addition, it analyses several markers related to the tumor progression. This Test can guide the medical doctor in the decision-making with respect to the treatment (chemotherapy, targeted therapy or immunotherapy).

OncoSELECT detects the modifications of the DNA from a simple blood Sample to identify resistance and sensitivity to the existing treatments as well as following the disease evolution.

OncoSTRAT&GO identifies the modifications of the DNA or RNA as well as proteins from a Sample of tumor tissue and a blood Sample to obtain a more comprehensive characterization of the tumor. This Test can guide the medical doctor in the decision-making with respect to the treatment (chemotherapy, targeted therapy or immunotherapy).

Monitoring Solution identifies the modifications of the DNA from a simple blood Sample. It allows to monitor the patient response to the ongoing treatment as well as the possible relapse. This Test is personalized for each patient since it analyses specific markers previously identified in a former genomic testing.

Moreover, the performance of the Test may lead to the detection of genetic anomalies likely to be inherited. In this case, your medical doctor will be informed by OncoDNA to recommend you, as well as your family, the corresponding genetic counseling.

2. WHAT ARE THE STEPS OF THE TEST PERFORMANCE?

OBTAINING THE INFORMED CONSENT

If you wish to complete the Test, you must give freely your consent by completing, signing and sending this ICF to OncoDNA before the beginning of the performance of the Test.

TEST REQUEST ON OncoSHARE

The Test request is to be made on the **OncoSHARE** platform (**www. oncoshare.com**). The Test can only be ordered by a medical doctor, directly or via the official distributor of OncoDNA (if any).

SAMPLE SHIPMENT

Your Sample will be identified by a unique barcode and placed in a collection kit by the medical staff to be sent to OncoDNA. This unique barcode ensures the traceability of your Sample throughout the Test performance.

TEST PERFORMANCE

The Sample is received by OncoDNA and forwarded to its subcontractor Bio.be S.A. or any other service provider, previously evaluated and selected by OncoDNA. Bio.be has its registered office at Avenue Georges Lemaître 25, 6041 Gosselies, Belgium and is registered at the Crossroads bank for enterprises under the company number 0861.738.595. The Test is carried out by Bio.be's mother company, the Institute of Pathology and Genetics ASBL (**« IPG »**) having its registered office at Avenue Georges Lemaître 25, 6041 Gosselies, Belgique and registered at the Crossroads bank for enterprises under the company number 0408.333.87. IPG is a specialized institute in pathological anatomy, clinical genetics and molecular diagnostics. The Analyses Results are transferred by IPG to OncoDNA.

REPORT CREATION

Thanks to its database, OncoDNA interprets the Analyses Results to draft the Report (in English) which is shared with your medical doctor on the **OncoSHARE** platform.

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EXPLANATION AND ACCES TO YOUR REPORT

The Report (drafted in English) is directly shared with your medical doctor on the OncoSHARE platform. The content of the Report shall be explained to you by your medical doctor in a consultation. To access to the Report, you shall send a request to your medical doctor. Your access to the Report shall be granted to you at the discretion of your medical doctor.

1 Any unused blood Sample is destroyed as soon as the medical doctor receives the Report. Any Sample of residual tumor tissue (**« Residual Sample »**) is returned to your medical doctor periodically or upon request. This request can be made directly by your medical doctor or via the official distributor (if any). If the Test has been ordered by the official distributor on behalf of your medical doctor, the Residual Sample is sent by OncoDNA to the official distributor in charge of dispatching each Sample to the original hospital or laboratory.

2 With your consent, OncoDNA can contact your medical doctor to be informed on the treatment decision which has been made based on the recommendations in the Report as well as your response status to the selected treatment.

3. WHAT IS THE NATURE OF THE REPORT?

Your medical doctor can keep the Report in your medical file. Nevertheless, OncoDNA draws your attention on the fact that the Report does not constitute and are not intended to replace an independent medical judgment and decision. The Report is merely one element among all available information regarding your health condition. All this information is essential and shall be considered by your medical doctor for the decision-making about the treatment. Therefore, your medical doctor will determine, as the sole responsible, whether to take or not to take the Report into account in the final therapeutic decision.

Consequently, OncoDNA assumes no liability for the possible consequences relating to your medical doctor's decision to follow or not follow the therapeutic recommendations in the Report.

4. HOW ARE MY PERSONAL DATA PROCESSED BY ONCODNA?

What personal data are processed?

- The Sample identified by a unique barcode
- **Personal data related to your OncoSHARE account (« Account Data »)**: first and last name, contact information of the medical doctor who ordered the Test, e-mail address (optional), phone number (optional). These data are entered by you or your medical doctor or the official distributor of OncoDNA (if any).
- **Personal data related to your health (« Health Data »)** completed in the OncoSHARE clinical form: sex, date of diagnosis, diagnosis, site of primary tumor, site of metastases, stage of cancer, date of biopsy/surgery, origin of sample, histological diagnosis (optional), indication on TNM (optional), any relevant information on the sample (optional), biomarkers already tested (optional), relevant comorbidities (optional), concomitant therapies (optional), previous systemic treatments (optional), current treatment (optional), future treatment plan (optional), any other relevant information related to the treatment and/or pathology (optional), ECOG status (optional), smoking status (optional), alcohol consumption (optional). These data are entered by your medical doctor or the official distributor (if any).
- **Post-treatment clinical data (« Follow-up Data »)**: the therapeutic decision of your medical doctor based on the Report, dosage of treatment, protocol followed, status of clinical response (complete response, partial response, evolving disease, stable disease, etc.), ECOG status and, any other anonymous data that may improve the predictive value of the OncoDNA's database for the future patients. With your consent, these data are provided by your medical doctor to OncoDNA, directly or via the official distributor (if any). This follow-up is done periodically (approximately every three months).
- **Results of analyses (« Analyses Results »)** such as immunohistochemical, sequencing and pathology analyses. With your consent, these data are integrated, in an anonymous way, into the OncoDNA's database to enhance its knowledge and, to provide increasingly accurate and personalized services as well as reports to future patients.

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- The Report elaborated through the interpretation of all the Analyses Results and that presents personalized recommendations with respect to the treatment options to the patient (drug with or without potential clinical benefit, drug associated to unknown clinical benefit, drug with potential toxicity and potential clinical trials).
- **Personal data related to your use of OncoSHARE messaging, chat and service (« Chat Data »)**: messages sent, date and time of the messages sent, e-mail and/or phone number (optional).

How long will your personal data be kept?

- Any unused blood Sample is destroyed as soon as the medical doctor receives the Report. Any Residual Sample is kept for up to two years before being returned to your medical doctor, periodically or upon request. With your consent, your Residual Sample can be kept the time required to conduct scientific researches studies and/or validations.
- Health Data, Follow-up Data and Analysis Results are kept the time required to perform the Test and to provide the services (for instance, the scientific support to your medical doctor, the update of the Report with the latest scientific publications, the monitoring of your response to the treatment). With your consent, these data may be kept, in an anonymous way, for an unlimited period to enrich the OncoDNA's database, and to provide increasingly accurate and personalized services and Report. *In this respect, please note that this database has already been enriched with data from previous patients who have consented to its integration and reuse to improve the Tests and Reports for the future patients.*
- The Report is kept the time required to provide the services (for instance, the scientific support to your medical doctor, the update of the Report with the latest scientific publications, the monitoring of your response to the treatment).
- Account Data and Chat Data are kept as long as your OncoSHARE account remains active and are deleted no later than one month after your unsubscription.

Who can access my personal data?

- Your Sample is available to the authorized and trained members of OncoDNA as well as those of its service providers and the official distributor (if any). With your consent, your Residual Sample can be used by OncoDNA and its partners in scientific research and/or validation.
- Your Account Data are available to your medical doctor, the authorized and trained members of OncoDNA as well as those of its official distributor (if any) to update your OncoSHARE account data and associate it to the selected Test.
- Health Data are available to your medical doctor, the authorized and trained members of OncoDNA as well as those of its official distributor (if any) to update the clinical information required to complete the selected Test.
- Follow-up Data are provided by your medical doctor, with your consent, to the authorized and trained members of OncoDNA and those of its official distributor (if any) for updating purposes.
- Analyses Results provided to OncoDNA by IPG or any other service provider, previously evaluated and selected by OncoDNA. These data are available to the authorized and trained members of OncoDNA to be interpreted and elaborate the Report.
- The Report published on the OncoSHARE platform is available to your medical doctor, the authorized and trained members of OncoDNA as well as those of its official distributor (if any) to periodically update its content with the latest scientific publications, potential clinical trials and to provide an answer to the possible questions of your medical doctor. With the prior authorization of your medical doctor, the Report can be shared with you, via your OncoSHARE account, by the authorized and trained members of OncoDNA and those of the official distributor (if any), or directly by your medical doctor. Moreover, your medical doctor can share your report on OncoSHARE with other **health professionals (« Expert Advisors»)**, in an anonymous way, for advising purposes and exchange medical expertise with respect to your treatment.
- Chat Data are available to the authorized and trained members of OncoDNA to handle your questions and/or requests. These data can be forwarded by OncoDNA to the official distributor (if any) in charge of answering your questions and satisfying your requests.

With your consent, OncoDNA can process and disclose your Health Data, Follow-up Data and Analyses Results to accredited research centers/institutes and competent authorities for biomedical researches purposes and/or to participate to clinical trials.

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Who is the data controller?

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

What are the purposes of your personal data processing?

- To perform the Test in order to elaborate the Report and to provide you with the related **OncoSHARE** services.
- To put your medical doctor in contact with pharmaceutical companies or clinical trial centers to assess the relevance of your participation in these clinical trials, when the Report has identified a treatment that is still in clinical development.
- To integrate the Analyses Results and Follow-up Data, in an anonymous way, into the OncoDNA's database to enhance its knowledge and to provide increasingly accurate and personalized reports and services to future patients.
- To conduct scientific research studies and/or to participate in clinical trials related to cancer treatment.
- To carry out validation analyses according to regulatory and/or normative requirements specific to third countries.

Your personal data and Residual Sample will not be processed or transferred to third party for other purposes than those indicated in this section, except for transfers (i) that are legitimate and authorized (such as in the event OncoDNA sells or transfers all or part of its business or assets to a third party) or (ii) required by law or (iii) as mentioned elsewhere in this ICF. In this case, OncoDNA will inform you prior to such transfer of your personal data and Residual Sample.

What is the legal basis for the processing of 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 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC

5. HOW ARE YOUR PRESONAL DATA PROTECTED?

- OncoDNA has put in place the necessary technical and organizational measures to ensure the integrity, confidentiality and appropriate security of your personal data, including their protection against unauthorized or illegal treatment, and their loss, destruction or accidental damage.
- OncoDNA complies with the general principles of data protection: transparency of processing, compliance with defined purposes, limitation of the data collection under the defined purposes, accuracy of the data processed, limitation of the data conservation and appropriate security of the data.

How are my personal data protected in case of transfer outside the European Economic Area?

In the event of the transfer of your personal data to a country outside the European Economic Area, in countries not considered by the European Commission as ensuring an adequate level of personal data protection, OncoDNA will ensure by contractual means that the necessary and adequate measures required by privacy legislation are taken before the transfer of personal data is completed.

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6. WHAT IS THE APPLICABLE LEGISLATION?

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

- **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016** on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (**« GDPR »**);
- Belgian Law of 30 July 2018 implementing GDPR, relative to the protection of natural persons with regard to the processing of personal data;
- 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.

7. WHAT ARE MY RIGHTS?

You have the right to withdraw your consent in writing, at any time and free of charge. To exercise this right, contact the Data Protection Officer by e-mail at dpo@oncodna.com or at the postal address of OncoDNA (rue Louis Breguet 1, 6041 Gosselies, Belgium) with a copy of your ID card or other identification document. Upon receipt of the written revocation, OncoDNA (i) will stop using your personal data, unless OncoDNA has already taken action on the basis of this consent, and (ii) will stop providing the service, without prejudice of the payment obligations as the case may be.

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

- 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 relating to you, which you have provided to OncoDNA, in a structured, commonly used and machine-readable format and the right to transmit those data to another data 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, contact the Data Protection Officer by e-mail at dpo@oncodna.com or at the postal address of OncoDNA (rue Louis Breguet 1, 6041 Charleroi, Belgium) with a copy of your ID card or other identification document.

In addition, you have the right to lodge a complaint with the Belgian Data Protection Authority by postal means at Rue de la Presse 35, 1000 Brussels, Belgium or by e-mail at contact(at)apd-gba.be or by phone: +32 2 274 48 00.

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