

PATIENT CONSENT FOR TISSUE ACQUISITION

PATIENT IDENTIFICATION INFORMATION

First Name

Last Name:

Address:

Date of Birth:

I instruct Oncologica to approach the following hospital/s;

1)..... (the main hospital where the biopsy or surgery has been performed)

Any additional hospitals where the patient has received treatment or had further biopsies:

2).....

3).....

to request the release of tumor tissue sample(s) (whether in formalin-fixed paraffin-embedded (“**FFPE**”), slide or block form) and any pathology reports to Oncologica UK Limited (“Oncologica”) for use for testing as indicated on the test request form that accompanies this consent.

Although it is unlikely that the DNA sample or tumour in the block(s) would be exhausted (meaning that the entire biopsy is destroyed in the process of extracting the DNA required) I understand that if this does occur, further testing may not be possible on the sample(s) submitted.

I agree to the provision of my personal information (name, date of birth, gender, phone number and a copy of the pathology report) to the Oncologica testing facility as required to process this request.

All the questions I have asked regarding the nature of the information that will be disclosed have been answered in a satisfactory manner and I confirm that I have read and agreed with the Oncologica terms and conditions as set out on the back of this form.

I consent to the release of the information to Oncologica who will be testing the sample/tissue.

I confirm that I the patient, have read and agree to the personal information submitted on the completed Oncologica test request form and I consent to the release of the Oncologica report to the email address/es given on the Oncologica test request form.

Patient signature..... Date.....

Witness' signature Date.....

Oncologica Test Terms and Conditions

1. DEFINITIONS

In these Terms and Conditions, the following definitions apply:

Agent: a sales agent engaged by Oncologica to seek orders for the Oncologica Test.

Charges: the charges payable by the Patient for the Oncologica Test, including costs of collecting the Sample.

Consent Form: the consent form signed by the Patient to authorise Oncologica to request the pathology reports and samples from the designated hospital and to carry out the Oncologica Test.

Contract: the contract between Oncologica and the Patient for the sale and purchase of the Oncologica Test.

Data Protection Legislation: all applicable laws and regulations relating to the processing of personal data and privacy, including the General Data Protection Regulation 2018 and the Data Protection Act 2018 as may be amended or replaced from time to time.

Insured Patient: a Patient whose Oncologica Test is paid for by a private commercial health insurance company including but not limited to BUPA, AXA PPB, Vitality Health, Aviva;

Oncologica: Oncologica UK Ltd registered at Suite 15-16, Science Village, Chesterford Research Park, Cambridge CB10 1XL in England and Wales with company number 09305104.

Patient(s): the person for whom the Oncofocus Test is ordered, and who is identified on the Patient Test Request Form

Patient Test Request Form: Oncologica's patient test request form completed by the Patient or the Patient's physician

Personal Data: has the meaning given to it in the Data Protection Legislation.

Oncologica Test Report: the final report in .pdf format produced by Oncologica showing the data produced by the Oncologica Test.

Sample: the sample of tissue required to enable Oncologica to provide the Oncologica Test.

Self-Funding Patient: any Patient who pays Oncologica or an Agent for the Oncologica Test other than through a private commercial health insurance company

Terms and Conditions: these Oncologica terms and conditions of sale

Oncologica Test(s): (a) the precision oncology test known as the "Oncofocus Test"; (b) the Immunofocus test to predict response to Anti-PD-1/PD-L1 directed immunotherapy, known as the "Immunofocus Test"; and (c) any other tests relating to guidance on treatment.

Working Day: a day other than a Saturday, Sunday or public holiday in England.

2. FORMATION OF CONTRACT

2.1 The Patient Test Request Form constitutes an offer by the Patient to purchase an Oncologica Test in accordance with these Terms and Conditions.

(a) The Patient Test Request Form shall be deemed to be accepted only when Oncologica receives payment from the Self-Funding Patient or, if the Self-Funding Patient has submitted the Patient Test Request Form through an Agent, when Oncologica receives payment of the Charges from the Agent. On receipt of such payment, the Contract shall come into existence to include these Terms and Conditions and the Oncologica Test will be performed by Oncologica.

(b) The Patient Test Request Form shall be deemed to be accepted only when Oncologica receives confirmation of the authorisation code of the private commercial health insurance company from an Insured Patient, or if the Insured Patient has submitted the Patient Test Request Form through an Agent, when Oncologica receives confirmation of the authorisation code from the Agent. Once the authorisation code is received by Oncologica, the Contract shall come into existence, to include these Terms and Conditions and Oncologica will perform the Oncologica Test, and either the Insured Patient or the Agent is responsible for payment of the Charge within the time period set out in the Oncologica invoice.

2.2 These Terms and Conditions govern the sale and supply of the Oncologica Test and the Oncologica Test Report to the exclusion of all other terms and conditions of business, including any that the Patient may provide, and any terms implied by law, custom or practice to the maximum extent permitted by law. These Terms of Sale shall apply whether the Patient purchases the Oncologica Test directly from Oncologica or through an Agent.

2.3 The Patient acknowledges that it has not relied on any statement, promise, representation, assurance or warranty made or given by or on behalf of the Agent or Oncologica which is not set out in the Contract. In particular, any marketing materials issued by the Agent or Oncologica, and any descriptions or illustrations contained in Oncologica's catalogues or brochures shall not form part of the Contract or have any contractual force.

3. THE ONCOLOGICA TEST

3.1 Oncologica will include the Oncofocus Test and the Immunofocus Test as one bundle.

3.2 Oncologica shall analyse the Sample to check its suitability for the Oncologica Test. If the Sample does not meet Oncologica's requirements at this pre-assessment stage, then, Oncologica shall inform the Patient or Agent and if a replacement Sample is provided, Oncologica shall again analyse the Sample, and confirm whether such replacement Sample meets Oncologica's requirements.

3.3 If neither the first Sample nor any replacement Sample meets Oncologica's requirements at the pre- assessment stage: then if Oncologica has received payment direct from the Patient, Oncologica shall refund the Charges to the Patient, less the pre -assessment costs which is 10% of the Charges. (If Oncologica has received payment from an Agent for the Oncologica Test, it shall refund the Agent and the Agent shall refund the Patient.)

3.4 If the Sample progresses through the pre-assessment stage and then fails the analysis stage then Oncologica will repeat the Oncologica Test, to attempt to obtain a result, at no extra cost to the Patient. If the Oncologica Test fails to yield results for a second time, the Patient will be given the option to have an additional Sample tested or receive a partial refund which will be assessed based on the work already completed. If this repeat Oncologica Test fails to yield results then there will be no refund.

3.5 If the Sample fails to meet Oncologica's requirements for the Oncofocus Test but meets the requirements of the Immunofocus Test, then if Oncologica has received payment direct from the Patient, Oncologica shall refund the Charges to the Patient, less the pre-assessment costs and less the Immunofocus Test (If Oncologica has received payment from an Agent for the Oncologica Test, it shall refund the Agent and the agent shall refund the Patient).

3.6 Oncologica warrants to the Patient that it shall carry out the Oncologica Test and prepare the Oncologica Test Report with reasonable care and skill.

3.7 Subject to Clause 3.1 to 3.5, Oncologica shall use reasonable endeavours to carry out the Oncologica Test within 15 Working Days of receipt of the Sample and payment of the Charges but time shall not be of the essence.

3.8 Following completion of the Oncologica Test, Oncologica shall send the Oncologica Test Report in pdf. format to the Patient if requested by the Patient and/or Patient's Physician. No intellectual property rights in the Oncologica Test Report shall transfer to the Patient and/or Patient's Physician.

3.9 The Patient or Patient's physician shall not amend or change the Oncologica Test Report.

3.10 Oncologica shall, return the Sample to the Patient's hospital.

4. CHARGES AND PAYMENT

4.1 Oncologica shall have no obligation whatsoever to the Patient until payment has been received in accordance with Clause 2.1 (a) or the authorisation code has been received in accordance with 2.1(b).

4.2 All amounts payable by the Patient under the Contract are exclusive of value added tax. If any value-added tax is due on the all or part of the Charges, the Patient shall pay such value-added tax.

4.3 Oncologica makes no warranty or representation that any third party, including any governmental healthcare program, will pay for the Oncologica Test.

4.4 Oncologica may charge the Patient if the hospital charges a fee for retrieval of the Sample from the pathology archives.

5. DATA PROTECTION

5.1 The Patient hereby explicitly acknowledges that Oncologica shall collect its Personal Data within the Patient Test Request Form, from the Patient and/or Agent and otherwise when carrying out the Oncologica Test. The Patient hereby explicitly consents to the processing by Oncologica of its Personal Data in order to carry out the Oncologica Test, prepare the Oncologica Test Report and fulfil its obligations under the Contract.

5.2 Oncologica shall comply with its obligations under the Data Protection Legislation in relation to a Patient's Personal Data, and in particular, shall treat all Personal Data of a Patient as confidential and shall maintain appropriate technical and organizational measures against unauthorized or unlawful processing of Personal Data and against accidental loss or destruction of or damage to Personal Data. If, in the unlikely event that Oncologica believes that the security of a Patients' Personal Data in Oncologica's possession or control may have been compromised, Oncologica may notify the Patient and shall use all reasonable endeavors to manage the situation and prevent further security compromises.

5.3 Oncologica shall be entitled to disclose a Patient's Personal Data to:

(a) service providers and subcontractors, including affiliates, retained to perform functions on behalf of Oncologica, or to provide services such as delivery and collection of the Sample, payment and refund processing;

(b) a person or entity, including affiliates, in the event of a sale, merger, consolidation or change of control of Oncologica; and

(c) a court, governmental or regulatory agency, or other third party in order to comply with applicable law or to audit compliance with our corporate policies, procedures, legal, or contractual obligations.

5.4 We will not transfer your personal data to any third parties unless we have your consent to do so and it is otherwise authorised under the Data Protection Legislation. Any such consent to a representative on your behalf receiving the Oncologica Test Report must be named by the Patient on the Consent Form.

6. LIABILITY – THE PATIENTS ATTENTION IS DRAWN PARTICULARLY TO THIS CLAUSE.

6.1 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

6.2 The Oncologica Test Report contains drug and clinical trial information. However, Oncologica does not warrant or represent that any drug or clinical trial identified by the Oncologica Test will guarantee a therapeutic response for a Patient or the Patient will have access to any such drug or clinical trial. The drugs listed in an Oncologica Test Report are ranked on clinical evidence as to the predicted efficacy or appropriateness for the Patient. The Patient shall ensure that its physician shall evaluate and interpret the Oncologica Test Report and investigate access to any drug or clinical trial identified by the Oncologica Test, along with all other available clinical information about the Patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, nor solely on the information contained in the Oncologica Test Report.

6.3 Subject to paragraph 6.9, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Test, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient's physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient's physician's professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician's use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient's physician.

6.4 Oncologica does not warrant or represent or guarantee that the Oncologica Test will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Test are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patients' cancer. **In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.**

6.5 The Oncologica Test identifies somatic genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also, note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline variants (those which are acquired sporadically rather than inherited from birth).

6.6 Information compiled in the Oncologica Test Report includes data from publicly available sources as well as proprietary sources. By updating the source database, Oncologica makes every effort to provide the most accurate and up-to-date information to the best of Oncologica's knowledge.

6.7 Subject to Clause 6.9, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:

(a) error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;

(b) loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;

(c) indirect or consequential loss (including lost profits, loss of revenue or sales, loss of use, diminution of goodwill, business interruption or the like) arising whether or not Oncologica has been informed or advised of the possibility of such losses.

6.8 Subject to the provisions of this Clause 6, Oncologica's total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Oncologica Test that is the subject of the claim.

6.9 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.10. If the Patient is a consumer (and not a business), then notwithstanding any other provisions of the Contract, none of the Patient's consumer statutory rights are affected.

6.11 The Patient expressly acknowledges and agrees that there is no right to cancel the Oncologica Test if the Sample has passed the pre-assessment stage to establish suitability for testing and the Sample has entered the processing stage.

6.12 In the event of the unfortunate circumstances of the death of the Patient after the Sample has passed the pre-assessment stage then no refund will be possible. Only in the event that the Patient has named a representative to receive the report on their behalf on the Consent Form, will the report be sent to that named representative.

6.13 If the Patient requests details of a Physician who may provide a second opinion on the Oncologica Test Report, (the Referral Physician), Oncologica may if applicable provide such contact details to the Patient and does not warrant or guarantee that such Referral Physician will provide a consultation to the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Referral Physician and the access to treatment or a clinical trial is solely that of the Referral Physician. The Patient expressly acknowledges and agrees that the Patient is responsible for contacting the Referral Physician and for organising the consultation and that Oncologica has no responsibility for the referral or outcome of the referral process.

7. FORCE MAJEURE

7.1 For the purposes of the Contract, Force Majeure Event means an event beyond the reasonable control of Oncologica including but not limited to strikes, lock-outs or other industrial disputes (whether involving the workforce of Oncologica or any other party), failure of a utility service or transport network, act of God, war, riot, civil commotion, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood, storm or default of suppliers or subcontractors.

7.2 Oncologica shall not be liable to the Patient as a result of any delay or failure to perform its obligations under the Contract as a result of a Force Majeure Event.

7.3 If the Force Majeure Event prevents Oncologica from carrying out the Oncologica Test for more than 4 weeks, Oncologica shall, without limiting its other rights or remedies, have the right to terminate the Contract immediately by giving written notice to the Patient.

8. GENERAL

8.1 Oncologica may at any time assign, transfer, mortgage, charge, subcontract or deal in any other manner with all or any of its rights under the Contract and may subcontract or delegate in any manner any or all of its obligations under the Contract to any third party or agent.

8.2 If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of the Contract.

8.3. A waiver of any right under the Contract or law is only effective if it is in writing and shall not be deemed to be a waiver of any subsequent breach or default. No failure or delay by a party in exercising any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict its further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

8.4 A person who is not a party to the Contract shall not have any rights to enforce its terms.

8.5 The Contract, and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be governed by, and construed in accordance with the law of England and Wales. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with the Contract or its subject matter or formation (including non-contractual disputes or claims).

8.6 We may amend these Terms and Conditions at any time to ensure that Oncologica remains compliant with relevant laws and regulations and to ensure that we are constantly improving your experience in using our services, so please ensure that you check our Terms and Conditions frequently. By continuing to use our services after any changes are made, you accept those changes and will be bound by them.

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