

# Patient Notice and Consent for Molecular Profiling and Data Transfer

## European Economic Area and Switzerland



This notice and consent form ("Notice") provides you information on how Caris MPI, Inc. d/b/a Caris Life Sciences ("Caris"), a specialized clinical laboratory operating in Phoenix, Arizona, USA, will process your personal data.

### Use, processing, transfer and disclosure of your specimen and personal data

Caris will process your personal data set for the purposes of tumor molecular profiling (Caris Molecular Intelligence<sup>®</sup>). As part of your care, your healthcare provider has recommended that a biological specimen from you be assessed to provide a unique molecular profile. The "molecular profile" for an individual's tumor or cancer consists of certain DNA, RNA or proteins that are referred to as "biomarkers," which may be present in cells, tissue or blood samples obtained from you. Different biomarkers associate with different therapeutics or drugs. Caris performs a series of tests to identify the unique biomarkers in your tumor, and this information may in turn help your healthcare provider with additional options to treat your cancer based on its molecular profile (this is commonly referred to as "targeted therapy" or "personalized treatment"). The molecular profiling results and interpretations are intended to supplement and not be a substitute for your physician's medical judgment or advice. There is no guaranteed benefit from having such testing performed.

Your specimen (biopsy, tissue or blood sample) along with your personal data will be sent by your healthcare provider, acting as the data controller of such data, to Caris in the United States where the tumor profiling tests are performed. As the data controller of your personal data, your healthcare provider is required by the GDPR to provide certain notices to you.

Caris acts as data processor (or equivalent term under local law) for your personal data. As a data processor for your healthcare provider, Caris is restricted both by applicable Data Protection Laws<sup>1</sup> and by our contract with your healthcare provider as to how we handle your personal data. Caris will process your specimen and your personal data in its laboratories in the United States. The data protection laws of the United States may not be equivalent to those in your country of residence. The European Commission has not issued a decision that the Data Protection Laws of the United States provide an adequate level of protection for personal data. However, we take steps to ensure that your personal data continues to be treated in accordance with this Notice and the Data Protection Laws regardless of where your personal data are processed.

Certain personal data may also be transferred or provided to Caris' offices in your region who coordinate with your healthcare provider, Caris distributors in your region or both in order to perform the molecular profile testing. For more information on regional office location please visit [www.carislifesciences.com](http://www.carislifesciences.com) or ask your healthcare provider which regional offices and Caris distributors will receive your personal data.

Caris will utilize your personal data in furtherance of performing the molecular profile tests on your specimen and providing the resulting data Molecular Data ("Molecular Data") to you, your healthcare provider, or other recipients as authorized by you. Caris may also process, transfer and disclose your personal data or Molecular Data for the following additional purposes and to the following additional recipients:

- the distributor of Caris services in your region, so that the treatment and services you receive may be billed to and payment may be collected from you, your insurance company, or a third party you designate;
- operational reasons as well as to review the quality of our services and to evaluate the performance of our staff; and
- as otherwise required by applicable laws in your region and the U.S.

Caris may use leftover specimen materials, molecular profiling information and clinical information, so long as such materials and information are de-identified and do not contain any of your personal data, for research, education and training purposes to optimize the different tests and improve healthcare operations, when permitted under applicable laws and regulations. Your personal data (i.e., your name, patient number, date of birth, gender, address, medical history and pathology report) will not be disclosed or otherwise used in this context without your specific additional consent.

Caris processes the following categories of your personal data exclusively on the basis of your consent:

- name;
- address;
- patient number;
- date of birth;
- gender;
- name and address of physicians, hospitals, and other healthcare providers involved in the treatment of the patient's tumor or cancer;
- data on patient's relevant treatment history and pathology reports;
- DNA, RNA, protein, and other molecular data; and
- other data required for the treatment and analysis of tumors or cancer.

For the purposes set out above, Caris will transfer your personal data to the following recipients:

- IT service providers that Caris uses;
- companies that are part of Caris' corporate group;
- your healthcare provider.

**By signing at the bottom of this document, you consent to the collection (if necessary), processing, use and transfer of your specimen and personal data by your healthcare provider and by Caris on behalf of your healthcare service provider, as described herein.**

### Specimen and personal data provided by your healthcare provider to Caris

Your healthcare provider will provide Caris with your specimen, as well as your personal and medical information (i.e., your name, patient number, date of birth, gender, address, medical history and pathology report) in order for Caris to perform testing. The data resulting from Caris' performance of the molecular profile testing based on your specimen will be provided to your healthcare provider upon completion of testing. Your Molecular Data is also considered to be personal data to the extent that it can be associated with you by the use of additional information (such as by your name or patient identification number being listed on a report). Caris has implemented reasonable technical, administrative and organizational security measures to comply with applicable Data Protection Laws to protect your specimen, personal data, and Molecular Data from unauthorized or inadvertent disclosure or accidental loss or destruction.

### Rights to your personal data

Your healthcare provider is the data controller with respect to your personal data. Besides the attached HCP Data Protection Notice, your healthcare provider may provide you with additional data protection notices and possibly with consent forms in connection with your health care more generally. You may have the rights to access, correct, restrict, delete and receive a copy of your personal data held by or on behalf of your healthcare provider. For further information on how your personal data is used, how security is maintained and to exercise your various data subject rights, please contact your healthcare provider. In the unlikely event that you do not receive a response from your healthcare provider because they are no longer in existence (for example, due to the healthcare provider's corporate entity being wound up or dissolved), you may contact us directly at [legal@caris.com](mailto:legal@caris.com).

### Consent

**I have read and I understand the information provided in this Patient Notice and Consent for Molecular Profiling and Data Transfer (including its attachments), have had all of my questions about it answered, and hereby voluntarily provide my express consent to the collection, use, processing, transfer and disclosure of my specimen and personal data (including medical information and sensitive data) as described in this Patient Data Protection Consent for Molecular Profiling.**

\_\_\_\_\_  
Patient Name (printed)

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

<sup>1</sup> Data Protection Laws shall mean: (i) the General Data Protection Regulation 2016/679 (the "GDPR"); (ii) any implementing, derivative or related legislation of any member state in the European Economic Area of the GDPR; and (iii) the Swiss Federal Act on Data Protection 1992 (as amended) and any successor legislation thereto.

# Your Healthcare Provider's Approved Data Protection Notice Regarding Caris' Molecular Profiling Services



<b>Name of controller and contact details (including of data protection officer, if there is one)</b>	You have received information concerning the name of the controller from your healthcare provider when you first became its patient, or through a subsequent communication from your healthcare provider. Your healthcare provider also will have provided information regarding whether it has a data protection office and how to contact that person either by a direct communication to you or via a publicly available listing such as on your healthcare provider's website.
<b>Purposes of the processing</b>	The purpose of the processing is to conduct molecular profile testing based on your tumor or other biological specimen and to provide a report to your healthcare provider upon completion of testing. That report will be used by your healthcare provider to make decisions about your health care.
<b>Legal basis (also known as the "lawful basis") for the processing</b>	<p>The legal basis for the processing of your personal data comprising Molecular Data or other health or genetic information is that the processing is necessary processing for the purposes of medical diagnosis and/or the provision of health or social care or treatment on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards set out in the GDPR.</p> <p>The legal basis for the processing of your billing-related information is the legitimate interest of the company (whether Caris or its distributors) that are contractually responsible for providing the services described in the Notice.</p>
<b>The legitimate interests of the controller or third party, where applicable</b>	As described immediately above, your billing-related information is processed based on the legitimate interest of Caris or its distributors (depending on which entity is responsible for billing based on arrangements with your healthcare provider) in receiving payment for its services.
<b>The categories of personal data concerned</b>	<p>The Caris molecular profiling services involve the use of the following categories of data:</p> <ul style="list-style-type: none"><li>• Sensitive personal data: medical history, genetic information, pathology report</li><li>• Personal data used to ensure your specimen and pathology report are correctly identified: name, patient number, date of birth, gender and possibly your address</li><li>• Personal data used for billing purposes: name, address and other contact details that you have provided for this purpose</li></ul>
<b>The recipients or categories of recipients of the personal data</b>	Caris MPI, Inc. d/b/a Caris Life Sciences and its distributor in your region (list available at <a href="http://www.carislifesciences.com">www.carislifesciences.com</a> ; specific details will be provided to you when your specimen is collected)
<b>Transfer of your personal data outside of the European Economic Area (EEA), destination country, lack of a Commission adequacy decision for the country, and safeguards for the transfer</b>	Your specimen and personal data will be transferred to Caris in the United States where the tumor profiling tests are performed. The USA does not have an adequacy decision from the European Commission, which means that the Commission does not deem the data protection laws of the USA to offer an adequate level of protection compared to the data protection laws of the EU. However, the USA does have data protection laws that protect health information, and Caris complies with those laws as well as the Data Protection Laws. Furthermore, Caris has committed to the safeguards described in the Patient Notice and Consent for Molecular Profiling and Data Transfer. Your healthcare provider (as the data controller) also has a written agreement in place with Caris or Caris' distributor (as the data processor) that meets the requirements of the GDPR. Further information about these safeguards is available upon request from your healthcare provider.
<b>The period for which the personal data will be stored, or if a set period cannot be determined in advance, the criteria for determining the retention period</b>	Your personal data will be stored by Caris for 50 years.
<b>Your rights to access, correct, restrict or delete your personal data, and object to processing</b>	The Data Protection Laws (including the GDPR) provide various rights to access, correct, restrict or delete one's personal data and to object to processing. These rights are subject to various limitations. To exercise any of these rights, please contact your healthcare provider's data protection officer or other designated contact, details of which have been provided to you separately in the context of the services that your healthcare provider provides to you regarding your general health care.
<b>The right to lodge a complaint with a supervisory authority</b>	You have the right to file data protection complaints with your national (or in some countries, regional) data protection authority.
<b>Absence of statutory or contractual requirement to provide any personal data</b>	There is no statutory or contractual requirement or other obligation to provide any personal data to your healthcare provider, but failing to do so means that you will not be able to have your specimen processed by Caris and you will not receive a molecular profile of your tumor or other specimen.