

Foundation Medicine Patient Authorization and Consent

Please read carefully and discuss with your ordering physician/person obtaining consent before signing. This form must be completely filled out and signed by you, and/or your parent, guardian or legally-authorized representative.

Purpose

Hoffmann-La Roche Limited ("Roche") is the official Canadian licensee of the American company Foundation Medicine, Inc. ("FMI"). FMI conducts tests designed to examine the genomic profile of your tumour and to identify specific genomic alterations (mutations or variants) that may be affecting its growth. This information may help your physician determine what targeted therapies may be available to treat your cancer or clinical trials in which you may be able to participate. Additional information about FMI's genomic tests are available at www.foundationmedicine.ca.

Process

A sample of your tumour, usually one removed in connection with a biopsy or completed surgery, or a blood sample will be sent to FMI's laboratories located in the United States, where it will be sequenced for genomic alterations. FMI will then send or make available to your physician a detailed report with information about your tumour's genomic makeup and potential treatment options and clinical trials. You and your doctor can then evaluate the results along with other information (e.g. your medical history, other tests) to determine what next steps are right for you.

Potential Risks and Benefits

It is possible that the results will show one or more genomic alterations that are "actionable", meaning that there may be commercially-available therapies that may treat your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer.

Knowledge about the impact of genomic changes is constantly changing. As a result, we may not yet understand the significance of certain mutations or variations we observe or whether anything can be done to address those mutations or variations. As a result, physicians may have different opinions about what the results mean and what treatment should be provided in light of the results. The tests do not identify every possible mutation or variant that may exist and our technology also may not identify all mutations related to your cancer. There is also a small possibility of testing errors. You may learn medical information about yourself that you did not expect, including learning of additional diagnoses or a change in your condition, which may or may not be treatable and may make you upset or cause distress. It is possible that the test results will not reveal the cause of your disease or help identify possible treatments.

Because genomic information is involved, it is possible that the results of these tests could impact your ability to obtain life, disability or long-term care insurance.

Personal Data

The results of the FMI genomic testing will become part of your medical record and form part of your Personal Data (i.e. data that on its own or in combination with other data, can identify an individual). The results will also be retained by your physician and FMI in accordance with applicable law, for the purposes set out in FMI's Privacy Policy, available at: <https://www.foundationmedicine.com/privacy>. They may be made available to individuals/organizations with authorized access to your medical records including, but not limited to, the physicians and nursing staff directly involved in your care, employees of FMI, third-party payers (for the purposes of reimbursement under insurance or government health care plans), others authorized by law or a court order, and others specifically authorized by you or your authorized representatives to gain access to your medical records. No other person or entity may have access to or retain your Personal Data without your written authorization.

You may request information on what Personal Data of yours FMI has and how FMI have used and shared your Personal Data during the one year period before the date of your request. FMI may charge a reasonable fee to cover the administrative costs of responding to your request for information. You may withdraw your consent to FMI's use, collection, sharing or processing of your Personal Data at any time. You understand that such withdrawal of consent may affect the continuation of FMI's provision of services to you.

Upon written request, FMI will return any unused sample tissue to your treating physician or the pathology laboratory once testing is completed.

To be completed by the patient and retained by the requesting clinician or institution

Roche and its agents, affiliates and distributors may receive Personal Data as part of its role in the sourcing, payment processing, administration and sending of tissue or blood samples to FMI, and providing customer support.

Your Personal Data may be held and used in any province or country worldwide.

Additional Use of Results

Results will be retained by FMI for internal quality assurance/operations purposes.

Furthermore, to the extent your consent is required by law (including the United States *Health Information Portability and Accountability Act* of 1996 ("HIPAA") and the Canadian *Personal Information Protection and Electronic Documents Act* ("PIPEDA")), you authorise FMI to de-identify your genomic information and results and to retain, use and disclose such de-identified genomic information and results for future unspecified research. You understand that this information will be de-identified in a manner that meets de-identification standards under the US HIPAA.

You understand that once your genomic information and results have been de-identified such that FMI will not be able to identify you or determine or re-identify which genomic information and results relate to you, you will no longer be able to withdraw your consent to FMI's future use or disclosure of such de-identified data.

General

You may cancel this authorization for additional use at any time. Your cancellation means that FMI will stop using and sharing your information, but does not apply to information already used or shared, including any de-identified genomic information that can no longer be linked to you.

If you have any questions, complaints or require additional information on FMI's collection, use, disclosure or retention of your Personal Data, or wish to cancel this authorization, you can contact Foundation Medicine Inc.'s Privacy Officer at privacy@foundationmedicine.com.

Signature

"By signing below, I confirm that my treating physician has explained the purpose, benefits and risks of FMI's genomic tests. I understand the information presented above and have had my questions answered. I agree to undergo the FMI genomic testing described above and authorize my care team to use and share my information and biological materials as described in this form."

"I also authorize _____ (name of pathology lab) to release my tissue and/or blood sample and disclose information from my health records to FMI for the purpose described in this form. I understand that there is a risk that my samples may be lost or damaged in transit, and I accept this risk."

Patient Name (Print)

Signature

Date

If Required:

Patient's Parent/Guardian
or Legally Authorized Representative

Signature

Date

Relationship to Patient