

Patient Authorization/Consent Form

To be completed by the Patient and the Treating Physician, and retained by the Local Laboratory

Please read carefully and discuss with your Treating Physician or Person Obtaining Consent before signing. This form must be completely filled out and signed by you, your parent/legal guardian or legally authorized representative.

Dear Patient, your Treating Physician has prescribed to you Foundation Medicine (FMI) Service(s) (FoundationOne® CDx, FoundationOne® Liquid or FoundationOne® Heme); a comprehensive genomic profile test for your cancer.

This test may help you and your Treating Physician determine what targeted therapies may be available to treat your cancer or clinical trials in which you may be able to participate.

Your signature below indicates that you have read, understood, and consented to the below points:

1. DATA PRIVACY

In order to receive FMI Service(s), you are asked to provide personal information such as but not limited to, your full name, date of birth, contact details; medical records ("Personal Data").

1.1. In order to optimally ensure the delivery of FMI services (including but not limited to place and track the FMI order, personalize your experience and respond to your inquiries), your Personal Data may be made available and retained by your Treating Physician, Foundation Medicine, Inc and F. Hoffmann La-Roche Ltd, its affiliated companies (together "Roche") or distributors, and Local Laboratories in accordance with applicable law (especially Lebanese Electronic Transactions and Personal Data Law No. 81), for the purposes set out in the Privacy Policy, which can be found at <https://www.foundationmedicine.com/resource/legal-and-privacy>

1.2. Your Personal Data may be made available and retained by individuals/organizations with authorized access to your medical records including, but not limited to, the physicians and nursing staff directly involved in your care, the government or third-party payers, including your current and future ones, for the purposes of reimbursement, others authorized by law, court order, or others specifically authorized by you or your authorized representative to gain access to your Personal Data, for the purposes set out in the Privacy Policy.

1.3. You may request removal or destruction of your Personal Data, including identifiable genetic information, from your medical record to the extent permitted by law.

1.4. You may request information on what Personal Data and identifiable genetic information of your Foundation Medicine, Inc. has and how it has been used and shared during the last year before the date of your request. Foundation Medicine, Inc. may charge a reasonable fee to cover the administrative costs of responding to your request for information. You may withdraw your consent to Foundation Medicine, Inc.'s use, collection, sharing or processing of your Personal Data and identifiable genetic information at any time; understanding that such withdrawal of consent may affect the continuation of Foundation Medicine, Inc.'s provision of services to you.

1.5. You understand and agree that your personal information will be collected, stored and used in accordance with Roche Privacy Policy for the below purpose of to receiving FMI Service(s).

2. ADDITIONAL USE

2.1. Your Results will be retained by Foundation Medicine, Inc. for internal quality assurance/operations purposes. F. Hoffmann La-Roche Ltd, its affiliated companies (together Roche") or distributors will retain your results, for operations purposes. No other person or entity may have access to or retain your test results without your written authorization.

2.2. F. Hoffmann La-Roche Ltd, its affiliated companies (together "Roche") or distributors, may receive Personal Data as part of its role in the sourcing and sending of tissue or blood samples to Foundation Medicine, Inc. Roche may also receive Personal Data information from third party payment providers related to credit card payments and bank transfers.

2.3. To the extent your consent is required by law (including the United States Health Information Portability and Accountability Act of 1996 (HIPAA), you authorize Foundation Medicine, Inc. to de-identify your genetic information (this information will be de-identified in a manner that meets deidentification standards under the HIPAA) and results and retain, use or disclose such de-identified genetic information/results for future genetic research.

2.4. You understand that you are not required to consent to de-identification of your genetic information/ results as a condition of receiving the Foundation Medicine services.

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

2.6. You have been asked if you have questions about or want a more detailed explanation of the Foundation Medicine services. You are satisfied with the explanation provided and do not need more information. If you have any questions, complaints or require additional information on Foundation Medicine Inc.'s collection, use, disclosure or retention of your Personal Data, you can contact Foundation Medicine Inc.'s Privacy Officer at privacy@foundationmedicine.com.

3. THE PROCESS

- 3.1. In order to perform the FMI Services you may be requested to prepare and provide all documents, including but not restricted to the prescription, detailed medical report, ID, and pathology report.
- 3.2. Once prepared, a Tissue or a Blood Sample is sent to a Local Laboratory. A Pathologist at the Local Laboratory will perform a confirmatory pathology review and quality control analysis to confirm that the sample meets the primary required specimen criteria.
- 3.3. The Local Laboratory then ships the Sample with all the related necessary documents to Foundation Medicine, Inc.'s laboratory in the United States.
- 3.4. Foundation Medicine, Inc.'s laboratory in the United States will perform a confirmatory pathology review and quality control analysis on each Tissue Sample received from the Local Laboratory. Foundation Medicine, Inc. will then perform a genomic analysis of the Tissue. The report will be delivered (where applicable) within a turnaround time (from the time the specimen reaches the Foundation Medicine, Inc. laboratory) of 11–14 days for FoundationOne® CDx and FoundationOne® Liquid tests, and, 14–21 days FoundationOne® Heme test. Administrative or technical issues in forms or tissue samples may cause delays in this turnaround time.
- 3.5. Should a Tissue or a Blood Sample fail testing due to technical reasons and no report is delivered to the patient, or the patient passes away before the report is delivered to the Treating Physician, the Local Laboratory will be notified and expected to refund the test. Failed testing does not include No Alteration Reports (where testing was successful but no genomic alterations were found in the tumor specimen) or Qualified Reports (where Tissue Sample was found to be sub-optimal; however, test was successful and report was delivered to the Local Laboratory).
- 3.6. Tissue Samples will be returned following analysis completion and upon request. Roche shall demand Foundation Medicine, Inc. to return any unused portion of the Tissue Sample and obtain suitable proof of its delivery.

4. POTENTIAL BENEFITS AND RISKS

- 4.1. It is possible that the Results will show one or more genomic alterations that are “actionable” meaning that there may be FDA-approved therapies available that target your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer. Knowledge about the impact of genetic changes is constantly changing.
- 4.2. As a result, Foundation Medicine, Inc. 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. These profiles do not examine every possible mutation or variant that may exist and our technology may not identify all mutations related to your cancer. There is also a small possibility of 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 profiles will not reveal the cause of your disease or help identify possible treatments.
- 4.3. Because genetic information is involved, it is possible that the results of these profiles could affect your ability to obtain life, disability or long-term care insurance.

Please check one of the following to specify the scope of your consent:

- [Full Consent] You consent to Foundation Medicine, Inc. conducting the requested profile: points 1-4**
- [Partial Consent] You consent to Foundation Medicine, Inc. conducting the requested profile (points 1-4) excluding de-identifying your genetic results and use for research as described above points 2.3 - 2.5).**

Patient Name

Patient Signature

Date (DD/MM/YYYY)

Parent/legal guardian or legally authorized
Representative name

Relationship to Patient

Date (DD/MM/YYYY)

The following has been discussed with the patient/parent/legal guardian or legally authorized representative and informed consent obtained. The following was signed in my presence:

Name of Physician or Person Obtaining Consent

Signature

Date (DD/MM/YYYY)

In case of any adverse event occurring with any Roche product, please report to the Roche Local Safety Line +961 76 700 322, or forward details to: beirut.safety_reporting.bs1@roche.com

Foundation Medicine® is a registered trademark of Foundation Medicine, Inc.

Roche is the licensed distributor of Foundation Medicine products outside of the United States; www.foundationmedicine.com

Roche Lebanon SARL | Pharmaceuticals Division | Atrium Building, 5th Floor | 33 Weygand Street | Beirut Central District, 11 - 5485 | Beirut, Lebanon | Phone +961 1 989 112 | www.roche.com

Roche Lebanon SARL is currently operating from a remote address (Omnipharma Bldg. B, 7th Floor, 28 Badaro St., P.O. Box 11-7956, Beirut, Lebanon)