Informed Consent Form

FOUNDATIONONE® FOUNDATIONONE® Heme Roche

Please ensure that both Sections A and B are completed.

SECTION A

STATEMENT OF HEALTH PROFESSIONAL	
Ordering Oncologist/Haematologist name:	Office/Practice/Institution name:
Submitting Pathologist name:	Office/Practice/Institution name:
I confirm that I am the responsible oncologist/haematologist with an appropriate knowledge of the FoundationOne/ FoundationOne Heme Service (the "**Service**") and that I have explained to the patient named below (the "**Patient**"): • the intended benefit of the Service and that it will involve the sending of the Patient's sensitive personal data to the USA (note that tissue samples may remain in the EEA (Germany)); • any possible risk in the use of the Service; • that they are free to decline the use of the Service; and • that they are able to withdraw their consent at any time, without reason.	
Signed (Oncologist/Haematologist):	Day __ __ Month __ __ Year __ __ __ __

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SECTION B

CONSENT OF PATIENT

- I confirm that the benefits and risks of the **FoundationOne/FoundationOne Heme service** (the "**Service**") have been explained to me and that I have had the opportunity to consider and question my understanding of the Service with my oncologist/haematologist named in Section A of this Informed Consent Form ("**Physician**").
- I understand that my Physician and the submitting pathologist named in Section A ("**Submitting Pathologist**") will be responsible for the preparation of my **tissue sample(s)** for the Service and that for this purpose my Physician will be required to send the Submitting Pathologist all relevant details relating to the analysis and, if required, further **supporting medical reports** and records as deemed necessary.
- I understand that Foundation Medicine, Inc. has laboratories in both **Germany** *(Foundation Medicine Germany GmbH Nonnenwald 2, Building 433, D-82377 Penzberg)* and the **USA** *(Foundation Medicine, Inc., of 150 Second Street, Cambridge, MA 02141)* (collectively, "**FMI**"). The Submitting Pathologist will, in full or in part, be required to send my tissue sample(s) together with the following **sensitive personal data**:
  - Date of birth
  - Sex
  - Diagnosis (including stage)
  - Tissue Specimen site
  - Tissue Specimen I.D.
  - Tumour genome/DNA (in tissue sample)
  - Date of tissue sample collection (as detailed on the initial test requisition form)
  - ICD code listed (in accordance with the test requisition form)

(together my "**Personal Data**"), to one or both of the FMI laboratories for analysis depending on the nature of the sample taken. I also understand that for the purposes of the analysis that FMI will be required to share my Personal Data between these two laboratories.

- I understand that my Personal Data will be held alongside my unique NHS Number or a Hospital Number ("**Patient Identification Number**", or "**PIN"**) and that my Physician, the Submitting Pathologist and FMI will have access to both my Personal Data and the PIN.
- I understand that my Personal Data and PIN will be used, stored and processed according to the **Data Protection Act 1998**.
- I understand that following the analysis of my tissue sample(s), FMI will issue a report detailing the results of the analysis directly to my Physician and the Submitting Pathologist ("**Report**").
- I understand that upon completion of the Service, FMI will return my tissue sample(s) to the Submitting Pathologist unless my Physician has requested otherwise.
- I acknowledge that **Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW ("Roche")** is the sole distributor for the Service of FMI for patients in the United Kingdom and that Roche may be provided with my PIN. I understand that Roche will not otherwise be supplied or have access to any of my Personal Data or the Report.
- I understand that in order to protect my anonymity I should not contact Roche or FMI directly in relation to the Service, but should contact my Physician to discuss the Service.
- I understand that FMI and/or Roche will use any ***anonymised (non-identifiable) data*** collected and analysed as part of the Service for scientific and research purposes relating to the investigation of the causes of genetic diseases. Such anonymised (non-identifiable) data may be shared within the Roche Group of companies (and externally with their services providers under contract) for such scientific and research purposes.

I give this consent voluntarily. I acknowledge that I am free to withdraw my consent at anytime by contacting my physician, without giving any reason and without my medical care or legal rights being affected.

Signed (Patient):	Name (Print)	Day __ __ Month __ __ Year __ __ __ __

A PHYSICIAN CAN WITHDRAW A PATIENTS CONSENT BY CONTACTING FMI AT PRIVACY@FOUNDATIONMEDICINE.COM. DO NOT RETURN THIS FORM TO ROCHE OR FOUNDATION MEDICINE

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