Cancer Research UK Special Terms and Conditions and Administrative Guidelines for Genomics England Ltd Sample Collection Grants

In addition to the *Cancer Research UK Terms and Conditions and Administrative Guidelines for Research Grants and Awards* (http://science.cancerresearchuk.org/funding/terms-conditions-and-policies/) (the "Terms and Conditions"), the following special terms and conditions of grant shall apply:

1. This is a performance-related award relating to introduction into the National Health Service of whole genome sequencing (the "Project") in respect of which the Award Amount referred to in the Grant Award Letter ("GAL") will, subject to the terms set out in the GAL, be payable to the Host Institution in arrears in equal quarterly instalments. The final instalment will be withheld pending receipt of the final sample report. Provided that the Host Institution collects and has made available to one or more sequencing organisation selected by Genomics England Ltd ("GEL") (each a "Sequencer") Samples (as such term is defined in paragraph 3.1 below) in the numbers prescribed in the GAL, Cancer Research UK shall pay to the Host Institution the full Award Amount. In the event that numbers of Samples prescribed in the GAL have not been collected and made available to Sequencer(s) by the date prescribed in the GAL, Cancer Research UK shall be discharged of any obligation to pay the final instalment to the Host Institution or shall be entitled to require that the Host Institution repays to Cancer Research UK the final instalment if it has already been paid.

2. Without prejudice to paragraph 1 above, Cancer Research UK may withdraw, reconcile or require repayment of part of the funding of the Award if Sample accruals are less than those required or the Host Institution fails to consistently provide the necessary samples and associated data required. This may include (but is not limited to) circumstances in which:

    2.1. no matching blood sample is provided;

    2.2. insufficient DNA is provided based on the agreed requirements;

    2.3. poor sample quality/preparation results in DNA of inadequate quality for Whole Genome Sequencing;

    2.4. the paired FFPE sample and blood sample provided by the Host Institution as Samples are identified by the Sequencer(s) to not be from the same patient;

    2.5. the Sequencer(s) does not receive the sample;

    2.6. the agreed SOP's for DNA extraction and quantification are not complied with; and/or

    2.7. the patient sample dataset is not collected and made available.

3. In addition to compliance with section 4.2 and 10 of the Terms and Conditions the Host Institute will be required to ensure that:

    3.1. FFPE samples and matching blood samples ("Samples") in the numbers and for the tumour type(s) specified in the GAL are collected and made available to one or more Sequencer(s) nominated by GEL from time to time. Multiple Samples from one patient will not be counted as separate Samples for the purpose of the Project

unless otherwise agreed with Cancer Research UK. Cancer Research UK may at its discretion, and on the same terms and conditions, request that the Host Institution makes available samples in excess of the number prescribed in the GAL;

3.2. it provides the Samples using agreed pseudonymised identifiers that allows the sample to be linked to patient clinical data specified by the Project;

3.3. it uses reasonable endeavours to work with GEL and Cancer Research UK to provide the patient clinical data specified by the Project including demographics, diagnostics (including molecular imaging, staging and pathology) and treatment data for use by researchers. Anonymised data will be provided by third parties at GEL's discretion;

3.4. you take reasonable steps to support Cancer Research UK and GEL in developing protocols for the collection of cancer tissue samples and associated clinical data;

3.5. the handling, transfer and processing of samples is conducted in accordance with GCP and SOPs and quality assurance standards approved from time to time by the Project's governance board and operations team; and

3.6. an appropriate proportion of the grant award is made available to the pathology department(s) responsible for tumour samples.

4. In addition to compliance with section 5.4 and 10 of the Terms and Conditions, the Host Institute will:

4.1. maintain authorisations and comply with the Human Tissue Act 2004, Data Protection Act 1988 and any other applicable legislation and local ethics committee approvals; and

4.2. obtain patient consent as contemplated by the ethics governance arrangements covering the Project and as requested by Cancer Research UK from time to time as may be necessary or appropriate to acquire, process and use Samples for the purposes of the Project and the other research uses referred to in those guidelines

4.3. ensure that comprehensive and customary insurance arrangements are maintained (for example through CNORIS) in relation to the collection and processing and use of Samples which insurance must provide satisfactory protection for Cancer Research UK. The Host Institution is solely responsible for Sample collection, processing and use by it of Samples and shall bear sole responsibility for, and indemnify and hold harmless, Cancer Research UK fully in relation to any liability arising from a negligent act or omission or other tort relating to the collection, processing and use of the Samples and any results of the Project by the Host Institution (including the use of results of the Project by clinical staff employed or otherwise retained by the Host Institution); and

4.4. ensure that any clinician employed or otherwise engaged by the Host Institution with access to the results of the Project is aware of the experimental nature of such results and that any diagnostic or treatment decisions made and any advice provided by such clinicians to patients are informed solely by conventional and validated techniques.

5. Notwithstanding section 7.1 of the Terms and Conditions, Funded Intellectual Property (as defined in the Standard Terms) shall vest in Cancer Research UK or its nominee.

6. Cancer Research UK expects that GEL will ensure that any Sequencer(s) to which the samples are sent shall agree to comply with the provisions of the Human Tissue Act 2004 as from time to time amended.

7. Without prejudice to section 12 of the Terms and Conditions, Cancer Research UK will not provide any indemnity in relation to the infringement of third party intellectual property rights arising from performance of any part of the Project.

8. Without prejudice to section 8.3 of the Terms and Conditions, in order to maximise the impact of the Project and to support Cancer Research UK's efforts to raise funds to support the Project from individual donors: Cancer Research UK expects: (a) press coverage of the performance of the Project (including in the form of press conferences) and you will be expected, as requested from time to time by Cancer Research UK's press office, to cooperate fully in promoting such positive press coverage (including through participation in such press conferences); and (b) that you will cooperate fully with any requests made by the Project Director and Cancer Research UK's Fundraising and Supporter Marketing Directorate to support any fundraising appeals made in relation to the Project including by addressing, and permitting laboratory visits by potential and actual donors and reporting to actual donors on the performance of the Project.