

## **Cancer Research UK Special Terms and Conditions and Administrative Guidelines for Stratified Medicine Programme Technology Hub Grants**

In addition to the *Cancer Research UK Terms and Conditions and Administrative Guidelines for Research Grants and Awards* (<http://www.cancerresearchuk.org/funding-for-researchers/applying-for-funding/conditions-of-your-grant>) (the “**CRUK Terms and Conditions**”), the following special terms and conditions of grant shall apply:

1. This is a performance-related award in respect of which the fixed payment referred to in this letter (the “**Fixed Sum**”) will, subject to the terms set out in the Grant Award Letter, be payable to the host institution in arrears in equal quarterly instalments. Provided that the host institution undertakes the DNA extraction and any agreed genetic analysis of FFPE samples and matching blood samples (if the sample requirements document in force from time to time specifies that blood is required) (“**Samples**”) in the numbers prescribed in the Grant Award Letter and reports on the results as required by any relevant molecular pathology guidelines, and performs any additional work Cancer Research UK reasonably requests to be performed, Cancer Research UK shall pay to the host institution the Fixed Sum. In the event that numbers of Samples prescribed in the Grant Award Letter have not been analysed and reported upon or any additional work has not been completed to the specifications agreed, 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 analysis is less than that required or the host institution fails to consistently perform the genetic analysis and provide satisfactory reports on the results thereof, or fails to perform additional work to Cancer Research UK’s reasonable satisfaction, as required for the Stratified Medicines Programme (the “**Programme**”). This may include (but is not limited to) circumstances in which:
  - 2.1. the handling and analysis is not undertaken in a timely manner and in accordance with Good Clinical Practice and standard operating procedures and quality assurance standards prescribed by Cancer Research UK from time to time; or
  - 2.2. the host institution fails to comply with any reasonable request made from time to time by Cancer Research UK (through the operations team established to oversee the performance of the Programme).
3. In addition to compliance with section 5.2 of the CRUK Terms and Conditions the host institution will be required to ensure that:
  - 3.1. Samples in the numbers prescribed in the Grant Award Letter are analysed and that the results of such analysis are made available in an agreed and standardised electronic format to Cancer Research UK on a pseudonymised basis (in compliance with the minimal requirements for trustworthy practice for the operations of a pseudonymisation service as described in ISO/TS 25237:208 Health Informatics – Pseudonymisation; including documentation of physical, procedural, technical and

personnel control) for use by Cancer Research UK and any third parties approved by Cancer Research UK and by the clinical hub from which Samples are sourced, on a non-anonymised basis (and in accordance with the Data Protection Act 1998 (or its equivalent in Scotland and in accordance with common law and customary practice concerning the confidentiality of patient records);

- 3.2. the host institution takes all reasonable steps to implement the required IT infrastructure to support the electronic transfer of test requests and results to and from (as appropriate) the clinical hub(s) from which Samples are sourced, as assigned by Cancer Research UK. This will be over a secure file transfer protocol (sFTP) and using structure XML messaging. These data will be pseudonymised in accordance with paragraph 3.1 above and NHS Information Governance (IG) principles;
- 3.3. the host institution provides such evidence as Cancer Research UK may require from time to time to demonstrate the validity of the analysis and the results generated;
- 3.4. the handling and analysis of samples is undertaken in a timely manner and in accordance with Good Clinical Practice and standard operating procedures and quality assurance standards prescribed by Cancer Research UK from time to time;
- 3.5. the host institution permits and cooperates fully with any inspection required by Cancer Research UK to ensure compliance by the host institution with its obligations under paragraph 3.4 above;
- 3.6. the host institution operates as a custodian of any and all nucleic acid extracted from samples provided and shall abide by, and comply promptly with, any requests for release of nucleic acid as may be made by Cancer Research UK or the Programme's governance board from time to time and that subject to requests made the host institution retains any nucleic acid samples for a period of at least five (5) years;
- 3.7. the host institution does not use any nucleic acid extracted from the samples provided for purposes other than any agreed genetic analysis or quality control for the study;
- 3.8. the host institution will return any surplus FFPE samples (and any other human tissue accessed in connection with the Programme) to the participating hospitals and shall not make them available to any third parties;
- 3.9. the host institution takes reasonable steps to support Cancer Research UK in developing protocols for the collection of cancer tissue samples and associated clinical data; and
- 3.10. any additional work is performed reasonably promptly and to Cancer Research UK's reasonable satisfaction.

4. In addition to compliance with sections 5.4 and 10 of the CRUK Terms and Conditions, the host institution will:
  - 4.1. maintain authorisations and comply with Human Tissue Act 2004, Data Protection Act 1998 (or its equivalent in Scotland, if applicable) and any other applicable legislation and common law and customary practice concerning the confidentiality of patient records and the analysis of genetic information and with local ethics committee approvals; and
  - 4.2. ensure that comprehensive and customary insurance arrangements are maintained in relation to all the activities of the host institution, which insurance must provide satisfactory protection for Cancer Research UK. The host institution is solely responsible for the handling, storage and analysis of samples from which it was received by the host institution, 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 any such activities by the host institution.
5. Notwithstanding section 7.1 of the CRUK Terms and Conditions, Funded Intellectual Property (as defined in the Standard Terms) shall vest in Cancer Research UK or its nominee;
6. Without prejudice to section 12 of the CRUK Terms and Conditions, the host institution shall undertake and perform its obligations at its own risk (including the risk of any claim maintained by any third party) and Cancer Research UK will not:
  - 6.1. provide any indemnity in relation to the infringement of third party intellectual property rights arising from performance of any part of the Programme;
  - 6.2. be liable to the host institution for any damages, costs and expenses suffered by the host institution arising from act or omission of Cancer Research UK in relation to the performance of the Programme for a sum exceeding in aggregate for any and all claims twenty thousand pounds. Nothing in this paragraph 6.2 (or paragraph 4.2) shall be treated as excluding Cancer Research UK's liability for death, personal injury or any fraudulent misrepresentation.
7. Notwithstanding section 8 of the CRUK Terms and Conditions (and without prejudice to paragraph 8 below), no publication of results shall occur without confirmation by Cancer Research UK that it is satisfied with the integrity of data comprised in such results (or upon which such results are based). Any delay to publication is not expected to exceed six months.
8. In order to maximise the impact of the Programme and to support Cancer Research UK's efforts to raise funds to support the Programme from individual donors, Cancer Research UK expects: (a) press coverage of the performance of the Programme (including in the form of press conferences) and the host institution will be expected, as requested from time to time by Cancer Research UK's press office, to cooperate fully in promoting

positive press coverage (including through participation in such press conferences); and (b) that the host institution will cooperate fully with any requests made by the Programme Director and Cancer Research UK's Fundraising and Supporter Marketing Directorate to support any fundraising appeals made in relation to the Programme including by ensuring that appropriate employees make presentations on the performance of the Programme to, and permit laboratory visits by, potential and actual donors.