

Cancer Research UK Special Terms and Conditions and Administrative Guidelines for Stratified Medicine Programme Clinical 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. The final instalment will be withheld pending receipt of the final sample report. Provided that the host institution collects, and has made available to Technology Hubs, Samples (as such term is defined in paragraph 3.1 below) in the numbers prescribed in the Grant Award Letter, 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 collected and made available to Technology Hubs by the date prescribed in the Grant Award Letter, 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 if the last version of the “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document requires one;
 - 2.2. insufficient FFPE samples or DNA and/or blood is provided for the agreed amount of DNA required by the Technology Hub(s), according to standard set by most recent “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document;
 - 2.3. poor FFPE sample quality/preparation results in DNA of inadequate quality for genetic testing according to standard set by the most recent “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document;
 - 2.4. DNA extracted locally is of inadequate quality for genetic testing according to standards set by the most recent “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document;
 - 2.5. where blood is required by the most recent “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document, the paired FFPE sample and blood sample provided by the Clinical Hub are identified by the Technology Hub to not be from the same patient;
 - 2.6. the Technology Hub(s) designated to perform the genetic testing does not receive the sample; or
 - 2.7. the minimum patient sample dataset is not collected and made available.

3. In addition to compliance with Clause 4 of the CRUK Terms and Conditions the host institution will be required to ensure that:
 - 3.1. FFPE samples, locally extracted DNA and matching blood samples (if required by the most recent “CRUK Stratified Medicine Programme 2 Patient and Sample Eligibility” document) (“**Samples**”) in the numbers and for the tumour type(s) specified in the Grant Award Letter (the “**Target Number**”) are collected and made available to one or more Technology Hub(s) nominated by Cancer Research UK from time to time. In effecting the transfer of Samples to any Technology Hub, no restrictions should be applied by the host institution to the further transfer or use of nucleic acid extracted from the Samples by the Technology Hub or others for any purposes contemplated by the Stratified Medicines Programme (the “**Programme**”). Multiple samples from one patient will not be counted as separate Samples by the Programme 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 Target Number;
 - 3.2. the host institution takes all reasonable steps to implement the required IT infrastructure to support the electronic transfer of test request and results. This will be over a secure file transfer protocol (sFTP) and using structure XML messaging. These data will be pseudonymised 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) and in accordance with NHS Information Governance (IG) principles;
 - 3.3. patient clinical data specified by the Programme including items from the Cancer Outcomes and Services Dataset (COSD) including tumour specific extensions i.e. LUCADA and covering demographics, diagnoses, treatment, details of death, and such other data as reasonably requested by Cancer Research UK from time to time are available for use by researchers from Cancer Research UK. Anonymised data will be provided to third parties at Cancer Research UK’s discretion following due process and governed via a data access committee;
 - 3.4. the terms of patient consent and necessary regulatory and ethical approvals permit access to any surplus genetic material, at Cancer Research UK’s request, to third parties;
 - 3.5. 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;
 - 3.6. 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 Programme’s governance board and operations team; and
 - 3.7. 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 Clause 4.4, 8.1 and 14 of the CRUK Terms and Conditions, the host institution will:

- 4.1. maintain authorisations and comply with the Human Tissue Act 2004, Data Protection Act 1988 (or their equivalent in Scotland if applicable) and any other applicable legislation and local ethics committee approvals; and
- 4.2. obtain patient consent as contemplated by the application guidelines and as requested by Cancer Research UK from time to time as may be necessary or appropriate to acquire, process and use tissue and blood samples for the purposes of the Programme 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 tissue and blood 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 Programme by the host institution (including the use of results of the Programme by clinical staff employed or otherwise retained by the host institution);
- 4.4. ensure that any clinician employed or otherwise engaged by the host institution with access to the results of the Programme is aware of the experimental nature of such results and that they should be used accordingly.
5. Notwithstanding section 11.1 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. Cancer Research UK shall ensure that any Technology Hub 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 clause 14 of the CRUK 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 Programme.
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 such 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 addressing, and permitting laboratory visits by potential and actual donors and reporting to actual donors on the performance of the Programme.
9. In addition to compliance with Clause 3.3 of these CRUK Special Terms and Conditions, the host institution will be required to ensure timely transfer of data classified as RESTRICTED from the SMP2 cohort to Public Health England (PHE). The Restricted data to be transferred include "personal identifiable information" (NHS number and date of birth)

from the host institution to PHE. PHE will use these data to identify the patients in the PHE dataset and extract their clinical information. PHE will link this information to the registry data, de-anonymise the resulting dataset (by taking away NHS number and date of birth) and send this information to CRUK where using the SMP2 ID it will be linked to the genomic data. The goal of this project linking the genomic data collected via SMP2 with the clinical history data held by the Cancer Registry is to identify within the genomic data potential prognostic and/or predictive biomarkers to first-line treatment.

For the purpose of the linkage, the host institution is required to ensure that the following steps are taken:

- 9.1. The Precision Medicine team will communicate to the host institution involved in the project a starting date for the preparation of the data and contact details at PHE.
- 9.2. Upon receiving from CRUK the list of SMP2 IDs required for the linkage, the host institution should collate these data in an excel sheet including the SMP2 ID and patients' identifiers (NHS number and date of birth). The files should be encrypted and the encrypted file should be sent to PHE using one of the channels used by the host institution for routine sharing of patient identifiable and sensitive information with the Cancer Registry.
- 9.3. Each host institution will be given 4 weeks from this starting date to complete the task.
- 9.4. When ready for the transfer, the host institution should notify the Precision Medicine team and the receiving party within PHE in advance of transferring the data.
- 9.5. Once PHE has received the file, they should then confirm with the host institution that they have acquired the file. If the file is password protected, the host institution will send the password.
- 9.6. At this point an email confirmation of end of the process should be sent from the host institution to the Precision Medicine team