ICR-CTSU

Data and Sample Access Policy

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1 Introduction

ICR-CTSU is committed to the responsible sharing of clinical trial data and research samples with the wider research community in order to improve scientific and medical knowledge about cancer. To enable data and samples to be effectively shared with others, an access policy and defined procedure is required to ensure that relevant legal, ethical or commercial constraints are recognised, and that data and samples are made available for new research purposes in a responsible manner. This document describes the policy and process for access to samples and/or clinical data collected as part of ICR-CTSU managed trials and has been developed with due consideration of local and national policies and guidelines (see section 9. References)

2 Scope

The availability of patient data and sample collections is vital for research into cancer. ICR-CTSU oversees a large resource of patient data and linked patient samples generated from its clinical trials and recognises the potential of this resource to address important research questions beyond those planned in the original trial protocol. Information about clinical trials managed by ICR-CTSU can be found at http://www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit.

ICR-CTSU has a responsibility to ensure that clinical trial data and samples are shared within the terms of the consent under which they were collected, in accordance with relevant governance and legislation, for research projects of the highest scientific probity and with due regard to the terms and conditions of the funders and sponsors and the original research.

ICR-CTSU's policy on data and sample access is therefore based on the need to:

- Protect patient's rights and confidentiality
- Ensure compliance with legal and regulatory requirements (e.g. the Data Protection Act 1998 and the Human Tissue Act 2004)
- Prioritise access to ensure the optimal use of the resource, especially the depletable sample resources
- Ensure high quality research and collaborations are fostered

3 Definitions

Access Agreement	Agreement covering transfer or samples and/or data
Access Committee	Committee which considers and decides upon sample and/or data access requests where the trial in question no longer has an active TMG
Access Request Form	The application form completed by the applicant to request access to data and/or samples from a collection
Applicant	An individual/group of researchers seeking access to data and/or samples from a collection

Data	Any dataset, including summary datasets, or those associated with patient samples
Collection	Data and/or samples that have been collected during the course of a clinical trial
Custodian	The research group, organisation, body or committee with formal responsibility for the collection at the time a request is received
ICR-CTSU	The clinical trials unit appointed by the trial sponsor to manage the clinical trial and maintain the clinical data
Independent Data Monitoring Committee	A committee of independent clinical and statistical experts responsible for safeguarding the interests of trial participants
Sample	Tumour tissue, healthy tissue or body fluids
Sponsor	The organisation(s) taking responsibility for securing the arrangements to initiate, manage and finance a clinical trial
Host laboratory	The laboratory appointed by the trial sponsor to maintain the clinical trial sample collection
Trial Management Group	A multidisciplinary group chaired by the Chief Investigator and consisting of key collaborators and ICR-CTSU staff responsible for the delivery of the trial
Trial Steering Committee	A committee of independent clinical and statistical members responsible for overseeing the trial on behalf of the funder and sponsor

4 Governance

Formal responsibility for collections should rest with institutions rather than with individual researchers (MRC Ethics Series: Human tissue and biological samples for use in research). This provides greater security for valuable collections, provides better assurance that patients' rights will be protected and ensures enduring governance beyond changes to individual circumstances of the investigators. Formal responsibility for data and samples collected within a clinical trial run by ICR-CTSU lies ultimately with the trial sponsor. Formal committee structures exist as described below to ensure that collections are used sufficiently and within the terms of this policy.

For all ICR-CTSU studies, initial review of data and sample access applications will be performed by the ICR-CTSU Data and Sample Access Review Group. This gives each ICR-CTSU trial team equitable access to the in-house expertise, ensures consistency of approach across different trial portfolios and allows oversight and monitoring of data/tissue sharing requests at the Clinical Trials Unit level.

For ongoing studies, the Trial Management Group (TMG), acting on behalf of the trial sponsor, considers applications for access to the data and samples in line with this policy. The TMG is responsible for overseeing the use of trial samples and data and prioritising access based on relevance and potential impact. TMG members formally accept their roles and responsibilities within a trial by signing a charter issued by ICR-CTSU. For studies with large or complex tissue collections, a translational sub-group may make recommendations to the wider TMG on proposals for translational research.

Access requests involving immature or intermediate trial data will also be referred to the trial Independent Data Monitoring Committee (IDMC). The IDMC are responsible for advising on the timing and nature of the release of any data from the trial relating to trial results or patient safety. Members formally accept their roles and responsibilities for a trial by signing a charter issued by ICR-CTSU.

Ultimate approval of access requests for trial samples or data is provided by the Trial Steering Committee (TSC). TSC members provide independent oversight of the trial on behalf of the sponsor and funders and are responsible for ensuring impartiality of access to samples and data and encouraging maximum use of collections. Members formally accept their roles and responsibilities for a trial by signing a charter issued by ICR-CTSU. In some cases, the TSC may delegate review and approval of access requests to the TMG or translations sub-group.

For completed studies, or those that no longer have an active TMG, review of sample or data access requests is provided by an Access Committee acting on behalf of the sponsor. The Access Committee will usually consist of the Chief Investigator, ICR-CTSU Scientific Lead and key clinical and scientific collaborators with responsibility for the original trial. Where such studies remain in the portfolio of a TSC, TSC approval for access will be required. If completed studies previously fell under the responsibility of an umbrella TSC (a TSC with a dynamic portfolio of trials within a defined clinical area) and that TSC is still active, ICR-CTSU will request that the study is "re-activated" on the TSC's portfolio if their approval for access is required.

5 Prioritisation

Access to collections will be prioritised on:

- Scientific merit (the importance of the hypothesis to the future diagnosis, treatment or understanding of cancer)
- Questions that can only, or most effectively, be answered using the requested trial resource (biomarker validation analyses are likely to be given higher priority than discovery work)
- Statistical power (the anticipated statistical power of any analyses should be clearly described, including an estimation of the likely minimum detectable effect size for any main effect or interaction where relevant)
- Originality and quality of proposal
- Consequence on the collection (considering the depletable nature of tissue collection)
- Competence and experience of applicant
- Participation of the applicant's centre in the original clinical trial
- Availability of funding to conduct work
- Ability to secure ethics approval for the research
- Potential for collaboration with methodologists at ICR-CTSU

Priority is given to projects from within the original trial proposal and access is usually reserved for trial purposes until those studies are concluded.

Priority thereafter is given to projects whose primary hypothesis can only be answered by the trial collection or that builds on the research question of the original trial.

Priority is given to those projects that involve active collaboration with ICR-CTSU for access, analysis, publication or other purposes.

6 Eligibility for Access

Applicants should be employees of a recognised academic institution, health service organisation or commercial research organisation with experience in medical research.

Applicants should be able to demonstrate their capability, experience and capacity to carry out the proposed study.

Applicants should be able to provide evidence that their methods and reagents have been sufficiently validated before samples are released.

Applicants should be able to demonstrate feasibility of their project and provide SOPs for all sample handling.

Applications should include details of the statistical analysis plan and any consultations that have taken place with ICR-CTSU statisticians.

Applicants must demonstrate that they have the facilities and staffing adequate for their research study.

Applicants must demonstrate that sufficient funding is available for their study prior to samples being released.

6.1 Limitations on availability

Data and/or samples will not be released where this could impact on the reporting of the primary research questions of the original trial.

As the samples are a depletable resource, applicants who propose similar studies may be put in touch, with a suggestion that they collaborate. If such collaboration is not possible then both applications will be considered individually. However, it is very unlikely that access to samples will be granted for two very similar studies.

To ensure that sample analysis is undertaken in a blinded fashion, outcome data and blinded treatment allocation will not normally be released. Linkage of sample results with the clinical data will usually be undertaken by ICR-CTSU. Where linked outcome data are released for external statistical analysis, a copy of the sample analysis data will usually be required prior to release and linked analyses will usually be conducted in collaboration with an ICR-CTSU statistician.

6.2 Limitations on use

Samples and/or data may only be used for research approved by an appropriate research ethics committee. Use may be limited by the scope of the consent under they were originally collected.

Samples and/or data are released for specific projects only as specified in the application and access agreement. Applicants must reapply if samples and/or data are to be used for additional projects.

7 Access request process

The application process consists of 4 stages which must be completed before samples and/or data are released:

- Determination of feasibility of the proposal
- Submission of the application form
- Consideration of the application for approval
- Agreement to the conditions of access

An overview of the process is given in Annex 1.

7.1 Determination of feasibility of the proposal

Applicants are encouraged to approach ICR-CTSU and / or the Chief Investigator informally in the first instance to discuss feasibility of the proposal including suitability of the collection for the proposed research. ICR-CTSU will consider the statistical aspects of the proposal and mode of collaboration. Limitations on the availability of the collection will also be considered at this point.

7.2 Submission of the application form

Once feasibility of the proposal has been established, formal applications for access to the collection should be made on the Sample and Data Access Request Form, obtainable from the relevant ICR-CTSU trial management contact, usually the Clinical Trials Programme Manager (CTPM) or Senior Trial Manager (STM), for consideration by the TMG. The form is also available on our website.

The application should include a clear statement of the study hypothesis, objectives and proposed methodology and details of the responsible person or persons who will carry out the work.

Applicants should include a statistical analysis plan and a power calculation for their study to assure the reviewers that it is adequately powered to test the hypothesis in question. ICR-CTSU can provide statistical support if needed.

In addition, for sample access requests, evidence of validated methods for analysis should be provided.

The CTPM/STM will review the application form for completeness and liaise with the applicant as necessary for any further information.

Once satisfied that the application form is complete, the CTPM/STM will forward initially to the Chief Investigator and ICR-CTSU Methodology Lead for preliminary review to ensure that the proposal is achievable by the proposed sample and/or data sharing and is scientifically sound. At the same time, the application form will be submitted to the ICR-CTSU Data and Sample Access Review Group. If the Review Group have confirmed that the ethical/governance considerations have been addressed and the request is agreed by the Chief Investigator and ICR-CTSU Methodology Lead, the CTPM/STM will forward to the TMG for their consideration.

7.3 Consideration of application for approval

When a trial has an active TMG, the completed application forms will be sent to the TMG for review and prioritisation.

The ICR-CTSU and the TMG reserve the right to consult with external experts to evaluate the scientific merit of the proposal. Applicants may suggest suitable reviewers or reviewers to whom they do not want the application sent.

Where requests involve access to intermediate or immature trial data, the application form will be submitted by ICR-CTSU to the trial Independent Data Monitoring Committee (IDMC) for consideration.

For completed studies, or those that no longer have an active TMG, the completed application form will be reviewed by an Access Committee acting on behalf of the sponsor.

Once an application has been agreed in principle by the TMG (and IDMC if necessary) or Access Committee it will be submitted by ICR-CTSU to the TSC for final approval, unless the TSC have delegated review and approval to the TMG or translational sub-group. In such cases, the TSC will receive notification of approved access requests via trial update reports. If the study no longer has a TSC (nor "umbrella" TSC) then TMG/Access Committee approval will suffice.

ICR-CTSU will notify the applicant in writing whether the application has been approved or the reasons for rejection.

7.4 Access agreement

The applicant must agree to the conditions of access in writing under an access agreement.
The agreement will be between the applicants host institution, the sponsor and originating laboratory (if host institution is different from the sponsoring institution).

The agreement will include standard terms on ownership, exploitation and dissemination of results.

7.5 Timing of applications

Applications may be submitted at any time and will be considered in the order in which they are received.

Applications for access to the collection can be made before funding and ethical approvals are obtained. In these cases, conditional approval may be granted subject to funding and ethical approvals. This conditional approval will effectively reserve any requested samples. If after 6 months, submissions have not been made, the samples may be made available to other applicants.

7.6 Resolution of disagreements

Access disputes will be referred to the TSC, who will make all efforts to resolve any disagreement between the applicant and the TMG.

8 Conditions of access

8.1 Sample and data identity

Identifying data will not be made available to applicants. Data will be shared in an anonymised (or linked anonymised where required) format only.

Samples will be released with a minimum of clinical data (unique id, age, sex, tissue type). Requests for any additional data must be justified in the application and subject to ethics approval.

Applicants must agree not to attempt to identify, trace or contact any individual subject.

8.2 Consent

Samples and data will only be supplied according to the original informed consent of the patients.

A condition of informed consent is that patients may withdraw their consent at any time. If a patient withdraws consent, ICR-CTSU will inform the applicant and request that any samples or data be destroyed and that this be confirmed in writing to ICR-CTSU.

8.3 Fees

Costs of processing and shipping will be the responsibility of the applicant.

ICR-CTSU reserves the right to charge for statistician and/or administration time where required. This would be based on level of complexity of the request (e.g. whether linking clinical data/samples) and whether the associated ICR-CTSU trial grant is still active. The usual fee for a standard data access request from an external (non-ICR) researcher is £5K.

8.4 Maintenance and disposal

Samples and/or data must be stored in a secure location with access strictly controlled and overseen by those named on the application.

Samples and/or data must be returned or disposed of at the end of the study as required by ICR-CTSU and the originating host laboratory and at the applicants own expense.
Samples and/or data may not be retained for future studies without the written agreement of ICR-CTSU.

8.5 Onward transfer

Samples and/or data may be used only by the applicants, and for the purposes agreed upon in writing, and may not be transferred to third parties without prior approval from ICR-CTSU.

8.6 Publication and transparency

ICR-CTSU supports the wider dissemination of information from research and increased cooperation between investigators. To this end, an abstract and lay summary of the proposed use of data and tissue samples may be made publicly available by ICR-CTSU before publication of the results.

Applicants will be asked to provide a lay summary of their research project, as well as an end of project report or publication of the results to the TMG. In order to recognise the contribution made by TMG members and collaborators to set up and maintain the collection, it is expected that representatives of the TMG would be offered co-authorship on any publication. Manuscripts should be submitted to the TMG for consideration at least 28 days before submission for publication.

Given the limited amount of material available, applicants should avoid duplicating results where possible. To this end, applicants are asked to provide details of experiments performed and agree to share results and data generated from the research with other researchers.

9 References

The use of patient data in research: Position Statement from The Institute of Cancer Research, London

NCRI Samples and Data for Research: Template for Access Policy Development

MRC Ethics Series: Human tissue and biological samples for use in research.

MRC Ethics Series: Personal Information in Medical Research

MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies

Annex 1: Process Diagram