ICR-CTSU

DATA AND SAMPLE ACCESS

REQUEST FORM

Project Title	
Lead Applicant	
ICR-CTSU Trial(s) Involved	
Application Date	dd-mmm-yyyy
Application Version	X.XX

Instructions For Applicants

Please read the ICR-CTSU Data and Sample Access Policy available from ICR-CTSU (icrctsu@icr.ac.uk) or the relevant trial contact before completing this application. Trial contact details are available on the ICR website (http://www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit).

Applicants are strongly encouraged to discuss the proposal with the CI and ICR-CTSU Scientific Lead at the outset and with ICR-CTSU statisticians before completion of the form so that the suitability and availability of the collection, the statistical analysis plan and modes of collaboration are fully understood.

For consideration, the applicant must complete and submit the data and sample access request form to ICR-CTSU. Please note the following:

- All parts of the form should be completed according to the specific instructions provided for each field.
- Relevant supporting information, including a 1-page CV for the lead applicant detailing grants awarded within last 5 years and 5 key relevant publications, should be submitted with the form.
- Forms will not be accepted with required fields left blank. Incomplete forms will be returned to the applicant for completion.
- Completed forms should be submitted to the relevant trial contact at ICR-CTSU.
- ICR-CTSU will review and process access requests in order of receipt and respond with an approved or not approved decision, or a request for further information if the objectives and/or analyses are not clearly understood.

The ICR-CTSU Data and Sample Access Request Form and Policy were developed based on the following:

MRC CTU Data Access Request Form

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

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

1. APPLICANT DETAILS

QUESTION	ANSWER
Lead applicant name	
Lead applicant institution	
Lead applicant address	
Lead applicant telephone	
Lead applicant Email	
List of Co-applicants Include institutions	
Roles and responsibilities Please describe the roles and responsibilities of both the lead applicant and co-applicants. [Max: 200 words]	

2. PROJECT SUMMARY

QUESTION	ANSWER	
Project title		
Motivation of request	Validation of key analysis	
	Re-analysis with alternative methods	
	Meta-analysis or combination with other study data	
	Basic science	
	Methodology	
	Other, specify:	
Lay summary ICR-CTSU have Patient & Public Involvement (PPI) membership on Trial Management Group (TMG) and Trial Steering Committee (TSC). Please provide a lay summary of the proposed study, identifying any potential benefits for patients.		

Lay Summary Flesch score	
Background Provide a brief description of the background and a summary of any relevant data that supports the proposed study. Evidence of validated methods for analysis should be provided. [Max: 250 words]	
Hypothesis State your specific hypothesis [Max: 250 words]	
Defined objectives State your objectives. [Max: 150 words]	
Justification of scientific merit Provide rationale for conducting the study and explain how the study will contribute to the proposed field of research. [Max: 250 words]	

3. STATISTICAL ANALYSIS PLAN (SAP)

QUESTION	ANSWER	
Named statistician Specify name of the statistician involved in developing the SAP. If not an ICR-CTSU statistician please provide the affiliation of the statistician.		
ICR-CTSU involvement Clarify the nature of involvement of the ICR-CTSU statistician, if any.	Full collaboration in development of the SAP	
	Review of SAP only	
	Advisory only	
	None	
	Other, specify:	
Endpoints Define the primary and secondary endpoints for the proposed research.		

Sample size Specify the sample size with power calculation. Articulate minimum detectable effect size for overall effect or interaction and explain why this effect size is realistic.	

4. STUDY MATERIALS & REQUIREMENTS

QUESTION	ANSWER	
Type of material Specify the type of material requested for this research proposal	Data only	
	Samples only	
	Data and Samples	
Why is material from this study requested for the research proposal?		
Why are they requested now?		
Is summary data requested or individual participant data?		
What data are required? Broad description of variables, with detailed list as further document, if possible. Which visits are needed? All participants or a subset?		
Which version of the data is required? Does this relate to the data used for a particular analysis or publication, or to the current data, or to a future dataset?		
What samples are required? Description of the type (tumour tissue, blood, urine etc), form (FFPE blocks, FFPE sections, fresh frozen, DNA, RNA etc) and amount of material required.		
Where will the clinical data and any sample analysis data generated as part of research proposal be held?		

Where will the samples be held?	
What are the timelines for the project? Include when the material is required by and when the research will report.	
Please describe requirements for collaboration with the CI and/or with ICR-CTSU (provisions of materials, preparation of material, statistical analysis)? Please note, outcome data will not normally be released. Linkage of sample results with the clinical data will usually be undertaken by ICR-CTSU.	
What processes will be in place to support the activities at ICR-CSTU? Description of financial support to cover staff time, material preparation and transfer.	

5. PUBLICATION & INTELLECTUAL PROPERTY

QUESTION	ANSWER
How and where do you plan to present and publish the results of this research? Co-authorship by relevant members of the TMG and ICR-CTSU is expected. Research should be published in an open access format at the applicants own expense	
What IP do you expect to be generated from this study?	
How do you plan to share data generated from this research? ICR-CTSU expects to agree the format of raw data published on websites/journal portals. ICR-CTSU expects to receive a copy of raw data to add to trial repository and reserves the right to share that	

data (anonymised) with other researchers in the future.	

6. FUNDING

QUESTION	ANSWER	
Do you have funding for this research project?	Yes	
	No	
If Yes, please provide details of the grant/award to support your proposed work. For example, title of grant, grant Ref No., 3rd party commercial funding source outside of the trial infrastructure, period of support, what aspects of the research will be funded.		
If No, indicate how work will be resourced, including whether submission of a grant is anticipated: If a grant application is planned the CI and ICR-CTSU Scientific Lead would expect to be named as co-investigators		
If funding is provided by a commercial entity, please confirm what their expectations of the collaboration are. For example, access to data, access to samples (or derivatives thereof), access to results, publication authorship, IP rights etc. *Please note that for trials funded or endorsed by CRUK the sponsor is required to enter into a fair and appropriate revenue sharing agreement with CRUK in relation to any monetary consideration received by commercial entities for the rights to the clinical trial results.*		

7. ETHICS

QUESTION	ANSWER	
Have ICR-CTSU confirmed that the proposed research is covered	Yes	
	No	

under the terms of the original consent and ethics approval?		
If no, has this proposal been submitted to your IEC/IRB and approved?	Yes	
	No	
If No, indicate plans for obtaining appropriate ethics approval.		

STANDARD CONDITIONS

1. Data and/or samples will only be released once approval has been obtained from the appropriate parties. A decision on approval will be based on a review of the detailed description of the project and the feasibility of the data extraction and/or data transfer and/or sample provision.
2. The data transferred are confidential, must be stored in a secure location, must not serve for any other purpose than those specified in the application for which approval for release is given and must not be discussed outside of the working group for the project named in this document. Any samples provided should only be used for the purposes specified in this document.
3. The applicant should regularly update ICR-CTSU on the progress of their project until the point of completion.
4. If data pertaining to the main aims of the original trial are released to the applicant before the main publication of the trial results, the data must not be quoted in any presentation or publication until the main trial paper has been published.
5. The applicant must provide any draft publication for review before it is used in any type of public presentation or submitted for publication. The ICR-CTSU trial(s) (and relevant registration or funders reference numbers) should be referenced. Authorship should include the CI, ICR-CTSU Scientific Lead and relevant TMG members unless otherwise agreed. A reprint of the resulting publication should be provided to the ICR-CTSU as soon as available.
6. The applicant will be expected to provide and pay for Open Access Publication.
7. ICR-CTSU expects to agree the format of raw data published on websites/journal portals.
8. ICR-CTSU expects to receive a copy of raw data to add to trial repository and reserves the right to share that data (anonymised) with other researchers in the future.
9. Upon completion of the project or publication of the results, all copies of the data held must be archived securely following ICR-CTSU guidelines or destroyed. Samples must be destroyed or returned as instructed by ICR-CTSU. No data or samples can be shared with third parties without prior approval of ICR-CTSU.
10. The sponsor is the custodian of all the samples and trial data and holds the Intellectual Property Rights over the data and samples and subsequent outputs unless otherwise clarified in a separate agreement.
11. This document considers the principles of data and sample release. If permission is granted a formal agreement must be drawn up and signed by the legal representatives of the parties involved before any data or samples are shared.
12. If samples or data are shared with a commerical entity, ICR-CTSU must be party to the contract negotiation with the commerical entity.

FOR COMPLETION BY THE LEAD APPLICANT		
I confirm that I have:	Completed all sections of the application form	
I have included copies of: [tick all that apply]	One page summary of my CV	
	Funding approval letter	
	REC/IRB approval letter	
	Statistical Analysis Plan	
	References supporting the proposed research	
	Other, specify:	

Name:		Signature:		Date:	

FOR COMPLETION BY ICR-CTSU		
Was the proposal discussed with ICR-CTSU or the Chief investigator before the application form was submitted?	Yes	
	No	
Date application form received:		
Does proposed research fall within the terms of the original consent?	Yes	
	No	
Date application reviewed by ICR-CTSU Data and Sample Access Review Committee		
Feedback from ICR-CTSU Data and Sample Access Review Committee	Approved	
	Rejected	
	Further details (if appropriate):	
Date application reviewed by TMG/Access Committee:		
Outcome of TMG/Access Committee review:	Approved	
	Rejected	
Did application require review by the IDMC?	Yes	
	No	
If Yes, date application reviewed by IDMC:		
Outcome of IDMC review:	Approved	
	Rejected	
Did application require review by the TSC?	Yes	
	No	
If Yes, date application reviewed by TSC:		
	Approved	

Outcome of TSC review:	Rejected	
Reason application was rejected:		
Date applicant was notified of outcome:		