

ICR-CTSU

data AND SAMPLE ACCESS

Request form

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

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| **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.
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| 1. **APPLICANT DETAILS**
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| **QUESTION** | **ANSWER** |
| Lead applicant name |  |
| Lead applicant institution |  |
| Lead applicant address |  |
| Lead applicant telephone |  |
| Lead applicant Email  |  |
| List of Co-applicantsInclude institutions |  |
| Roles and responsibilitiesPlease describe the roles and responsibilities of both the lead applicant and co-applicants. [Max: 200 words] |  |
| 1. **PROJECT SUMMARY**
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| **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: |  |
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| **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] |  |
| HypothesisState your specific hypothesis [Max: 250 words] |  |
| Defined objectives State your objectives. [Max: 150 words] |  |
| Justification of scientific meritProvide rationale for conducting the study and explain how the study will contribute to the proposed field of research. [Max: 250 words] |  |
| 1. **STATISTICAL ANALYSIS PLAN (SAP)**
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| **QUESTION** | **ANSWER** |
| Named statisticianSpecify name of the statistician involved in developing the SAP. If not an ICR-CTSU statistician please provide the affiliation of the statistician. |  |
| ICR-CTSU involvementClarify 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:  |  |
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| **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. |  |
| 1. **STUDY MATERIALS & REQUIREMENTS**
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| **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. |  |
| 1. **PUBLICATION & INTELLECTUAL PROPERTY**
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| **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. |  |
| 1. **FUNDING**
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| **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* |  |
| 1. **ETHICS**
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| **QUESTION** | **ANSWER** |
| **Have ICR-CTSU confirmed that the proposed research is covered under the terms of the original consent and ethics approval?** | Yes |  |
| No |  |
| **If no, has this proposal been submitted to your IEC/IRB and approved?** | Yes |  |
| No |  |
| **If No, indicate plans for obtaining appropriate ethics approval.** |  |

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| **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.
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| **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 propose research |  |
| Other, specify: |  |
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| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature: |  | Date: |  |

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