



DATA RELEASE REQUEST FORM FOR OUCRU STUDIES

Project Title	
Lead Applicant	
Application Date	dd-mmm-yyyy
Application Version	X.XX
OUCRU Study (ies) Involved	
Project Code	

Notes

This application form provides the basis for review of the proposed project and the development of the necessary agreements. Further supporting documents will be included



1. Lead Applicant

QUESTION	ANSWER
Lead Applicant Name	
Lead Applicant Institution	
Lead Applicant Address	
Lead Applicant Telephone	
Lead Applicant Email	
List of Co-Applicants Include institutions	
Applicant Qualifications Describe qualifications that are sufficient to process and analyse the requested information	



2. Project Summary and Supporting Information

This section should cover no more than two sides of A4

QUESTION	ANSWER
2.1 Project Title	
2.2 Source of request Mark one	<input type="checkbox"/> Internal to OUCRU <input type="checkbox"/> Internal to the Oxford University (not OUCRU) <input type="checkbox"/> External
2.3 Motivation of request Mark all that apply	<input type="checkbox"/> Replication of key analysis <input type="checkbox"/> Re-analysis with alternative methods <input type="checkbox"/> Meta-analysis or combination with other study data <input type="checkbox"/> Clinical <input type="checkbox"/> Basic science <input type="checkbox"/> Methodology <input type="checkbox"/> Other, specify:
2.4 Background What is the setting for the project?(Maximum 250 words)	
2.5 Rationale* What is the reason for undertaking the project? (Maximum 250 words)	
2.6 Defined objectives What are the expected outputs or deliverables? (Max 150 words)	
2.7 How is the project funded? How will the project be funded? Has this funding already been secured?	

* Keeping in mind the potential impact and benefit to OUCRU and the larger scientific community.



QUESTION	ANSWER		
<p>2.8 What other approvals are required for this project?</p> <p>Give details of ethics and regulatory submissions, and peer review processes. Include reference numbers and dates if already awarded.</p>			
<p>2.9 Provide relevant documents to support the application</p> <p>These should be included as separate documents with this application form</p>	Document	Status	
	Protocol		Attached
			Not attached
			Not applicable: specify below
	Statistical Analysis Plan		Attached
			Not attached
			Not applicable: specify below
	Grant application		Attached
			Not attached



			Not applicable: specify below
	Other documents eg ethics committee approval		Attached: specify below
			Not attached
			Not applicable: specify below

3. Study Data and Requirements

QUESTION	ANSWER
3.1 Why are data from this study requested for this project?	
3.3 How does the proposal fit with the study's consent process? Provide clarification and justification, preferable including a copy of the Participant Information Sheet (PIS) highlighting the relevant parts; If not, give details of the proposed process	
3.4 Is summary data requested or individual participant data	
3.5 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?	



<p>3.6 What are the timelines for the project?</p> <p>Include when is data required by and when the project will report.</p>	
<p>3.7 Which version of the data are required?</p> <p>Does this relate to the data used for a particular analysis or publication, or to the current data, or to a future dataset?</p>	
<p>3.8 What efforts and activities are requested of OUCRU CTU?</p> <p>eg Provision of clinical trial data, provision of samples, chasing of data.</p>	
<p>3.9 What processes are in place to support the activities at OUCRU CTU?</p> <p>eg financial support to cover staff time</p>	
<p>3.10 Where will data be sent and what are the specific regulatory issues in such a transfer?</p>	



4. Publication Policy and Intellectual Property Rights

QUESTION	ANSWER	
<p>4.1 Publication policy</p> <p>How and where do you plan to present and publish the results of this project?</p>		
<p>4.2 Authorship and acknowledgements policy</p>		OUCRU study Investigator(s) as co-author(s)
		OUCRU TMG members as co-author(s)
		OUCRU TMG members acknowledged
		OUCRU CTU staff as co-author(s)
		OUCRU CTU staff acknowledged
		Study site members as co-authors
		Study site members acknowledge or listed
		Group authorship including study
		Other or none: explain below
<p>4.3 Open Access publishing</p>		Following Gold open access publishing policy
		Following green open access publishing policy
		No open access publishing: explain below
<p>4.4 Intellectual property rights</p> <p>The data remain under Oxford University custodianship. Specify what will be the proposed intellectual property rights over the outputs and deliverables. Intellectual Property Rights will be finalized in a formal agreement.</p>		



5. Standard Conditions

These are the standard conditions under which data or samples collected or pledged as a part of a OUCRU CTU-led studies, and stored in the OUCRU CTU database or under Oxford University guardianship, can be shared with external groups for research purposes. A specific agreement would be developed between the appropriate bodies if approval is granted for data and/or samples to be released.

1. The research project described must conform to relevant ethics and research governance requirements and the Applicant must provide evidence of this before data or samples are released.
2. Data 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.
3. 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.
4. If data pertaining to the main aims of the parent study are released to the Applicant before the main publication of the study results, the data must not be quoted in any presentation or publication until the main study paper has been published.
5. The Applicant must keep the link person at the OUCRU CTU informed of the process of the project and must provide any draft publication for review before it is used in any type of public presentation or submitted for publication. The OUCRU study (ies) should be referenced and the link person included as an author unless otherwise agreed. A reprint of the resulting publication should be provided to the OUCRU CTU as soon as available.
6. The Applicant will be expected to follow and pay for Open Access Publication.
7. Upon completion of the project or publication of the results, all copies of the data held must be archived securely following Oxford University guidelines or destroyed. No data can be shared without discussion with and consent from OUCRU CTU.
8. The Oxford University is the custodian of all the samples and study data and Oxford University holds the Intellectual Property Rights over the data and subsequent outputs unless otherwise clarified in a separate agreement.
9. This document considers the principles of data release if permission is granted. A formal agreement must be drawn up and signed by the legal representatives of the parties involved.
10. The recipients of data should regularly update OUCRU CTU on the progress of their project until the point of completion.



6. Signature

The answers in this document are true and accurate to the best of my knowledge. I have read and understood the conditions above.

Applicant Name:

Applicant signature:

Date:



Figure 1 Process Diagram.

