

OCTRU – New Project Background Information Form

Lead Applicant/Chief Investigator

Name	
Job Title	
Institution/Hospital	
Address	
Phone Number(s)	
Fax	
Email	
Key Collaborators: Please provide the names and roles of key collaborators involved in this project.	

Project Details

Current title of project	
Current status	Protocol mature <input type="checkbox"/> Protocol first draft <input type="checkbox"/> Protocol outline <input type="checkbox"/> Idea only <input type="checkbox"/>
Background/justification: Give brief details.	
Objectives: Please summarise the key objectives.	
Design: Give a brief outline of the anticipated study design to be used or attach a flowchart.	
Setting: State the health service setting(s) in which the study will take place (e.g. general practice, hospital outpatients).	
Target population: Define the population involved (e.g. women with advanced ovarian cancer)	
Sample size: Give an estimate of the anticipated size of the study and what factors were taken into account arriving at that number.	
Expected start date: Start of the project, not start of recruitment.	
Project timetables including recruitment rate: Indicate the anticipated duration of the study.	
Study sites: How many study sites do you expect to involve? In how many countries?	

CTUs: Have you approached or discussed this project with any other CTU?	
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Funding

Do you have funding secured for this study? If yes, please provide details of awarding bodies, companies etc.	
If no, please indicate planned applications/sources of funding.	

OCTRU Services

Which services/advice would you like OCTRU to provide?

Service	Please tick	Comments
Trial design (including statistics)	<input type="checkbox"/>	
Funding application preparation	<input type="checkbox"/>	
Protocol writing	<input type="checkbox"/>	
Site selection and feasibility	<input type="checkbox"/>	
Site initiation and management	<input type="checkbox"/>	
Trial document design (including CRFs, DSMC/TSC charters)	<input type="checkbox"/>	
Ethics submission preparation	<input type="checkbox"/>	
Regulatory submission preparation	<input type="checkbox"/>	
Database design	<input type="checkbox"/>	
Randomisation service	<input type="checkbox"/>	
Data entry and cleaning	<input type="checkbox"/>	
Site monitoring	<input type="checkbox"/>	
QA including SOP writing and audit	<input type="checkbox"/>	
Medical monitoring / SAE review	<input type="checkbox"/>	
Clinical research training	<input type="checkbox"/>	
Analysis and interpretation (inc statistics)	<input type="checkbox"/>	
Paper-writing and presentations	<input type="checkbox"/>	
Other (please specify)	<input type="checkbox"/>	

Please provide any other information which you feel would be helpful at this stage:

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Print Name: _____ Signature: _____ Date: _____

Please return the completed form to: enquiries@octo-oxford.org.uk or by post to
 OCTO, Dept of Clinical Pharmacology, University of Oxford, Old Road Campus Research Building, Old Road Campus, Roosevelt Drive, Headington, Oxford, OX3 7DQ.

For OCTRU use only

List those contacted and their replies, meetings arranged, and decisions

Date	Action