



**New trial/research proposal form
For consideration at the Surrey Clinical Trials Unit (CTU) the Trials Review Group**

Completion and submission of this form will enable a new trial proposal to be considered for conduct at the Surrey CTU. This minimal information allows a quick decision from the CTU as to whether the CTU is able to support the proposal. It is essential that the proposal is submitted at the earliest opportunity (ideally 3 months before a submission deadline).

The intention of this part of the Trials Review Group process is to ensure that:

- Each new trial proposal is reviewed by the CTU TRG as soon as possible
- Investigators are provided with the best possible service
- Trials can be costed in a timely fashion
- The CTU maintains a comprehensive and balanced trial portfolio

If the applicant requires the trial to be sponsored by the University of Surrey please indicate in the form below so that this can be considered simultaneously.

Review Process

Please complete the form below and return it to the CTU Email: CTU@surrey.ac.uk

Proposals should be kept brief – Please limit to 2 pages if possible

Please use 10 point font. Boxes will expand as necessary when typing.

1. On receipt the completed form will be allocated the next available TRG submission no
2. The applicant will be notified of the number and given an estimated response date

Proposed Trial/study title:	Disease Area :
CI name: CI on previous Surrey CTU trial? <input type="checkbox"/> Y <input type="checkbox"/> N	CI Institution:
CTU contact:	CI email or phone no:
Status of proposed research:	Anticipated funding or approval submission date:
	Anticipated Funding Committee/Body name:
	Discussed with CSG/ sub-group or other specialist group? <input type="checkbox"/> Y <input type="checkbox"/> N
Is the study likely to be a multi-centre study	Name of group:
	<input type="checkbox"/> Y <input type="checkbox"/> N
Type of trial/research:	Currently, the surrey CTU will collaborate for trials that are multi-centre. For single centre studies, contact the Clinical Research Centre (CRC)
	First in man <input type="checkbox"/> Phase II (non-rand) <input type="checkbox"/> Other research <input type="checkbox"/> Phase 1 <input type="checkbox"/> Phase II (rand) <input type="checkbox"/> Phase III <input type="checkbox"/> type:
Co-investigators:	
Give a brief summary of background & justification for trial. Including how this proposal fit in with previous or ongoing trials in this area?	
Trial design - include: Main inclusion/exclusion criteria. Summary of treatment(s). Identify control arm & justify choice of experimental arm/s. For complex designs please attach separate trial flowchart/diagram.	
Feasibility of trial and potential impact include how trial results will be used & population size i.e. how many patients p.a. would be eligible for the trial	
Potential major issues e.g. with trial design, feasibility, drug supply etc	
Primary end-point: (if known)	
Sample size (approx)	UK sites only? <input type="checkbox"/> or UK and international sites? <input type="checkbox"/>

		No. expected UK sites:																		
		If international: which countries (+no. of sites)?																		
		What is rationale for inclusion of this/these countries?																		
IMP(s) involved?	<input type="checkbox"/> Y <input type="checkbox"/> N	Products involved: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Name:</th> <th style="width: 33%;">Licensing status:</th> <th style="width: 33%;">Free/ discounted?</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>	Name:	Licensing status:	Free/ discounted?															
Name:	Licensing status:		Free/ discounted?																	
ATMP(s) involved?	<input type="checkbox"/> Y <input type="checkbox"/> N																			
Medical device(s)?	<input type="checkbox"/> Y <input type="checkbox"/> N																			
CE mark?	<input type="checkbox"/> Y <input type="checkbox"/> N																			
Supplier(s) involved? If yes, name(s):	<input type="checkbox"/> Y <input type="checkbox"/> N																			
Funding?	<input type="checkbox"/> Y <input type="checkbox"/> N																			
Who is the expected sponsor																				
What is the bid submission date																				
If the Bid is successful please confirm anticipated start and end dates of Trial		<table style="width: 100%;"> <tr> <td style="width: 50%;">Start Date</td> <td style="width: 50%;">End Date</td> </tr> </table>	Start Date	End Date																
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DO NOT EXCEED 2 pages