

**Director**

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**Cancer Research UK Liverpool Cancer Trials Unit**

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<http://www.lctu.org.uk>

**Please complete the following form outlining your proposal for a clinical trial / study.**

**Contact Lead Investigator**

Name:

Email address:

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**Clinical Area (please choose one area)**

Clinical Area:	Pancreatic Cancer	Haemato-oncology
	Head and Neck cancers	Lung cancer
	Palliative Care	Radiotherapy
	Other (please specify below)	Melanoma

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**Type of study design**

Phase I	Phase IV
Phase II	Systematic review
Phase III	
Other well designed trial/study (please specify below)	

**Lead investigator affiliation**

University

Hospital

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**Have you already discussed your application with the LCTU management team?**

Yes

No

If yes, with whom

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**Are you seeking funding for this project?**

Yes

No

If yes, please give details of funding body and deadline for grant application submission

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**Has the trial been developed or approved by an NCRI Clinical Studies Group?**

Yes

No

If Yes, please give details

If no, please comment on whether (and when) you plan to approach a CSG

## **Study Details**

**Please list the research questions that your proposal seeks to address**

**Please provide a clear explanation of the problem to be addressed and why it is important to healthcare**

**Please provide a summary of the evidence. Give reference to any relevant systematic review(s) and discuss the need for your trial in the light of the(se) review(s). Please give details of other trials currently underway, both nationally and internationally, which are relevant to the proposed study.**

**Please explain why this trial is needed now**

**Please provide a brief summary of your project using the following headings as appropriate:**

- *Design*: Give a brief statement of the type of study design to be used
- *Setting*: State the setting(s) in which the study will occur.
- *Target population*: Define the population from which the study sample will be recruited (e.g. women over 60, people with learning disability, people with advanced cancer).
- *Interventions being evaluated*: Give a clear definition of the intervention to be evaluated.
- *Measurement of outcomes and duration of follow up*: Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives, the proposed duration of treatment period and frequency and duration of follow up. Validated surrogate markers are acceptable, where appropriate.
- *Sample size*: State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation
- *Planned analyses*: Please give details of the planned analyses
- *Project timetables including recruitment rate*: Indicate the anticipated duration of the study, and expected recruitment rate with justification for your estimate.

**Thank you for completing this form.**

**Please submit the form and send the draft protocol (if available) to:**

Dr Seema Chauhan, Operational Director

**Liverpool Cancer Trials Unit**

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