Version 1.0 160413

UoB Pre-Award Sponsorship Checks for Clinical Trials

The table below outlines the checks that the University of Birmingham Sponsor Office will make pre-award for planned studies which will not be managed by a UKCRN registered University of Birmingham Clinical Trials Unit ('UoB CTU'). It gives examples of considerations which will be taken in to account, as well as indicating what the Research Governance Team will do where it is unable to show that a criterion is met on the basis of the submitted documentation.

Abbreviations:

CI – Chief Investigator

CTIMP- Clinical Trial of an Investigational Medicinal Product

CTU – Clinical Trials Unit

CTOC – Clinical Trials Oversight Committee

UoB – University of Birmingham

RGT – Research Governance Team

Check Item	Criterion to be met	How checked:	Documents/actions needed from the research team:	Examples	Action if not satisfied
There is an appropriate level of UoB involvement in the protocol design and /or management and/or conduct of the trial.	UoB should be substantially responsible for the design and/or management of the trial.	RGT to assess this on the basis of a brief description of the trial team and their involvement in the trial. Level of involvement will be compared to the UoB involvement criteria (see table below).	Brief description of trial team and what they will do in the trial.	Where a trial has a UoB CI and is managed at UoB, the UoB would normally sponsor the trial. The UoB would not normally sponsor a trial with an external CI unless a UoB CTU were managing the trial.	Refer to CTOC for adjudication.

Check Item	Criterion to be met	How checked:	Documents/actions needed from the research team:	Examples	Action if not satisfied
Appropriate scientific peer review has/will be done.	Quality of trial to be validated by independent peer review proportionate to the risks associated with the trial.	Has an acceptable peer review been / or will be done? Consideration of the peer review being done by the funder (e.g. do they meet the standards that NIHR Non-Commercial partners self-certify to)[1].	Indicate funder and peer review body.	Cancer Research UK are known to perform acceptable peer review; the Big Lottery Fund does not normally perform acceptable peer review. Peer review can be organised by the researchers/CTOC but this must be performed using a reputable source with independent experts in the field (a minimum of 2, possibly more depending on the trial).	Work with trial team to identify an appropriate peer review body for assessment once funded. Where there is doubt about acceptability of peer review CTOC to adjudicate.
The CI is appropriately qualified by training and experience including appropriate GCP training.	CI meets regulatory requirements (i.e. medical professional for CTIMPS) and is GCP trained within 3 years of application for Sponsorship. CI has experience as Principal Investigator/Co-Investigator or Chief Investigator on an appropriate clinical trial or appropriate mentorship is in place.	Assessed by CV submitted with sponsor application.	CI CV indicating medical training, experience of running trials and evidence of GCP training. Where a mentor is used, submit CV of mentor as well.	CI on a CTIMP should have experience as a Co-investigator/Principal Investigator on a CTIMP and/or appropriate mentorship is in place.	Refuse sponsorship until qualified CI found or appropriate mentorship measures put in place. Borderline cases to be referred to CTOC.

[1] See Appendix one clause 3 of: http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Portfolio/Documents/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support%20-%20Version%204%20%28February%202011%29.pdf

Check Item	Criterion to be met	How checked:	Documents/actions needed from the research team:	Examples	Action if not satisfied
The level of resource available is appropriate, including funding, staff and facilities.	That i) there is sufficient trial specific funding or the trial forms part of a programme grant which has sufficient funds available for the trial and/or ii) the department is willing to fund or resource the trial from an alternative source.	Check that funding is being/has been applied for and/or that the relevant department has confirmed willingness to fund.	Pink form. If not all funding sources are included on the form then will also need breakdown of cost of trial and sources of funding for it. Confirmation from relevant department of that they are willing to fund and of the funding source (if applicable).	Fully funded trial including money for trial coordination and plan for sourcing IMP will be approved; trial where it is not clear that available funding will cover the project expenses may be queried.	Will ask for advice from a CTU member of CTOC and/or refer to CTOC in case of doubts
The planned quality management arrangements for the trial are appropriate to the risk of the trial.	An external UKCRN registered CTU is managing the trial or the trial has been discussed and found acceptable by the CRCT	For external UKCRN registered CTU managed studies, CRCT to confirm that the CTU's quality management system (QMS) has been reviewed and found to be acceptable, for non-CTU managed studies CRCT to confirm that the planned quality management arrangements are acceptable. Where a team already have acceptable quality management arrangements in place for other studies this	Request review and subsequent confirmation from CRCT that quality arrangements in place for the trial are acceptable.	For external UKCRN registered CTUs, CRCT will review their QMS to ensure appropriateness. If the trial is to be conducted outside a registered CTU, Investigators will need to follow the UoB SOPs. Trial specific procedures and guidelines may also need to be implemented. The need for procedures will be discussed with the CRCT at the start of the trial, and further quality checks of the CRCT may be conducted throughout the trial (depending on risks).	Any approval will be provisional on CRCT confirmation that appropriate standards can be met.

Check Item	Criterion to be met	How checked:	Documents/actions needed from the research team:	Examples	Action if not satisfied
		may be taken in to account.			
Insurance cover is possible.	Trial does not fall within one of the areas that the University cannot insure or the cost of the insurance would be cost prohibitive	RGT to assess on basis of trial description and UoB's insurance criteria.	Trial description and responses on the insurance questionnaire or relevant sections of the Pink Form.	Areas that could cause difficulty include: large number of participants, risky procedures, IMPs listed on the insurers high risk list, obstetrics, overseas sites, trial design/protocol developed by another organisation.	Refer to insurer for confirmation of whether cover will be possible.
Does the trial involve extraordinary or unusual circumstances that may cause difficulties overseeing and managing the trial?	That the trial will be run within a context which allows for appropriate sponsor oversight and that any difficulties can be appropriately dealt with.	If trial is being run in a non-standard way (i.e. that it is not recruiting all its patients through NHS organisations), that there is an appropriate account of how issues raised by this will be managed and how any expenses associated with this have been costed into funding applications.	The extraordinary or unusual circumstances should be brought to the attention of the RGT and documentation should be provided concerning how issues arising from them should be addressed.	If conducted outside of the UK, greater resources may be required to monitor and manage the trial. Would also need to address possible extra insurance costs and regulatory requirements. (e.g. non NHS recruitment/treatment, running through a shared care centre, conducted outside of the UK).	Refer to experienced trialists and/or the CRCT and/or members of CTOC to determine whether resources are sufficient to enable issues to be addressed.

The following table outlines the criteria by which the University of Birmingham determines whether its involvement in a clinical trial is sufficient for it to consider taking on the Sponsor role for that trial. The table applies to all clinical trials whether or not they are managed by a UoB CTU.

UoB involvement criteria:			
UoB CI	UoB Protocol and Design	UoB Managed	Outcome:
Yes	Yes	Yes	UoB Sponsor
No	Yes	Yes	UoB will sponsor (or co-sponsor) if managed by a UoB CTU. If not managed by CTU will refer to CRCT/ CTOC to determine whether planned management is sufficient
No	No	Yes	UoB will only sponsor if managed by UoB CTU
No	No	No	UoB will not sponsor
Yes	No	No	UoB will not sponsor
Yes	Yes	No	UoB may co-sponsor
Yes	No	Yes	UoB may sponsor, subject to possible further checks
No	Yes	No	UoB will not sponsor