Sponsorship for multi institutional research projects in LMIC's

The concept of research sponsorship in the United Kingdom is historically grounded within a context of commercial clinical trials, in which the same organisation (in most cases pharmaceutical companies) funds, designs and carries out a clinical trial. The WHO /GCP and ICH/GCP guidelines mirror this understanding in their definition of a sponsor as "an individual, a company, an institution or an organisation which takes responsibility for the initiation, management and/ or financing of a clinical trial"[1]

International research projects are often multi- institutional, non-commercial, and collaborative partnerships, therefore do not fit in so well with this model of sponsorship. Moreover, in non-commercial research the funder is external (usually a charity, foundation, public authority) who maintains its own conditions. The ICH/GCP definition has been criticised by others (Ravinetto et al 2015[i]) as not differentiating between commercial and non-commercial research, specifically the lack of separation of funding responsibilities. The European Regulation on Human Trials Medicinal Products provided a nuanced definition of sponsorship as "an individual, company, institution which takes responsibility for the initiation, the management, and *setting up* the financing of a clinical trial. Whilst In the UK, the Research Policy Framework for Health and Social Care Research definition of a sponsor mirrors that of the ICH/GCP, however, within the framework, legal and financing responsibilities are split between the funder and sponsor.

In addition to being externally funded, research carried out with collaborators in Lower Middle Income Countries (LMIC's) can comprise of a project proposal, with a number of sub studies or work packages. In such scenarios, the institutions involved in the consortium will lead onsite study activity, and each work package will require its own local ethics approval. When UCAM is the legal sponsor, ethics review for the whole project can be obtained by completing a cover letter to UREC, setting out an outline of the study, and specific activities to be carried out in Cambridge. The local ethics approvals need to be submitted for review.

Conditions for sponsored LMIC research

- UCAM is the lead institution, and the Chief Investigator(CI)is employed by the University
- The protocol is designed and/ or led by the UCAM CI
- Overseas study activity is being undertaken by UCAM CI and/ or study team
- Funding and contract terms are clear that the project sponsor is UCAM

Conditions for non- sponsored LMIC research

- UCAM is the lead institution, but its role in Cambridge is limited to financial management and coordination of the study, therefore only financial responsibilities are held.
- There are no study activities to be carried out overseas by UCAM employees
- UCAM is not the lead institution in a funded project, and the study activity is limited to analysis carried out in Cambridge
- UCAM employees are involved in a consultancy role, which is defined in a service agreement

[1] Guideline for good clinical practice E6(R2) EMA/CHMP/ICH/135/1995

Delegation of activities

The legal sponsor is responsible for the scientific, ethical, regulatory, legal and financial aspects of a study, ensuring that full resources are planned for, and compliance with ethical and regulatory requirements. Some of these responsibilities are delegated to the lead investigator, and in turn to the collaborating investigator at participating sites.

The table below summarises the responsibilities of the parties, both for activities where one party has sole responsibility, and activities where the responsibility is shared. The table can be incorporated into a collaboration agreement, and tailored to suit arrangements for each study.

Study activity	**Key responsibilities**	**Sponsor**	**Participating site** **Name:**
Study preparation	Ensure that the study and its protocol have received robust and favourable scientific peer review	S	
	The research proposal respects the dignity, rights, safety and wellbeing of participants.	S PS	
	Appropriate arrangements are in place for obtaining informed consent from those who cannot give consent themselves		PS
	Prepare Participant information sheet, consent form and assent forms where applicable		PS
Regulatory approvals	Obtain approvals from in country Ethics Committee(s), National drug authorities and research permits as relevant		PS
	Obtain favourable University Ethics approval	S	
Legal and financial	Ensure appropriate insurance is in place for the design and management of the study	S	
	Ensure that indemnity arrangements are in place to cover participating site liabilities		PS
	Ensure that insurance or indemnity arrangements are in place to cover sponsor liabilities	S	

	Ensure that the appropriate contracts including Data Transfer Agreements and or Material Transfer Agreements are in place for the Study	CI	
Study conduct	Ensure that the study is managed, monitored and reported as agreed in the protocol and/or agreed monitoring plan Report protocol deviations and breaches at local site to CI Ensure relevant Protocol deviations, and all serious breaches of Study conduct and/or GCP are reported to the Sponsor Report serious breaches of study conduct and/or GCP to relevant ethics committees and regulatory authorities (as applicable) Report suspected research misconduct, identified by the Participating Site, to the Sponsor Notify the Participating Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) of the end of the Study	 S S S S	PS PS
Data Management	Process and code study data Ensure appropriate analysis of study data	S	
Publication	Prepare and submit abstracts, posters and publications of the study endpoints	S	
Archiving	Ensure that all Study records held at site are archived appropriately when notified by the sponsor and retained as required by the protocol	S	

[i] Ravinetto et al (2015) International Health and Human Rights BMC International Health and Human Rights