

## Guidance document on sponsorship of international studies carried out in Low- and middle-income countries (LMICs)

This document provides guidelines for the types of international health research in LMICs the University of Cambridge (UCAM) will solely sponsor, and in some cases co-sponsor.

UCAM will not solely sponsor any studies that are a Clinical Trial of an Investigational Medicinal Product (CTIMP). In some instances, co-sponsorship can be considered, providing that the proposed co-sponsors have a verifiable record of facilitating CTIMPS in those countries where studies will be conducted. Co-sponsorship will be considered with institutions such as; The London School of Hygiene & Tropical Medicine, Medical Research Council, Oxford University, Liverpool School of Tropical Medicine, and the International Vaccine Institute. This is not an exhaustive list.

### Types of international health research<sup>1</sup> that the University will solely sponsor

- **Medical devices**

UCAM will solely sponsor the following medical device research:

- Using [CE](#) marked medical devices<sup>2</sup> as per their authorised use
  - Apps and stand-alone software that have a medical purpose.
  - In vitro diagnostic medical devices intended mainly to provide the analysis of samples taken from the body. This includes the associated equipment and any accessories needed.
- **Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology.** The study involves no clinical interventions or procedures, includes administering a questionnaire, or conducting interviews or focus groups with participants; and will use quantitative analysis, or a mix of quantitative and qualitative analysis methods.
  - **Study limited to working with human tissue samples (or other human biological samples) and/or data.** The study is based entirely on the analysis data and/or use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. Material Transfer Agreements (MTA's), Data Transfer Agreements (DTA's) or collaboration agreements must be agreed and signed with international partners.

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<sup>1</sup> Is my project research? <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>

<sup>2</sup> Guidance: Medical device stand-alone software including apps (including IVDMDs) MHRA [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/548090/Medical\\_device\\_stand-alone\\_software\\_including\\_apps.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/548090/Medical_device_stand-alone_software_including_apps.pdf)

**Types of international research are considered on a case-by-case basis for whether University sponsorship would be appropriate and permissible**

- **Clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.** This is clinical research not involving investigational medicinal products or medical devices.

Such clinical studies would need to be risk assessed and considered on a case-by-case basis

**Other International constraints that may be material on a case-by-case basis**

- **Agreement that UCAM will act as sponsor or co-sponsor of any international study will be dependent on the local context of the studies, for example the extent to which the study, research team and participants are at risk because of local circumstances and in accordance with the national regulatory requirements that apply for each study.** Importantly, all clinical studies must be conducted with all relevant insurance policies in place and on the condition that any/all additional insurance premiums that may be required are met from the study budget that applies in each case.

## Appendix

**Sole sponsorship.** The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator of the research study<sup>i</sup>.

**Co- sponsorship.** A sponsor can delegate specific responsibilities to any other individual or organisation that is willing and able to accept them. Any delegation of responsibilities to another party should be formally agreed and documented by the sponsor<sup>ii</sup>.

**Clinical Trial of an Investigational Medicinal Product (CTIMP).** An investigation of one or more Investigational Medicinal Products (IMPs) in human participants in order to determine their safety, efficacy, clinical effectiveness, or pharmacological or pharmacodynamic effects<sup>iii</sup>

**Investigational Medicinal Product (IMP):** A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form<sup>iv</sup>.

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<sup>i</sup> UK policy framework for health and social care research v3.3 07/11/17

<sup>ii</sup> UK policy framework for health and social care research v3.3 07/11/17

<sup>iii</sup> EU CT Directive 2001/20/EC, Article 2(a)

<sup>iv</sup> EU CT Directive 2001/20/EC Article 2 (d)