**GD\_024 GUIDANCE DOCUMENT: INTERNATIONAL STUDIES**

**1.0 Purpose**

This document sets out the UH Bristol position on taking part in international studies.

**2.0 Sponsorship of international studies and legal representation**

UH Bristol (like most NHS organisations) does not have the insurance cover or the infrastructure to sponsor research outside of the UK. The options are:

* To find a UK organisation that can, e.g. a university
* To run the research as a parallel study with an organisation in the collaborating country acting as sponsor, and using an identical protocol. Suitable collaboration and data sharing agreements would need to be in place.

**3.0 UH Bristol acting as legal representative or UK lead site for international studies**

**3.1 Clinical Trials of Investigational Medical Products (CTIMPS)**

If any of the sponsor(s) of a CTIMP is not based in the European Economic Area (EEA), e.g. an American or Japanese company or institution, it is a statutory requirement to appoint a legal representative based in the EEA for the purposes of the trial. Where the study is sponsored by an organisation in a country outside of the EEA, UH Bristol can consider acting as legal representative. We need to agree well in advance the roles and responsibilities of the sponsor and of UH Bristol, and will need to charge a fee. For example regarding portfolio adoption, monitoring, pharmacovigilance, HRA/REC applications, reporting, amendments, provision of IMP (shipping and/or manufacturing), local packs, payments to sites.

**3.2 Non-CTIMPs**

Non CTIMP’s do not require an NHS site to be legal representative in the UK, but would require a lead NHS site. UH Bristol can take on this role, but we would need to clarify well in advance the roles and responsibilities of the sponsor and of UH Bristol, and may need to charge a fee. For example regarding oversight of other UK sites, submit to HRA/REC, annual reporting, amendments, set up subcontracts, payments to sites.

We would expect such studies to have appropriate funding and be eligible for NIHR Portfolio adoption.