SPONSORSHIP CHECKLIST

Study Title:	
Sponsor Reference:	AC
Chief Investigator:	
Sponsor Representative:	
Sponsor:	☐ University of Edinburgh ☐ NHS Lothian ☐ UoE / NHSL Co-Sponsorship ☐ Other (specify) _____

			Justification
1.	What is the regulatory status of the study?	☐ Non-regulated ☐ CTIMP (Regulated drug trial) ☐CIMD (Regulated device trial) ☐ Combined CTIMP/CIMD	
2.	Will the study be covered under the existing University of Edinburgh insurance policy?	☐No ☐ Yes	
3.	Are there any special conditions to be flagged to the insurance office?	☐No ☐Yes	
4.	Will the study be required to undergo combined risk assessment as per GS002?	☐No ☐Yes	
5.	Will the study be subject to reduced monitoring as per CM004?	☐No ☐ Yes ☐ NA	
6.	Is there sufficient funding for the research?	☐No ☐ Yes	
7.	Are there any NHSL Service Support Costs and/or Excess Treatment Costs associated with the study?	☐No ☐ Yes	
8.	Are there any areas of legal/custom divergence between participating countries	☐No ☐Yes ☐ NA	

Once Sponsorship is confirmed, the Sponsor Representative should sign this document. An electronic copy must be retained in the appropriate electronic Sponsorship Review Folder.

	Sponsor Representative Signature		Position		Date

Notes

1.	Please provide justification for classification. If the classification is not uniform across all participation countries, justification for country-specific classification should be provided. In the case of CTIMPs (or trials where there is uncertainty regarding the regulatory status of the trial) please attach a completed MHRA CTIMP algorithm All regulated trials must be co-sponsored
2.	Please provide details of insurance if not UoE
3.	Special conditions include Phase I/FIH trials, Blood borne pathogens, Pregnant women, prisons, sites out with the UK, CI not contracted with UoE, children under 5
4.	All regulated trials must be risk assessed, Any complex non-regulated trial (e.g. involving a clinical investigational agent or involving other significant risk) should be considered for risk assessment
5.	Only applicable for studies not subject to a combined risk assessment, If the study involves a product (including device) and/or surgical procedure, and is randomised with no trial manager or research nurse support, study is eligible for reduced monitoring (SOP CM004). Justification to be provided if reduced monitoring is not applicable.
6.	Please provide details of funding
7.	Please provide details of excess costs

8.	Have fees for submissions and amendments been considered for each country? • Standard of Care provisions • Age of legal capacity • Cultural norms • Personal Insurance Arrangements • Data handling/storage/transfer Biological sample handling/storage/transfer to be considered