ANNEX A

COIs Considered by the COI Sub-Group January 2019 – 31 December 2019

#	Issue	Potential COI	Proposed mitigating action	CET COI subgroup decision (including any required mitigating action)
1	**NIBSC** - Distribution of UK Stem Cell Bank's (UKSCB's) cell lines by NIBSC.	Although the work is very similar to biological reference standards, a key difference is that the cells could become part of a medicinal product and could therefore be subject to review by the Regulator	Standing contractual obligation for companies to highlight NIBSC's involvement when submitting data to the Regulator.	Agreed that this work could proceed, managing the potential COIs.
2	**NIBSC** - Testing of clinical trial sera for PHE to (with regards to Polio immunisation)	NIBSC's involvement could lead to MHRA Inspectorate inspecting NIBSC as part of a GCP inspection.	If a GCP inspection is required at NIBSC this should performed by another regulatory agency such as PEI or HPRA with whom the Agency has an agreement in place to perform inspections and to review test data as necessary.	Agreed that there was public health justification for his work and that it could proceed, managing the potential COIs as proposed.
3	**Devices Division** - Engagement with NHIR	Activity 1 - to join a Panel selecting projects/products to receive NIHR funding. Activity 2 - to join a steering group for a project that is developing outcomes for the evaluation of new surgeries & surgical devices.	Mitigations for Activity 1 to be explored further and brought back to Sub-Group. Activity 2 - Sub-Group agreed there was no COI and this element could proceed.	Activity 1 - Further paper to be brought to the Sub-Group for discussion:(Note: Not taken forward) Activity 2 - Agreed there was no COI.
4	**NIBSC** - Preclinical testing of candidate vaccines for Emerging Diseases	The results of these studies are likely to be included in dossiers submitted to regulators to seek a licence for this candidate vaccine in European and other markets. The perceived COI would be from MHRA regulators evaluating a licence application containing NHP data produced by scientists at NIBSC.	MHRA will request the opinion of another regulator (PEI in first instance). NIBSC to include wording that should the customer include any of NIBSC's data in a CTA submission to the UK, or a MA application in Europe, it must give the MHRA as much advance notification as possible.	Agreed the proposed mitigations and for NIBSC/MHRA (IES) to keep in touch to enable MHRA (IES) to have early sight of projects that may need a fresh assessment of COIs.