Insurance Referral Criteria for King's College London Sponsored Research Projects

For KCL sponsored studies/trials meeting any of the criteria in Column A, please use the corresponding notes in Column B to assess whether the study will require referral. **Please note all CTIMP, ATIMP and Clinical Device trials should be referred – regardless of the criteria below.**

If a study/trial requires referral, please contact the KCL Insurance Manager, Tania.Pattenden@kcl.ac.uk, outlining the reason(s) for referral and attach the relevant study/trial documentation to your email (e.g. IRAS form, REMAS form, protocol, grant application) as soon as possible. The KCL Insurance Manager will review and advise whether the study/trial will be covered by existing KCL policies and/or will be subject to an insurance premium that would need to be covered by the project costs.

	A: Criteria for Assessment (using notes in column B)	**B: Assessment/Notes for Referral**
1.	Any study/trial where pregnant participants are actively recruited or included	**Do refer** all studies regardless of level of activity or study type except where the research is limited to secondary data analysis only.
2.	A study/trial involving any subject who is under the age of 5 years at the time of participation	**Do refer** if the study involves a physical or mental health intervention as defined under **Guidance Note 1* on page 3 below.**
3.	Study/trials conducted outside of the UK. This includes any of the following activities: • Kings' researcher is travelling outside of the UK for the study • Participants are recruited outside of the UK • Research activity is taking place abroad with a partner/collaborator outside the UK Please note, a study funded by a non-UK organisation where no research activity is being conducted outside of the UK would not classify.	**Do refer** if the study involves either of the following: • A physical or mental health intervention as defined under **Guidance Note 1*** • The activity is happening in a high-risk environment as outlined under **Guidance Note 2****
4.	Any study/trial involving more than 5,000 participants.	**Do refer** all studies
5.	A study/trial involving a substance (e.g. food, drug, medicine) or a medical device. Please note medical devices can include algorithms, AI, apps and software as defined under **Guidance Note 3*****	**Do refer** if the study/trial involves any of the following: • The substance or medical device under investigation has been designed, manufactured or modified by King's College London **AND/OR** the substance/medical device is being used for a medical purpose within the research (e.g. diagnostic/therapeutic/influencing clinical care of participants). • Medical Devices loaned or gifted from third parties where sufficient product

		liability by the manufacturers has not been confirmed. Please note liability from third party manufacturers must be confirmed through the appropriate contracts and agreements via the KCL contracts team. • Any study/trial involving an invasive medical device/product (defined by the policy as products that remain within the body for > 30 days)
6.	A study/trial involving genetic engineering	**Do refer** all studies
7.	Any study/trial involving Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named.	**Do refer** all studies
8.	Any study/trial associated with Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).	**Do refer** all studies
9.	Any study/trial involving perfluorinated compounds (PFCs), including perfluoroalkyl and polyfluorinated alkyl substances (PFAS), perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) or related chemicals.	**Do refer** all studies
10.	Any study/trial in which the medicinal purpose is either assisting with or altering in any way the process of conception or investigating or participating in methods of contraception.	**Do refer** all studies
11.	Any trial involving gene/cell therapy including gene editing	**Do refer** all studies
12.	Any trial where the intervention is a therapy targeting the brain, blood-brain barrier or Cerebrospinal fluid	**Do refer** all studies
13.	Any trial where the intervention is a therapy for COVID-19	**Do refer** all studies

Guidance Note 1: Definition of Physical/Mental Health Intervention

For the purposes of the referral criteria, a physical or mental health intervention includes any of the following –

1. *The taking of any blood, saliva or any other bodily fluids containing human cells and deemed relevant material by the Human Tissue Act 2004.*
2. *Where the risk of cross infection is greater than would be experienced in everyday life. For example, placing in the mouth of any item for dental or respiratory related research.*
3. *Study which involves the administration of substances. This can include licenced and unlicenced food products, nutritional supplements, medicinal products or solutions which may be taken orally, topically, intravenously etc.*
4. *Any imaging techniques such as MRI scans or ultrasound*
5. *Any sources of non-ionising radiation (e.g. lasers, DEXA scans)*
6. *A mental health intervention.*
7. *Procedures which involve the removal of clothes. This does not include the rolling up sleeves to take blood pressure but would include removing clothing for: placement of ECG electrodes, changing into swimwear to use a bod pod (used in nutritional research), having body measurements taken such as skinfold thickness.*

Guidance Note 2- Definition of High-Risk Environments

A high-risk environment would include any of the following:

- *Areas where the FCO have advised against travel - https://www.gov.uk/foreign-travel-advice*
- *Country's marked as amber or red on the University's heat map here - International homepage - Power BI (if you cannot access the heat map please contact the RGO or the KCL insurance manager who will confirm)*
- *High risk countries included on the current list of the International Regulations Manager: Russia (including the physical territory of the Ukraine occupied by Russia), Belarus, North Korea, Syria, Iran, Sudan, Cuba*
- *Any environment or situations where an individual (s) might be exposed to a significant/greater degree of risk than that of normal/usual day to day activities. For example, locations where hazardous substances/chemicals/explosives are present, mines, offshore and extreme height or under water, nuclear zones i.e. Chernobyl.*

This list is not exhaustive and if unsure then a referral should be made.

Guidance Note 3- Definition of Medical Devices

Please refer to the MHRA criteria/flowcharts here:

- *Medical devices: software applications (apps) - GOV.UK (www.gov.uk)*
- *Factsheet: medical devices overview - GOV.UK (www.gov.uk)*
- *Notify the MHRA about a clinical investigation for a medical device - GOV.UK (www.gov.uk)*