**Initial JRO Risk Assessment (CTIMPs & non-CTIMPs)**

Form to be completed by Sponsorship Contact when considering UCL/H Sponsorship, as per JRO Sponsorship SOPs.

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| **Trial / Study details** Please **tick if study is NOT a CTIMP** [ ]   |
| Full title: |  |
| Short name /acronym: |   | CTU trial ref:(if applicable) |  |
| Chief Investigator: |  | CTU / JRO:  |  |
| CTU / JRO contact name: |  | Email address: |  |

1. **Automatic High Risk to sponsor**- *Should as a minimum one category apply, the trial is to be referred to the UCL SOC*

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| --- | --- |
| **Automatic High Risks elements:** | **Yes / No** |
| 1.1 Advanced Therapy Medicinal Product | [ ]  Y [ ]  N |
| 1.2 IMP without a marketing authorisation (MA) and no human experimental data (i.e. First In Human) | [ ]  Y [ ]  N |
| 1.3 Novel or intrusive interventional study with no human experimental data (or CI was not involved in collecting pre-clinical data) | [ ]  Y [ ]  N |
| 1.4 IMP classified as needing advice from the ‘Expert Advisory Group’ or ‘Commission on Human Medicines’ from the MHRA | [ ]  Y [ ]  N |
| 1.5 Patients <16 years old where interventions are not standard of care or drug used out of indication | [ ]  Y [ ]  N |
| 1.6 Subjects are ‘healthy’ volunteers not patients | [ ]  Y [ ]  N |
| 1.7 Subjects are pregnant women | [ ]  Y [ ]  N |
| 1.8 Emergency consent required | [ ]  Y [ ]  N |
| 1.9 Patients unable to consent for themselves | [ ]  Y [ ]  N |
| 1.10 CI has no experience of conducting any research (IMP, ATIMP or other interventional trial) | [ ]  Y [ ]  N |
| 1.11 CI is/has been under investigation for misconduct | [ ]  Y [ ]  N |
| 1.12 Non CE marked trial device to be manufactured by UCL/UCLH | [ ]  Y [ ]  N |
|  |  |  |

1. **Other High Risk Elements** - *Please complete risk and mitigation plan for all applicable risks. JRO representative will assess and inform the trial contact if the trial is to be referred to the UCL SOC, GDPR or other committee.*

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| **High Risks:** | **Yes** | **Mitigation plan(s)** |
| Trial Design |  |  |
| 2.1 Phase I or IIa | [ ]  |  |
| 2.2 CTU >50 sites or >500 patients **OR** JRO trials only >5 sites or >200 patients | [ ]  |  |
| 2.3 Study intending to involve commercial collaboration(s) and/or intended commercialisation of a product/intervention, where the collaborators intend to retain or receive data / IP / publication rights etc. | [ ]  |  |
| 2.4 International sites | [ ]  |  |
| 2.5 Interventional Trial treatment duration and follow-up >10 years | [ ]  |  |
| 2.6 High risk data study: identifiable patient data using novel Artificial Intelligence / machine learning / algorithm research; unconventional data flow between organisations | [ ]  |  |
| 2.7 Surgical sham procedure involved | [ ]  |  |
| IMP/ Intervention |  |  |
| 2.8 Biological or biotechnological product | [ ]  |  |
| 2.9 IMP never given previously in patient group / not used within its indication or usual administration method | [ ]  |  |
| 2.10 IMP not licenced in UK and/or EU | [ ]  |  |
| 2.11 Intervention is the removal of standard care (IMP) with no new treatment added | ☐ |  |
| 2.12 Licensed drugs / CE marked medical devices to be used where manufacturers intend to retain data / IP / publication rights etc.  | [ ]  |  |
| 2.13 Significant risk of side effect profile e.g. teratogenic | [ ]  |  |
| 2.14 Non CE marked device used as trial intervention | [ ]  |  |
| 2.15 No experience of the other trial interventions or vulnerable patient population (if applicable) by CI, CTU or site | [ ]  |  |
| Patient population |  |  |
| 2.16 Patients with a life expectancy of <6 weeks | [ ]  |  |
| 2.17 Women of child bearing potential where no contraception is specified and there is a known risk due to the intervention.  | [ ]  |  |
| Data / Trial management |  |  |
| 2.18 Personal (identifiable) data to be transferred outside UK | [ ]  |  |
| 2.19 Samples to be transferred outside UK | [ ]  |  |
| 2.20 Data being transferred to a commercial organisation or another academic organisation (excluding safety data as per manufacturer’s responsibilities) | [ ]  |  |
| 2.21 Trial to be managed by non-UCL CTU or CRO | [ ]  |  |
| CI Experience |  |  |
| 2.22 CI has declared a conflict of interest | [ ]  |  |
| Funding |  |  |
| 2.23 Trial is underfunded or under-resourced | [ ]  |  |
| 2.24 Study requires referral to UCL insurers  | [ ]  |  |
| ***Other (please specify):*** | [ ]  |  |

1. **Assumptions-** *To the best of the knowledge of the person completing this Risk Assessment, the following items have been considered and are underway:*

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| **Assumption** | **Yes or n/a** |
| Full costing to be completed and funding to be applied for | [ ]  Y [ ]  n/a |
| Other adequate resource available (e.g. core staff) | [ ]  Y [ ]  n/a |
| Named statistician involved in trial design (n/a for descriptive statistics only)  | [ ]  Y [ ]  n/a |
| Additional UCL insurance to be applied for and / or additional insurance premium issue investigated (if applicable)  | [ ]  Y [ ]  n/a |

1. **Signatures**

|  |  |  |  |
| --- | --- | --- | --- |
| Initial Risk assessment completed by: | *Name:* | *Role:* | *Date:* |

*To be completed by JRO representative:*



|  |  |  |  |
| --- | --- | --- | --- |
| Referral to SOC: | YES [ ]  NO [ ]  | EDGE ref: | Sponsor UCLH [ ]  UCL [ ]  |
| JRO Reviewer: | *Name:* | *Role:* | *Date:* |