**Imperial Investigators (College or Trust) should complete this form if:**

* **They are planning to carry out a clinical trial of an investigational medicinal product and would like to request sponsorship from the Research Governance and Integrity Team, Academic Health Science Centre (Trust or College)**.
* **Please email the completed form with any supporting documents to:** **RGIT.ctimp.team@imperial.ac.uk**

Please tick the level of risk involved, either high medium or low;

**Sponsor mitigation strategies** – the sponsor will complete this column with a brief plan to eliminate or manage the risk, if medium or high, should be given, and to what or whom the risk is (subjects, staff, trial outcome, regulatory, organisation, budget) if considered necessary. Please state if no adequate risk management plan can be devised. Include monitoring mitigation where applicable, for e.g., increase in number of on-site visits, identifying triggers for on-site visits, increase in frequency of compliance forms completion, or visits for additional training

If there is substantial amendment that is likely to affect to a significant degree, the safety or integrity of patients or the management of the trial, there may be a need to re-assess the risk assessment of the trial.

Where indicated; multiple risks in the same category may be listed, e.g. if there is more than one IMP each one must be listed in the appropriate category.

If a question cannot be answered please state not known and assign the highest risk category.

|  |
| --- |
| **Administrative Information** |
| **Title of Proposal:** |  |
| **Short Title:** |  |
| **RGIT sponsor number:** |  |
| **Chief Investigator’s Name:** |  |
| **Employer:** |  |
| **Proposed sponsor organisation:** |  |
| **Date Risk Assessment completed** |  |
| **If amendment to initial Risk Assessment indicate new date and area(s) where risk has changed** **(add additional rows, if required)** | **Date:**  | **changes in question/section Nos:** |
| **changes in question/section Nos:** |

|  |
| --- |
| **Who has been involved in the development of the protocol?** |
| * CI produced alone
 | * CI and Statistician produced together
 |
| * External Organisation/CTU
 | * PPI - Have you involved patients or patients’ representative

 groups in the design of your trial? |
| Comments: |

|  |  |  |  |
| --- | --- | --- | --- |
|

|  |
| --- |
|  **Risks associated with trial IMP/interventions:** [ ]  **Type A = Comparable to the risk of standard medical care** *Trials involving medicinal products licensed in any EU Member State if: they relate to the licensed range of indications, dosage and form or, they involve off-label use (such as in paediatrics and in oncology etc) and if this off-label use is established practice and supported by sufficient published evidence and/or guidelines*[ ]  **Type B = Somewhat higher than the risk of standard medical care** *Trials involving medicinal products licensed in any EU Member State if: such products are used for a new indication (different patient population/disease group), or substantial dosage modifications are made for the licensed indication, or if they are used in combinations for which interactions are suspected.**Trials involving medicinal products not licensed in any EU Member State if the active substance is part of a medicinal product licensed in the EU (A grading of TYPE A may be justified if there is extensive clinical experience with the product and no reason to suspect a different safety profile in the trial population)*[ ]  **Type C = Markedly higher than the risk of standard medical care** *Trials involving a medicinal product not licensed in any EU Member State (A grading other than TYPE C may be justified if there is extensive class data or pre-clinical and clinical evidence)* |

 |

|  |
| --- |
|  **Justification**  |

 |

|  |
| --- |
| **Chief Investigator and resources** |
|

| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| --- | --- | --- |
| 1) CI experience  | High | Has no experience of being CI on any clinical trial. |  |  |
| 'Has no experience of this trial phase if trial phase I/IIa or no experience of complex trial management (i.e. dose escalation). |  |  |
| Has no experience of being CI on non-commercial trials |  |  |
| Medium | Has experience of being CI, but no experience of running multiple site trials (where the proposed trial is multi-site) |  |  |
| Has limited experience of being CI on this trial phase or in non-commercial trials  |  |  |
| Low | Experienced CI  |  |  |
| 2) GCP Training | High | Never completed GCP training or last GCP training completed before implementation of CT regulations (1 May 2004) |  |  |
| Low | Completed previously (post 1 May 2004) |  |  |
| 3) CI experience of IMP(where use implies: handling, administration and familiarity with safety profile of the IMP(s)), (if more than one IMP is to be used in the trial, please list all IMPs and state IMP name in risk management column)  | High | No experience of using one or more of the investigational medicinal product(s) (IMPs) |  |  |
| Medium | Has treated less than 50 patients with one or more of the IMP(s) |  |  |
| Low  | Extensive experience (ie treated 50 or more patients) in use of all the IMP(s) used in the trial. |  |  |
| 4) Involvement of other (non-IMP) study interventions which are high risk/novel procedures eg surgical, radiological (please state intervention in risk management column) | High | No experience of using the study intervention |  |  |
| Medium | Limited experience with study intervention (i.e. use in less than 50 patients) |  |  |
| Low  | Experienced in use of study intervention (ie use in 50 or more patients) |  |  |

|  |
| --- |
| **Chief Investigator Comments Q1-4** |
|  |

 |

|  |
| --- |
| **Trial Size and Sites** |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| **5) Total** number of patients planned? | High | >200 patients |  |  |
| Low | <200 patients |  |  |
| 6) Anticipated total trial duration? | High | >5 years |  |  |
| Medium | 2-5- years |  |  |
| Low | <2 years |  |  |
| 7) No. and location of planned sites? | High | >5 sites |  |  |
| Medium | 2-5 sites |  |  |
| Low | 1 site |  |  |
| 8) National or International? | High | International outside EEA |  |  |
| Medium | International within EEA |  |  |
| Low | National UK |  |  |
| 9) If international, number of countries outside UK? | High | >1 |  |  |
| Medium | 1 |  |  |

|  |
| --- |
| **Chief Investigator Comments Q5-9** |
|  |

 |

|  |
| --- |
| **Trial Design and Complexity** |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| 10) Phase of Trial | High | Human Pharmacology (First in man) (Phase l) |  |  |
| Safety and dose ranging study (Phase I/IIa) |  |  |
| Medium | Therapeutic exploratory (Phase ll) |  |  |
| Therapeutic confirmatory (Phase lll) |  |  |
| Low | Therapeutic use (Phase lV) |  |  |
| 11) Number of arms | High | 4 or more |  |  |
| Medium | 2-3  |  |  |
| Low | 1  |  |  |
| 12) Randomisation | Medium | Yes |  |  |
| Low | No |  |  |
| 13) Blinded trial | High | Yes |  |  |
| Low | No |  |  |
| 14) Has an unblinding system (24 h system) been set up/identified? | High | Internal system |  |  |
| Medium | 24 h external system requiring input from trial team (e.g. use of web-based system) |  |  |
| Low | Validated external system  |  |  |
| Not applicable |  |  |
| 15) Cross Over design | High | Yes |  |  |
| Low | No |  |  |
| 16) Risks associated with the subject groups  | High | Subjects are ‘healthy’ volunteers not patients |  |  |
| Vulnerable adults |  |  |
| Pregnant or nursing women |  |  |
|  Patients incapable of giving consent personally |  |  |
| Patients in emergency situations (e.g. unconscious) |  |  |
| Children under 16 years of age where interventions are not standard of care |  |  |
| Women of Childbearing potential (no contraception requirement in protocol) |  |  |
| Patients with poor prognosis/terminal disease  |  |  |
| Medium | Subjects are patients with capacity, but with comprehension or cognition difficulty e.g. certain neurological conditions, early dementia |  |  |
| Low | None of above |  |  |
| 17) Will any NIMPs be used in the trial? | High | NIMP(s) has/have no marketing authorisation within EU. |  |  |
| Low | NIMPs to be used have marketing authorisation within UK and to be used as per SmPc  |  |  |
| No NIMPs to be used |  |  |

|  |
| --- |
| **Chief Investigator Comments Q10-17** |
|  |

 |

|  |
| --- |
| **eCRF** |
| * Will the study use OPENCLINICA
 |
| * Other, please specify here:
 |
| **PLEASE NOTE: It is a sponsorship requirement for all CTIMPs that the OPENCLINICA database is used and hence this requires appropriate costing. The sponsor green light to commence will not be issued unless the Trial OPENCLINICA database is live and therefore it is important to discuss these requirements with the OPENCLINICA team as early as possible.** |

|  |
| --- |
| **Are any of these Committees in place for the trial:** |
| * Trial Management Group (TMG)
 | * Independent Data Monitoring Committee (IDMC)
 |
| * Trial Steering Committee (TSC)
 | Comment: |

|  |
| --- |
| **Trial and Data Management** |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| 18) Is there a CRO or an external Clinical Trials Unit supporting the management of the trial? | High | Yes |  |  |
| Low | No |  |  |
| 19) Is data being transferred outside of Imperial? | High | Yes, identifiable data to be transferred |  |  |
| Medium | Pseudo anonymised data to be transferred |  |  |
| Low | No data to be transferred, or anonymised data only to be transferred. |  |  |
| 20) If answered yes to previous high-risk category, is the identifiable data being transferred outside the UK? | High | Yes, outside the EEA |  |  |
| Medium | Yes, outside the UK but within EEA |  |  |
| Low | No |  |  |
| 21) Is sensitive patient data being collected? (eg Mental Health data/ substance abuse etc) | High |  Yes |  |  |
| Low |  No |  |  |
| 22) Is there a data management plan? | High | Unlikely to be in place at the start of the trial |  |  |
| Medium | Some; have begun to consider software, security and QC process. |  |  |
| Low | Yes, appropriate database and statistical software has been identified, procedures for QC of data in place. |  |  |
| 23) Samples to be transferred outside site | High | Yes, outside the UK |  |  |
| Medium | Yes, within the UK |  |  |
| Low | No |  |  |
| 24) Are there any third-party vendors or central service providers (where multiple vendors will be used please list all in the appropriate category) | High | Yes, not known to Imperial |  |  |
| Medium | Yes, known to Imperial |  |  |
| Low | No |  |  |
| 25) Is there an intention to audit the IMP manufacturer or central service providers (e.g. central laboratory)? (Has this been included in study costings? | High | Manufacturer and/or central service provider require auditing but insufficient trial funding available |  |  |
| Manufacturer and/or central service provider require auditing but not completed before start of trial |  |  |
| Medium | Manufacturer and/or central service provider require auditing and there is sufficient trial funding available |  |  |
| Low | Manufacturer and/or central service provider have been audited by appropriate Sponsor staff within the last 2 years |  |  |
| Audit by questionnaire required only |  |  |

|  |
| --- |
| **Chief Investigator Comments Q18-25** |
|  |

 |

|  |
| --- |
| **IMP information***Please tick all that apply and multiple score a category if it is applicable to more than one IMP* |
|

| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| --- | --- | --- |
| 26) Status of trial IMP(s) | High | Not licensed in EU |  |  |
| Medium | IMP used outside EU MA.  |  |  |
| Low | IMP used within their EU marketing authorisation(s)  |  |  |
| IMPs used off-label if this off-label use is established practice and supported by sufficient published evidence and/or guidelines (such as in paediatrics and/or oncology) |  |  |
| 27) If high risk in previous category, please complete relevant category here | High | IMP without a marketing authorisation (MA) and no human experimental data. |  |  |
| Medium | IMP without a marketing authorisation (MA) with some human experimental data. |  |  |
| Low | IMP without a marketing authorisation (MA) in the EU, but with MA outside EU. |  |  |
| 28) Type of IMP | High | Advanced Therapy Medicinal Product |  |  |
| IMP classified as a Genetically Modified Organism  |  |  |
| IMP consisting of manipulated tissues or cells |  |  |
| Medium | Biological or biotechnological product |  |  |
| Low | None of above |  |  |
| 29) IMP manufacture | High | IMP requires manufacture specifically for this trial |  |  |
| Medium | IMP requires further manipulation specifically for this trial e.g. over encapsulation, radiolabelling |  |  |
| Low | None of above |  |  |
| 30) IMP sourcing | High | IMP requires sourcing from outside UK |  |  |
| Medium | All IMPs provided for trial from UK source |  |  |
| Low | Hospital stock used for all IMPs |  |  |
| 31) If previous question was answered as high risk, please specify if IMP is sourced from within or outside EEA. | High | Outside EEA |  |  |
| Low | Within EEA(Confirm provisions for QP oversight as per MHRA guidance on importing IMPs into Great Britain from approved-countries, guidance under the link [*here*](https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries) |  |  |
| 32) IMP classified as needing advice from the ‘Expert Advisory Group’ or ‘Commission on Human Medicines’ form the MHRA | High | Yes |  |  |
| Low | No |  |  |
| 33) Is Imperial responsible for producing IB and IMPD? | High | Yes |  |  |
| Low | No  |  |  |

 |
| 34) IMP processes at site. Are there any elements to be considered here, dose escalation, IMP supply to participants etc | High | Yes |  |  |
| Low | No |  |  |

|  |
| --- |
| **Chief Investigator Comments Q26-33** |
|  |

|  |
| --- |
| **Conflict of Interest** |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| 34) Will the IMP be provided free of charge by a company specifically for use in this trial | Medium | Yes |  |  |
| Low | No |  |  |
| 35) Is the CI, PI or any study team member that can influence the CI, PI study related decisions being paid by any commercial party for his/her involvement in the trial? | High | Yes |  |  |
| Low | No |  |  |
| 36) Is the CI, PI or any study team member providing data to any of the commercial parties involved in the trial for the purpose of licensing the IMP or varying the current marketing authorisation? | High | Yes |  |  |
| Low | No |  |  |
| 37) Does the CI, PI or any study team member occupy a position of Director, Partner, Consultant, Trustee, Sole or Co-Owner in any of the commercial parties involved in the trial? | High | Yes |  |  |
| Low | No |  |  |
| 38) Is the CI, PI or any study team member a member of a committee providing advice to any of the commercial parties involved in the trial? | High | Yes |  |  |
| Low | No |  |  |
| 39) Does the CI, PI or any study team member have any Significant Financial Interests in any of the commercial parties involved in the trial? | High | Yes |  |  |
| Low | No |  |  |
| 40) Are there any potential intellectual property issues? | High | Yes |  |  |
| Low | No |  |  |
| 41) Will the trial produce data that could be used for commercialisation purposes? | High | Yes |  |  |
| Low | No |  |  |
| 42) Does the CI, PI or and study team member or members of his/her family have any significant financial interests in the company/manufacturer supplying the IMP or funding the trial?  | High | Yes |  |  |
| Low | No |  |  |

 |

|  |
| --- |
| **Chief Investigator Comments Q34-42** |
|  |

|  |
| --- |
| **Other Issues – sponsorship** |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| 43) Is the CI currently under investigation for misconduct, or for any other reason? | High | Yes |  |  |
| Low | No |  |  |
| 44) Are there any other issues that may impede on the decision of Imperial to take on sponsorship/ EU representation for the above trial? | High | Yes |  |  |
| Low | No |  |  |

 |

|  |
| --- |
| **Chief Investigator Comments Q43-44** |
|  |

|  |
| --- |
| **COVID Mitigations -**  |
|

|  |  |  |
| --- | --- | --- |
| **Area of Risk** | **Tick** | **Sponsor mitigation strategies (To be completed by Sponsor)** |
| 45) Will participants from a COVID vulnerable group be recruited to the trial? | High | Yes |  |  |
| Low | No |  |  |
| 46) Will a full COVID Risk Assessment be completed as part of trial setup, including use of PPE, social distancing, IMP home delivery etc? | High | No |  |  |
| Low | Yes |  |  |

 |
| 47) Has the IMP(s) been assessed against the currently accessible COVID-19 vaccines? *Is there a risk of interactions between a deployed COVID vaccine and the IMP? Are there any other risks to be considered? Please provide further details* | High | No |  |  |
| Low | Yes |  |  |

|  |
| --- |
| **Chief Investigator Comments Q45-47** |
|  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Count risk factors (RF) in each category** | **Score for each RF** | **Category Score** | **Downgraded RFs** | **Adjusted Score** |
| High Risk |  | 2 |  |  |  |
| Medium Risk |  | 1 |  |  |  |
|  |  | **TOTAL** |  | **ADJUSTED TOTAL** |  |

Where more than one risk category has been checked in a question (e.g. one high and one medium) please count them both.

Downgrade RFs into the category immediately below if a risk management plan is in place which eliminates or substantially ameliorates the risk. For each RF you downgrade, subtract 1 from the Category Score column. For instance, if a High risk is downgraded to Medium, subtract 1; if two Mediums are downgraded to Low risk, subtract 2.

|  |  |  |
| --- | --- | --- |
| **Adjusted Total** | **Rating** | **Sponsorship Decision** |
| 26 +  | High Risk | Refer to Head of Research Governance and Integrity |
| 16 – 25 | Moderate Risk | Consider referring to Head of Research Governance and Integrity, depending on proportion of high risks. |
| 0 – 15 | Moderate/Low Risk | Discuss with Clinical Trials Manager to issue Sponsorship  |

|  |  |
| --- | --- |
| **Date risk assessment finalised with Clinical Trials Team:** |  |
| **Decision****(select one choice):** | 🞎 Sponsorship issued🞏 Sponsorship rejected |
| **Name and signature of Clinical Trials Manager** |  | **Date** |
| **Name and signature of Head of Research Governance and Integrity** |  | **Date** |

This declaration of information is required to streamline information flows between College and Trust units. It is important to ensure that this study is sponsored by the correct legal organisation. This information is also required by the RGIT so a risk assessment of the project can be undertaken.