**Risk Assessment form for First in Human (FIH) Phase I trials**



The information provided within this form will allow the FIH Phase I committee to identify, assess and mitigate the risks associated with conducting the trial within a NHS Greater Glasgow and Clyde (NHS GG&C) site, thus ensuring the safety of the research participants.

The form should be completed for **FIH Phase I trials only**, sponsored and/ or hosted by NHS GG&C. If NHS GG&C is the sponsor of a multi site FIH Phase I trial, this should be clearly indicated within this risk assessment.

It is the responsibility of the person directing the research (i.e. the Principal Investigator) to ensure that the FIH Phase I committee requirements are complied with and any changes to the risk assessment or non-compliances, serious breaches or safety issues are reported to the FIH Phase I committee.

The review of amendments following R&D Management Approval of FIH Phase I trials will be undertaken by the R&D department and do not need to be submitted to the FIH Phase I committee unless the FIH administration has yet to occur.

**Please complete this form and email to the** Governance Team **along with a copy of the IB, protocol, MHRA comments and REC comments, if available.**

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| **1. FIH Phase I trial details** | |
| **Research title** |  |
| **NHS GG&C R&D No.** |  |
| **IRAS No.** |  |
| **EudraCT No.** |  |
| **CTA No.** |  |
| **Status of MHRA authorisation** |  |
| **Status of REC opinion** |  |
| **Did the study require the MHRA to seek Clinical Trials Expert Advisory Group (CTEAG) advice? If yes, please detail the advice.** |  |
| **Sponsor** |  |
| **Sponsor contact (e.g. safety officer/medical officer)** |  |
| **Above sponsor contact details** |  |
| **Chief Investigator** |  |
| **Chief Investigator contact details** |  |
| **Principle Investigator (if different from Chief Investigator)** |  |
| **Principle Investigator contact details (if different from Chief Investigator)** |  |
| **Proposed start date** |  |
| **Proposed end date** |  |
| **Current protocol version** |  |
| **Documents submitted for FIH Phase I committee review (to include IB, protocol, MHRA comments, REC comments)** |  |

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| **2. Hospitals and locations where Phase I trial will primarily be carried out** | |
| **Hospital(s)** |  |
| **Exact location within hospital (department, floor, ward, unit, etc.)** |  |
| **Contact details for relevant departments** |  |

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| **3. Principal investigator contact details** | |
| **Name** |  |
| **Position** |  |
| **Address** |  |
| **Phone** |  |
| **Email** |  |

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| **4. Principal investigator information** |
| Please ensure CV detailing qualifications and publications relevant to Phase I trials. (On first submission to the FIH Phase I committee, please provide this information. This information is only required to be submitted once unless the information changes significantly.) |
| **Section A: Pharmacology qualifications and experience** (On first submission to the FIH Phase I committee, please complete this Section A. This information is only required to be submitted once unless the information changes significantly.)   1. Do you have a postgraduate qualification or speciality training in pharmacology and/ or pharmaceutical medicine?   If **yes**,please describe qualification and year awarded.   1. Do you have Pharmacology experience such as PhD, industry expe**r**ience or academic experience?   If **yes**, please describe. |
| **Section B: Research experience** (On first submission to the FIH Phase I committee, please complete this Section B. This information is only required to be submitted once unless the information changes significantly.)   1. Have you been a PI or CI on a Phase I trial before?   If **yes**, for how many trials?   1. Have you been a sub investigator in a Phase I trial before?   If **yes**, for how many trials?   1. Have you experience in FIH trials?   If **yes**, please describe role and number of trials.   1. Have you experience in dose escalation trials?   If **yes**, please describe role and number of trials.  If **no** to any of the above, please give details of mentor in section D below. |
| **Section C: Role of PI**  Please describe the role of PI in this trial (e.g. will the PI be administering the study drug(s), overseeing the administration, determining SAEs and SARs?). *Please note that the PI is required to be physically present or available during the very first IMP administration*  Please indicate roles that have been delegated. Include a copy of the delegation log (if available). |
| **Section D: Supervision of PI**   1. Does the PI require some supervision or mentoring for this Phase I trial? 2. If **yes**, does the PI have someone to provide that support?   If **yes**, to either of the above please provide the name, qualifications and experience of the supervisor or mentor. |
| **Section E: Training of PI**  Describe the study specific training that you have or will receive (include training specific to pre clinical trials, patient safety and emergency contingency planning including treatments to manage adverse reactions).  Date of training:  How was this delivered (slides e-mailed, trainer delivered, include name of trainer)?  Date of last GCP training (this must be within the last two years):  Name of Provider:  Date of last immediate life support (ILS) training (this is recommended annually for all investigators conducting Phase I trials):  Name of provider:  Date of last advanced life support (ALS) training (this is recommended annually for all investigators conducting CTEAG reviewed Phase I trials:  Name of provider:  If the investigator does not have ALS training, please state how advanced life support will be accessed if required. |

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| **5. Study team information** |
| Please list the researchers and other staff conducting the study including co/ sub-investigators, registrars, pharmacists, nurses, radiologist, etc. These will be the individuals who will be listed on the delegation log. Clearly indicate which individual(s) will be administering the study drug(s) if this is not carried out by the PI.  Please indicate their training and experience, including pharmacology experience, GCP training, ILS training and Phase I training and experience. |

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| **6. Preclinical information and literature reviews** (for all drugs classed as IMPs) |
| **From the IB summarise any Early Clinical studies using the IMP(s).**  Which targets have potential for drug interaction, e.g. CYP?  Are any specific systems highlighted for specific monitoring, e,g, hepatic, renal etc? |
| Summarize any preclinical animal studies (including species), toxicology and in vitro studies (reference protocol and investigators brochure(s)) |
| Provide evidence of risk analysis of the preclinical, in vitro, previous human studies (where relevant for new combinations) and available literature of the IMP(s) on the safety of patients (adverse events, on and off target areas). |
| Describe how you have interpreted the animal studies, toxicity information, immunological or observational data on the impact on the safety of the patient(s) you will be recruiting? |
| Highlight any likely toxicity expected from this class of drug. |

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| **7. Investigation medicinal products (IMPs) to be used in trial** |
| Please describe IMP and the mode of action of the drug giving consideration to:   * Molecular target(s) * Biochemical pathway affected and the biological effects of targeting this pathway * Preclinical work or knowledge of the mechanism of action indicating a possibility of an adverse biological cascade or cytokine release * Other predicted drug interactions based on preclinical work or biochemical assay * Is this IMP first in class?   Does the level of expression and biological function of the target differ between healthy volunteers and subjects with the relevant disease? |

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| **8. Administration of IMP(s).** For multiple IMPs please repeat the table. | |
| Name of IMP |  |
| Route of administration |  |
| Rate of administration |  |
| Proposed starting dose |  |
| Has an independent re-calculation of the starting dose been performed? |  |
| Rational and method of first dose |  |
| Name of person(s) responsible for checking calculations at dosing and administration time |  |
| Estimated exposure time/ half life of IMP and estimated continual effect time?  How does this compare to preclinical data, in vitro data, literature and previous human studies? |  |
| Indicate the time interval between the initial dose administration to the first subject and subsequent subjects. |  |
| Describe strategy for dose escalation and justification. |  |
| Name of individual administering IMP(s) |  |
| Names of study team present during administration  *Please note that the PI is required to be physically present or available during the very first IMP administration.* |  |
| Location of administration including justification |  |
| What is the period of observation of the first patient and names of individuals who will be responsible for this? |  |
| What is the lag period for observation before any subsequent doses to the first patient? Justify time period. |  |
| What is the period of observation between patients? Justify. |  |
| Describe the medical cover available on dosing day and the location of this medical cover?  Provide evidence that this individual(s) will be aware of the trial including the specific and relevant information on the IMP being given?  Please describe the arrangements for immediate maintenance of life support (resuscitation and stabilization) and onward transfer of research participants, where necessary.  Is there an easily and rapidly accessible emergency trolley/ bag available in the dosing area? |  |
| Provide communication plans with High Dependency Unit(s) and where appropriate High Acuity Units (Beatson and Gartnavel only trials), including transfer arrangements from place of administration to High Dependency/High Acuity in case of medical emergency. Include the names of the HAU and HDU consultants who have been given the appropriate information, including but not limited to the IMP and dosing time, in the event of a transfer. |  |

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| **9. Adverse events** |
| Describe measures site staff will employ to monitor adverse events based on the preclinical studies. |
| Describe the strategy to manage adverse events, reactions and in particular infusion reactions. |
| For each IMP, taking into account the IB and known information please describe   * + Probability of severe events occurring   + The likely seriousness of any reactions   + Potential short and long term reactions   + Is there an effective way to counteract the IMPs biological effects?   + Contingency plans for any adverse reactions that cannot be counteracted, |
| Detail the safety system to be used for this trial including how you will capture events if the patient is under the treatment of another doctor such as HAU or HDU consultant. |
| Please state the 24-hour emergency contact number that will be provided to research participants for when they are outside the hospital. |

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| **10. Pharmacy** (to be completed by pharmacist when information available) |
| Source of IMP(s)  List where the IMP(s) is coming from. |
| Is the IMP from the same batch used for preclinical work?  If **no**, what tests were used to determine specificity and potency?  Are these tests validated? **Yes** 🞏 **No**:🞏  Are there any differences from the batch used for preclinical work? |
| Is supply guaranteed for the duration of the trial?  Will multiple batches of IMP be used? |
| Please attach QP certification and further requirements to prepare and handle IMP(s). |
| What is the expiry of the IMP?  Once prepared are there any specific time frames or storage requirements: **Yes** 🞏 **No**:🞏  If **yes**, describe the plan in place to meet these requirements.  . |
| What measures have been taken to ensure small doses or methods used to deliver the dose are providing an accurate dose? |

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| **11. Additional information from trial team** |
| Please use this box to provide additional information or comments. |