This Sponsorship Risk Assessment must be completed by the Chief Investigator (CI) for applicable health and social care research to be considered by Lancaster University for sponsorship. It is expected that queries or actions are discussed with the CI and research teams and plans for mitigation agreed as part of the sponsor review process.

Risk can be defined as the likelihood of a potential hazard occurring and resulting in harm to the participant and/or organisation, or to the reliability of the results. This can be graded low, medium, and high likelihood of the hazard occurring and result in harm. If you are uncertain, you should contact the clinical research governance office (sponsorship@lancaster.ac.uk) and referring to the Risk Analysis Matrix (HSCR-GD005).

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| **Section 1 – Study Overview** |
| **Full Study Title** |  |
| **Short Study Title** |  |
| **IRAS Number** |  |
| **Proposed Start Date** | Click or tap to enter a date. | **Proposed End Date** | Click or tap to enter a date. |
| **Study Type (please select one)** | **Clinical Trial of an Investigational Medicinal Product (CTIMP)**  |[ ]
|  | **Is this study a clinical investigation or other study of a medical device?** |[ ]
|  | **Is the study a combined trial of an investigational medicinal product and an investigational medical device?** |[ ]
|  | **Is the study a clinical trial, novel intervention or randomised clinical trial to compare interventions in clinical practice?** |[ ]
|  | **Basic science study involving procedures with human participants** |[ ]
|  | **Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology** |[ ]
|  | **Study involving qualitative methods only** |[ ]
|  | **Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)** | [ ]   |
|  | **Study limited to working with data (specific project only)** |[ ]
|  | **Research tissue bank** |[ ]
|  | **Research database** |[ ]
|  | **Other study type** |[ ]
| **Funder** |  | **Funding Total (GBP)** |  |
| **Is this study being undertaken as part of an educational qualification?** | **Yes** [ ]  **(please specify)** | **Please provide details of the educational qualification:** |  |
|  | **No** [ ]  |  |  |
| **Section 2 – Chief Investigator Details** |
| **Title** | **Prof.** [ ]  **Dr.** [ ]  **Mr.** [ ]  **Mrs.** [ ]  **Ms.** [ ]  **Other:** | **Post Title(s)** |  |
| **Forename(s)** |  | **Work Email** |  |
| **Surname** |  | **Work Telephone** |  |
| **Substantive Employer** | **Lancaster University** [ ]  | **NHS Employer (if applicable)** |  |
|  | **Other (please specify):** |  |  |
| **Lancaster University Faculty** | **Arts and Social Sciences (FASS)** [ ]  | **Health and Medicine (FHM)** [ ]  | **NHS Contract Type** | **Substantive Contract** [ ]  |
|  | **Science and Technology (FST)** [ ]  | **Management School (LUMS)** [ ]  |  | **Honorary Clinical Contract** [ ]  |
| **Section 3 – Participant Recruitment** |
| **In which countries of the UK will research sites be located?** | **England** [ ]  | **Northern Ireland** [ ]  | **If applicable, in which countries outside of the UK will research sites be located?** |  |
|  | **Scotland** [ ]  | **Wales** [ ]  |  |  |
| **If this is a multi-centre study, how many research sites?** |  | **NHS research sites?** | **Yes** [ ]  **No** [ ]  |
|  |  | **NHS Participant Identification Centres? (PICs)** | **Yes** [ ]  **No** [ ]  |
| **If NHS research sites or PICs are involved, please name:** |  |
| **Please name the lead NHS organisation** |  |
| **Total number of participants** |  | **Number of Patients** |  | **Number of Healthy Volunteers** |  |
| **Do you plan to include any of the following participants?** | **Children** [ ]  | **Prisoners/young offenders in the custody of HM Prison Service** [ ]  |
|  | **Adults lacking the capacity to consent** [ ]  |  |
| **Inclusion Criteria** |  |
| **Exclusion Criteria** |  |

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|  | **Section 4 – Clinical Procedures and Devices (Check here if NA and move to next section**[ ] **)**  |
| **Does the study involve the use of any ionising radiation?** | **Yes** [ ]  **No** [ ]  |  | **Does the study involve exposure to radioactive materials?**  | **Yes** [ ]  **No** [ ]  |
| **Will you be taking new human tissue samples (or other human biological samples)?** | **Yes** [ ]  **No** [ ]  |  | **Will you be using existing human tissue samples (or other human biological samples)?** | **Yes** [ ]  **No** [ ]  |
| **Please identify all devices that will be purchased, gifted or loaned as part of the study e.g. medical devices, mobile devices etc. as well as their supplier name.** |  |  |
|  | **Section 5 – External Services****Will this study require services provided by external organisations? (Check here if NA and move to next section**[ ] **)** |
| **Clinical Trials Unit / Clinical Research Unit** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Imaging Facilities e.g. MRI, PET etc.** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Pharmacy** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Radiology** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Laboratory** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Other (please specify)** | **Yes** [ ]  **No** [ ]  |  | **If ‘Yes’, please provide organisation name** |  |
| **Section 6 – Risk Assessment of the Intervention (Check here if NA and move to next section**[ ] **)****Where risks associated with the intervention are somewhat or markedly higher than those of standard medical care (i.e. Type B or Type C trials), details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described. Please add rows where needed.** |
| **Risks associated with intervention:**[ ]  **Type A:** risk comparable to that of standard medical care [ ]  **Type B:** risk somewhat higher than that of standard medical care [ ]  **Type C:** risk markedly higher than that of standard medical care  |  | **Justification: Please** give reasons why Type A/B/C was applied for this study |
|  |  |
| **Intervention** | **Body System** | **Hazard** | **Risk Score** (Please state both Likelihood andImpact score, as well as calculated risk scores see HSCRS-GD005 for how to calculate risk score) | **Mitigations**  | **Risk Score after mitigations have been implemented.**(Please state both likelihood, and impact score, as well as calculated risk score)  | **Comments/actions**  |
| e.g. ABC123 | e.g. Metabolic | e.g. Hyperglycaemia | e.g. Likely and moderate 3x4=12  | e.g. Blood glucose monitoring |  eg: possible and moderate 3x3=9  | e.g. monitoring will be done 4 hourly. Enhanced oversight.  |
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|  | **Section 7 – Risk Assessment of the Medical Device****(Check here if NA and move to next section**[ ] **)** **Where risks associated with device are higher than normal (i.e. device used outside of CE marking, or device without CE marking), details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described. The device risk assessment should be based on available information (e.g. Investigator Brochure, Device Technical Specification)** |
| **Use of the medical device (please select ONE only):**[ ]  CE marked device used within its intended purpose(s) [ ]  CE marked device which has been modified or will be used outside its  intended purpose(s) [ ]  Non-CE marked device  | **Justification** |
|  |
| **Intervention** | **Body System** | **Hazard** | **Risk Score** (Please state both Likelihood andImpact score, as well as calculated risk scores see HSCRS-GD005 for how to calculate risk score) | **Mitigation** | **Risk Score after mitigations have been implemented.**(Please state both likelihood, and impact score, as well as calculated risk score) | **Comments/actions** |
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| **Section 8 – Research Risk Assessment****Mark risk as ‘N/A’ if not relevant for this study. List any other risks identified for this study in ‘Other’** |
| **Risk Factor***Potential source of harm* | **Concerns Identified** Provide details of study-specific considerations/ risk concerns | **Likelihood and impact score**(see HSCRS-GD005 for scoring guidance)  | **Risk Score** (see HSCRS-GD005 for scoring guidance)  | **Mitigation Strategies** Address all concerns identified | **Likelihood and impact score after mitigation strategies have been implemented**(see HSCRS-GD005 for scoring guidance)  | **Total Score after mitigation strategies have been implemented** (see HSCRS-GD005 for scoring guidance)  |
| **Participant population** Healthy volunteer/patient;age/vulnerable group;Rare disease/illness;Non-adherence to study intervention |  |  |  |  |  |  |
| **Recruitment**Eligibility criteria;Withdrawal procedures |  |  |  |  |  |  |
| **Consent**Verbal/written;Emergency situation;Consultee/legal representativeConsent for data/tissue |  |  |  |  |  |  |
| **Data protection**Data access;Processing is “likely to result in a high risk to the rights and freedoms of natural persons” or consider if activities undertaken require a DPIA (Please refer to point 6.2 of the university data protection policy to confirm)Appropriate permissions in place to access patient data;Collection person identifiable data;Collection of personal sensitive dataData sharing/transfer outside UK/EU or NHS organisation;Storage of data;Destruction/archiving of data |  |  |  |  |  |  |
| **Study assessments** Samples/tests/biopsies/procedures;Visit schedule vs. standard care; Psychological assessments; |  |  |  |  |  |  |
| **Study team suitability**Appropriate qualifications;Research experience;ICH GCP trained;Protocol training;Awareness of Sponsor SOPs;Resource allocation;Research Passport arrangements;Delegation log |  |  |  |  |  |  |
| **Researcher considerations**Lone working;Distress protocol;Knowledge of relevant local policies and procedures in relation to safeguarding;Overseas travel |  |  |  |  |  |  |
| **Partner organisations**Additional sites – NHS, third sector;External service/third party providers;Geography; Language;International regulations |  |  |  |  |  |  |
| **Study management**Adequate lead site staff;Trial manager;Responsibilities of CTU |  |  |  |  |  |  |
| **Feasibility of delivery**Access to suitable patient population/recruitment rate;Research site identification and support via departments/clinics/ wards;Equipment supply/maintenance |  |  |  |  |  |  |
| **Data collection/management**Source data;(e)CRF design and completion;Database design and entry;Quality control/verification checks |  |  |  |  |  |  |
| **Sample collection/management** Storage and sample tracking; Temperature monitoring;Shipment to external labs |  |  |  |  |  |  |
| **Study recruitment power**Feasible recruitment target; Expected attrition rate;Participant withdrawal;Loss at follow-up |  |  |  |  |  |  |
| **Blinding and/or randomisation**Blinded allocation;Single/double blind;Un-blinding procedures |  |  |  |  |  |  |
| **Complexity of study design** Intervention;treatment arms/groups;Visit schedule and follow-up |  |  |  |  |  |  |
| **Trial master file maintenance** |  |  |  |  |  |  |
| **Insurance/indemnity arrangements** |  |  |  |  |  |  |
| **Protocol, regulatory and SOP compliance** |  |  |  |  |  |  |
| **Finance and Funding**Costed appropriately;Confirmation of funding;Funds cover duration of study;NHS research costs included at all sites |  |  |  |  |  |  |
| **Contracts and agreements**Appropriate funder contract in place; Appropriate sub-contracts in place with contractors and research sites |  |  |  |  |  |  |
| **IP Issues** |  |  |  |  |  |  |
| **Oversight**Monitoring/auditing required; Risk of not completing monitoring and audit; Safety reporting;Management groups;Steering committee;Meetings; A*dequate patient safety monitoring and reporting**[oversight bodies, documents]. Unblinding procedures* |  |  |  |  |  |  |
| **Lancaster University Reputational Risk** |  |  |  |  |  |  |
| **Approval and Compliance***Compliant with regulations* *Is it a clinical trial, HTA regulations, etc* |  |  |  |  |  |  |
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| **Other (please specify)** |  |  |  |  |  |  |
| **Other (please specify)** |  |  |  |  |  |  |
| **Other (please specify)** |  |  |  |  |  |  |

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| **SECTION 9-ACTION PLAN**  |
| **Area of Risk**  | **Action Plan**  | **Priority**  | **Action Taken By**  | **Target Completion Date** | **Completion Sign and Date** |
| Eg: Data Collection Use of special category data  | Eg: DPIA assessment required. Enhanced level of monitoring to take place and focus on data collection procedures and documentation and storage of personal data.  | High  | HY | 09/12/2024 |  |

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| **SECTION 9-CI Signature** |
| **Completed by:** |  | **Date:** |  |
| **Signature:** |  | **Position:** |  |
| **SECTION 10-Sponsor Signature** |
| **Reviewed By:**  |  | **Date:** |  |
| **Signature:**  |  | **Position:** |  |

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| **Risk Assessment Form (RAF) Completion, Review and Revision Record****This Risk Assessment should be reviewed and amended if necessary whenever substantial amendments are made. An annual review of the RAF should be made whether or not there have been any amendments. It is recommended that this occurs at the same time as the submission of annual reports to REC.** |
| **Risk Assessment Completion or Review Date** | **Completed by** | **State Reason for Initial Completion or Reason for Review** | **Version of RAF Reviewed** | **Protocol Version and Date** | **Outcome of Review****(Revision Required/** **no revision required)** | **Summary of Revisions** |
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