| **Project Information** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PID** |  | | | | | | | **Principal Investigator** | | | |  | | |
| **IRAS Number** |  | | | | | | | **REC Reference** | | | |  | | |
| **Study Title** |  | | | | | | | | | | | | | |
| **Sponsor** |  | | | | | | | | | | | | | |
| **Division(s) / department(s)** |  | | | | **Sub-division(s) / directorate(s)** | | | | | |  | | | |
| **Study Summary**  *Include a brief summary of the study and scientific rationale* |  | | | | | | | | | | | | | |
| **Recruitment** | | | | | | | | | | | | | | |
| How many eligible patients do you see in clinic per month who meet the protocol inclusion / exclusion criteria? | | | | | | Number (Per Month): | | | | | | | | |
| Are there any specific or key eligibility criteria that would make patients difficult to recruit? | | | | | |  | | | | | | | | |
| What percentage of potentially eligible patients would you expect will be motivated to take part?  *Estimates could be from 20% to 40% it is highly unlikely for all potential participants to agree to participate.* | | | | | |  | | | | | | | | |
| How does the study protocol differ from the normal clinical pathway? | | | | | |  | | | | | | | | |
|  | | | | | | **Yes** | | | | **No** | | **N/A** | **Details** | | | |
| Is the indication classed as a rare disease? | | | | | |  | | | |  | |  |  | | | |
| Is the indication a rare sub-category of a more common disease? | | | | | |  | | | |  | |  |  | | | |
| List other research studies / clinical trials within your Directorate / Division which are already underway within this disease area(s)? | | | | | |  | | | |  | |  |  | | | |
| Is there strong competition nationally to recruit to this trial? | | | | | |  | | | |  | |  |  | | | |
| Are we, as a site, joining this study late?  *If other sites are now being added at a late stage, the trial may close before anticipated* | | | | | |  | | | |  | |  |  | | | |
| Can you foresee any other barriers or practical implications? If yes, please give details  *These may be local or national issues that you think may cause problems, or practicalities in the patient group?* | | | | | |  | | | |  | |  |  | | |
| *In view of the above points:*  What is the planned OUH participant recruitment target – for the duration of the study? | | | | | |  | | | | | | | | |
| What is the recruitment end date set by the Sponsor?  *In our experience recruitment can end early – sometimes 3 – 6 months, in that case would the OUH recruitment target for the study still be achievable? Does a lower target need to be considered?* | | | | | |  | | | | | | | | |
| Participant Recruitment Total for insertion into the Contract with the Sponsor, reportable to the NIHR | | | | | |  | | | | | | | | |
| **Management** | | | | | | | | | | | | | | |
|  | | | | | | Yes | | | | No | | N/A | Details | |
| Has this study been approved at your steering group? | | | | | |  | | | |  | |  |  | |
| Does the protocol and PIS align with expectation of delivering the study at site and are they appropriate for use. | | | | | |  | | | |  | |  |  | |
| Do you have a planned SIV date? Please give details | | | | | |  | | | |  | |  | Date: | |
| What is the OUH Target site start date?  (The date you would like to start recruiting patients, this is different to above) | | | | | |  | | | |  | |  | Date: | |
| Has the sponsor / CRO communicated a planned study open date? | | | | | |  | | | |  | |  |  | |
| Is there a chance of a global first or national first patient recruited? | | | | | |  | | | |  | |  |  | |
| **Capacity & Capability and Staffing** | | | | | | | | | | | | | | |
|  | | | | | | | Yes | | No | | | N/A | Details | | | |
| Please assess the need for confirmation from the support departments below and outline any outstanding issues. | | | | | | | | | | | | | | |
| Pharmacy:  Pharmacy.Clinicaltrials@ouh.nhs.uk | | | | | | |  | |  | | |  |  | |
| Radiology:  For application form:  [EthicsRadiationEnquiries@ouh.nhs.uk](mailto:EthicsRadiationEnquiries@ouh.nhs.uk)  To discuss capacity:  [CHRadiologyRd@ouh.nhs.uk](mailto:CHRadiologyRd@ouh.nhs.uk) | | | Ionising | | | |  | |  | | |  |  | |
| Non-ionising | | | |  | |  | | |  |  | |
| NB. All staff should have completed the Research Radiation Assurance e-assessment, workbook and e-learning available via this link: <https://www.enterprisestudy.com/View.aspx?p=100633&c=303460&courseid=303460> | | | | | | | | | | | | | | |
| Pathology: | | | | | | |  | |  | | |  |  | |
| Laboratories: | | | | | | |  | |  | | |  |  | |
| Clinical Engineering: | | | | | | |  | |  | | |  |  | |
| Studies with psychological medicine aspects:   * Does your study involve interviews or questionnaires which include questions about psychological experiences e.g. depression, anxiety, traumatic experiences, suicidal thoughts, hallucinations, confusion? * Does your study involve any kind of psychological or psychiatric intervention? * Does your study seek to recruit participants with a psychological problem e.g. depression, cognitive impairment, confusion? | | | | | | |  | |  | | |  | If yes, please contact the following to discuss and confirm capacity/resources:  [Jane.Walker2@ouh.nhs.uk](mailto:Jane.Walker2@ouh.nhs.uk) | |
| Gene Therapy Medicinal Products (GTMP):  For application form/submissions:  [ATMPandGMSCcommittee@ouh.nhs.uk](mailto:ATMPandGMSCcommittee@ouh.nhs.uk) | | | | | | |  | |  | | |  |  | |
| Advanced Therapy Medicinal Products (ATMPs):  For application form/submissions:  [ATMPandGMSCcommittee@ouh.nhs.uk](mailto:ATMPandGMSCcommittee@ouh.nhs.uk) | | | | | | |  | |  | | |  |  | |
| Are there any external organisations involved with the delivery of the conduct of the trial?  *Consider whether some services will be provided by external or third parties? This may require a separate Service Level Agreement* | | | | | | |  | |  | | |  |  | |
| Does the study involve transfer of data or samples to external organisations?  *Consider whether a data sharing agreement or material transfer agreement will be required; or is this information sufficient in the Organisational Information Document (OID)* | | | | | | |  | |  | | |  |  | |
| Do you have the appropriate space required to conduct the study?  *Consider space, confidentiality, access to tests and treatments, ease of access for patients etc.* | | | | | | |  | |  | | |  |  | |
| Is there any specialist expertise or training required for the study which might impact on site feasibility? If yes, please give details.  *Consider, for example, whether a surgeon needs training on how to use the trial equipment? Or New device training?* | | | | | | |  | |  | | |  |  | |
| Have you secured support from the CRN?  If yes, please provide detail of what type of support will be made available to you. | | | | | | |  | |  | | |  |  | |
| Is it planned that the PI will be working at the trust for the lifetime of the project?  *Consider the commitment required for this and other studies, who would stand in as PI in the absence of this named PI?* | | | | | | |  | |  | | |  |  | |
| **STAFFING:** If any team members do not have a substantive or honorary contract of employment please request a research passport application from R&D and discuss this with your governance reviewer. | | | | | | | | | | | | | | |
| **Equipment and Supplies** | | | | | | | | | | | | | | |
| Is there any equipment that the sponsor is intending to loan or provide to the study team, for the lifetime of the project, for example:   * Medical devices (Stents, valves, DBS) * Centrifuges, BP or ECG machines, laptops   If so please complete the appended form and send to clinical engineering. | | | | | | | | | | | | | | |
| Please identify any other issues that you wish to draw to the attention of R&D | |  | | | | | | | | | | | | |
| Completed by Name: | | | | Role: | | | | | | | | | | Date: |

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| **R&D GOVERNANCE USE ONLY  *Ensure comments below are updated in Studyline*** | | |
| **DATE** | **Comment** | **RSS** |
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