| **Project Information** |
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| **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 To discuss capacity: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  |
| Gene Therapy Medicinal Products (GTMP):For application form/submissions:ATMPandGMSCcommittee@ouh.nhs.uk |  |  |  |  |
| Advanced Therapy Medicinal Products (ATMPs):For application form/submissions: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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