**NuTH-Sponsored Study Site Capability Form**

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| **RESEARCH DETAILS** | | | | | | | | | | | |
| **1. Study title:** | |  | | | | | | | | | |
| **2. R&D reference:** |  | | **3. IRAS ref:** | |  | | | **4. Phase** (if ctIMP/ATIMP): |  | | |
| **5. Research Team:** | |  | | | | | | **6. Division:** |  | | |
| **7. Principal Investigator:** | | |  | | | | | | | | |
| **8. Research Nurses:** | | |  | | | | | | | | |
| **9. Trial Co-ordinator:** | | |  | | | | | | | | |
| **10. Data Manager:** | | |  | | | | | | | | |
| **11. Funding Category**: | | | Commercial / Non-Commercial | | | | | | | | |
| **12. CTU** (if applicable): | | |  | | | | | | | | |
| **13. Is the study eligible for portfolio adoption:** *Guidance* [*here*](https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/) | | |  | | | | | | | | |
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| **14. Does the study require review by the Early Phase Group?**  If yes, please provide confirmation of review. | | | | | | | | | | | Yes / No |
| **15. Does the study require review by the New Interventions Committee?**  If yes, please provide confirmation of review. | | | | | | | | | | | Yes / No |
| **16. Does the study require review by the Gene Therapy Advisory Group?**  If yes, please provide confirmation of review. | | | | | | | | | | | Yes / No |
| **17. Does the study involve collection and storage of tissue samples at either NuTH or Newcastle University?** Material requiring storage under the HTA must be stored in a location approved by the Designated Individual. Please provide confirmation of approval and location of samples. | | | | | | | | | | | |
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| **18. Please provide a brief summary of the research and what interventions are involved (in lay/as if explaining to a patient):** | | | | | | | | | | | |
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| **19. What is the agreed NuTH site recruitment target?** | | | | | | |  | | | | |
| **20. Where will this study take place?** please state hospital location / clinical area / directorate | | | | | | | | | | | |
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| **21. Has local Caldicott approval been obtained?** | | | | Yes / No | | **21a. What is the Caldicott ID number?** | | | | |  |
|  | | | | | | | | | | | |
| **22. Who holds the funding for this study?** (If it is held by someone other than NuTH, please provide details of what agreement is in place to transfer funding allocated to NuTH. Please include relevant costing template). | | | | | | | | | | | |
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| **PROPOSED TIMEFRAMES:** | | | | | | | | | | | |
| **23. First patient first visit date at NuTH**  (as agreed with support departments): | | | | | | **DD / MM /YYYY** | | | | | |
| **24. Pharmacy ready date** (if applicable): | | | | | | **DD / MM /YYYY** | | | | | |
| **25. Recruitment end date:** | | | | | | **DD / MM /YYYY** | | | | | |
| **26. Last Patient Last Visit date:** | | | | | | **DD / MM /YYYY** | | | | | |
| **27. End of study date:** | | | | | | **DD / MM /YYYY** | | | | | |
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| **DEPARTMENTAL CAPACITY:** | | | | | | | | | | | |
| **28. Is there sufficient nursing support available within the research team for the duration of the study?** | | | | | | | | | | Yes / No / NA | |
| **29. Is there sufficient study coordination support available within the research team?** | | | | | | | | | | Yes / No / NA | |
| **30. Is there sufficient data management support available within the research team?** | | | | | | | | | | Yes / No / NA | |
| **31. Has pharmacy/PPU (if applicable) confirmed available support for the study in accordance with the timeframes outlined above?** Please attach email confirmation. | | | | | | | | | | Yes / No / NA | |
| **29. Has radiology (if applicable) confirmed available support for the study in accordance with the timeframes outlined above?** Please attach email confirmation. | | | | | | | | | | Yes / No / NA | |
| **30. Have laboratories (if applicable) confirmed available support for the study in accordance with the timeframes outlined above?** Please attach email confirmation. | | | | | | | | | | Yes / No / NA | |
| **31. Are any additional support departments required and confirmed available support?** Please attach email confirmation. | | | | | | | | | | Yes / No / NA | |

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| **DECLARATION:**  **I confirm that the information provided above is accurate to the best of my knowledge and that I am willing to support the undertaking of this study in accordance with the information provided above:** | | | |
| **Principal Investigator**  **signature: :** |  | **Date:** |  |
| **Team Lead**  **signature:** |  | **Date:** |  |
| **Delivery Lead**  **signature:** |  | **Date:** |  |
| **Research Clinical Lead**  **signature:** |  | **Date:** |  |