**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?** |  |
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| **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:** |  |