**DIRECTORATE OF RESEARCH AND INNOVATION**

**Note to File**

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| --- | --- |
| **Protocol Title:** |  |
| **R&D Number:**  |  |
| **Principal Investigator (PI):** |  |
| **Note to File Title:**  |  |
| Based on SOP/R/004 Archiving, the study file can be archived once the close-out letter has been filed, and the GOSH/ICH Named Archivist has given permission. The study team does not need to wait for the final study report to archive the study. It is the Sponsor’s responsibility to send out the final study report in a timely manner to the study PI and Research.Governance@gosh.nhs.uk. If this is provided after the study has been archived, it will be filed electronically with the study records on EDGE by the appropriate R&D team. ***Additional text to add if applicable:****This study has been registered on [insert publicly accessible database where the research study has been registered e.g. ClinicalTrials.gov, or ISRCTN]. A summary of results may be published here by the Sponsor when available.* |
| **File Note Author** |
| **Name:** |  | **Role:** |  |
| **Signature:** |  | **Date:** |  |
| **Principal Investigator** |
| **Signature:** |  | **Date:** |  |
| **Sponsor Representative(s)/CRA *(please add additional rows if required)*** |
| **Name:** |  | **Role:** |  |
| **Signature:** |  | **Date:** |  |