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| **CLINICAL RESEARCH STUDY ARCHIVING PLAN** |
| **Sponsor R&D No:** | **REC No:** |
| **EudraCT No (if applicable):**  | **Chief Investigator (CI):**  |
| **Retention period: 5 years/15 years or Other (Please specify)** | **Study Type: 🞏 CTIMP 🞏 NCTIMP 🞏 Paediatric** |
| **Study Archiving Contact Name: Contact Details (email/phone):** |

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| **TMF/SMF Component** | **Paper or Electronic****(Please specify)** | **Location****(Please specify)** | **Contact** |
| CTIMP Sponsor File (separate boxes) | Paper | NHS Tayside Off Site/Contracted Vendor | TASC Senior Research Governance Manager |
| TCTU/DM FileOther DM File | Paper | NHS Tayside Off Site/Contracted Vendor | TCTU Clinical Trials Information Systems Manager *Or Specify* |
| TCTU Stats File (including programming)Other Stats File (including programming) | Paper | NHS Tayside Off Site/Contracted Vendor | TCTU Trial Statistician*Or Specify* |
| CTIMP PV File |  | NHS Tayside Off Site/Contracted Vendor | TASC Pharmacovigilance Monitor |
| Legal File | Paper | NHS Tayside Off Site/Contracted Vendor | TASC Head of Legal Services |
| Tayside ISF (including pCRFs, pICFs, training logs) | Paper | NHS Tayside Off Site/Contracted Vendor | CI/Study Archiving Contact |
| CTIMP NHST CTP PSF | Paper | NHS Tayside Off Site/Contracted Vendor | NHST Clinical Trials Pharmacist |
| Electronic Correspondence | Paper & Electronic | Essential paper – on TMF; Other - electronic | N/A |
| CTIMP Tayside Pharmaceuticals | Paper | Tayside Pharmaceuticals | Tayside Pharmaceuticals |
| Other e.g. external CTU File, Regional Site Files, CRO File, UoD Pharmacy File, GP/GDP File, Vendor file *Specify* | Paper/Electronic |  |  |
| eCRF *Specify* | Electronic |  |  |
| Trial Database (data/metadata) *Specify* | Electronic |  |  |
| Other data/bases (e.g. TRuST, PMS) *Specify* | Electronic |  |  |
| Removable media *Specify media & data held* | Electronic |  |  |
| **Site Archiving** |  |  |  |
| ISFs (including pCRFs, pICFs, training logs) | Paper |  |  |
| CTIMP Site PSFs | Paper |  |  |

Please file this document in TMF/SMF/ISF For CTIMPs please send this document and any updated versions to tay.tascarchiving@nhs.scot