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| Form number | **53.014A** | Version | **1.0** |
| Title | **External Sponsor Monitoring Process Arrangement** | | |

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| **Study Title –**  **R&I Reference -** |

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| **Sponsor name:** |  | | | | |
| **Monitoring Processes** | | | | | |
| Will NHSGGC Monitoring SOPs be used? | | **Yes** |  | **No** |  |
| If No, please provide details: | | | |
| Is the Sponsor providing financial support for monitoring? | | **Yes** |  | **No** |  |
| If No, please confirm the source of funding: | | | |
| **Monitoring Activities** | | | | | |
| Who will be responsible for developing the monitoring plan/risk assessment for the trial/investigation? | | **Monitoring Plan:**  **Monitoring Risk Assessment:**  **Items to be documented:**   * **Frequency of visits** * **Remote or on-site** * **SDV requirement etc.** | | | |
| Please confirm the agreed monitoring report templates, Follow up letters and action/resolution document. | |  | | | |
| Confirm who will be responsible for report review and approval. | |  | | | |
| Trial/investigation activity required – e.g. TMG, meetings, preparation of TMF monitoring section etc. | |  | | | |
| Who will be responsible for reporting findings to sites and managing resolution? | |  | | | |

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| Please confirm non-compliance reporting process | **NHSGGC** |  | **Ext. Sponsor** |  |
| If External sponsor processes will training be provided : | | | |
| **Yes** |  | **No** |  |
| Describe training: | | | |
| Please detail the report completion timelines – NHSGGC SOP and QMS or external Sponsor? | **NHSGGC** |  | **Sponsor** |  |
| Timeline: | | | |
| Expected trial/investigation duration - |  | | | |
| Details of responsibilities will be outlined in the Research contract agreement. | | | | |
| Do you foresee any issues with undertaking these responsibilities? | **Yes** |  | **No** |  |
| If yes, please provide details: | | | |
| Sites And Recruitment | | | | |
| Anticipated number of sites? |  | | | |
| Anticipated number of patients per year recruited? |  | | | |
| Any other matters not already captured |  | | | |

**Lead Clinical Trial Monitor/Research Governance Manager**

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| --- | --- |
| **Print Name** |  |
| **Role** |  |
| **Signature** |  |
| **Date** |  |

**Form signatories**

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| --- | --- | --- | --- |
| Prepared by |  | | |
| Signature | Sheila McGowan | Date |  |
| Approved by |  | | |
| Signature | Caroline Watson | Date |  |

**Document history**

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| **Version** | **Date** | **Description** |
| 1.0 | 29/04/2024 | First Release |

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