**Supervision Plan – SWSLHD Sites**

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| **Protocol Title:** |  | | |
| **Protocol Number:** |  | **Sponsor:** |  |
| **Primary Site Name:** |  | **SWSLHD Site Name/s:** |  |
| **Principal Investigator:** |  | **Investigators at SWSLHD Site/s:** |  |
| **Department:** |  | **Department at SWSLHD Site/s:** |  |

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| **Clinical Trial Activity** | **Responsible Parties** | | | | **Comments** |
| **Primary Site Responsibility** | **SWSLHD Site Direct Supervision from Primary Site** | **SWSLHD Site with Support from Primary Site** | **SWSLHD Site Responsible** |
| **Communication** | | | | | |
| Conducting, coordinating & documenting participant visits |  |  |  |  |  |
| Coordinating regular trial meeting to discuss participants & trial progress (e.g. using teletrials or video conference |  |  |  |  |  |
| Coordination of Sponsor monitoring visits |  |  |  |  |  |
| Arranging Sponsor visits to satellite site |  |  |  |  |  |
| **Education & Competence** | | | | | |
| Ensuring all staff at the SWSLHD sites are trained in appropriate aspects of the trial and GCP and are competent to perform their role |  |  |  |  |  |
| Ensuring staff are aware and understand relevant SOPs |  |  |  |  |  |
| Ensuring staff are aware of/ trained on amendments |  |  |  |  |  |
| **Staff Coverage** | | | | | |
| Arranging for back up staff as required at the SWSLHD site |  |  |  |  |  |
| **Clinical Care Decisions** | | | | | |
| Allocating responsibility for trial related management decisions and management of hospitalised participants at the satellite site (e.g. progression, need for additional investigations) |  |  |  |  |  |
| **Funds Management** | | | | | |
| Creating a SWSLHD site SSA application (where applicable) |  |  |  |  |  |
| Creating site-specific documentation |  |  |  |  |  |
| Obtaining local site HOD sign-off |  |  |  |  |  |
| Submitting to the local site RGO |  |  |  |  |  |
| Responding to local site RGO |  |  |  |  |  |
| **Research Governance at the SWSLHD Site: Start Up** | | | | | |
| SWSLHD site start up (general) |  |  |  |  |  |
| SWSLHD site start up (Pharmacy) |  |  |  |  |  |
| SWSLHD site start up (Pathology) |  |  |  |  |  |
| SWSLHD site start up (Imaging) |  |  |  |  |  |
| Providing other trials related equipment |  |  |  |  |  |
| Contracting third party provider/ suppliers |  |  |  |  |  |
| **Investigational Medicinal Product (IMP)/ Device for SWSLHD Site** | | | | | |
| Transport of the IMP/ Device to the satellite site |  |  |  |  |  |
| Ordering of IMP/ Device |  |  |  |  |  |
| Receiving & storage of IMP/ Devices |  |  |  |  |  |
| Dispensing of IMP/ Devices |  |  |  |  |  |
| Reconciling IMP/ Devices |  |  |  |  |  |
| Training pharmacy staff |  |  |  |  |  |
| **Screening of Potentially Eligible Participants at the SWSLHD Sites** | | | | | |
| Screening (inclusion/ exclusion criteria) |  |  |  |  |  |
| **Consent Process at SWSLHD Site** | | | | | |
| Consenting either remotely or at the SWSLHD site |  |  |  |  |  |
| Documenting consent in participants medical records |  |  |  |  |  |
| **Essential Document Management** | | | | | |
| Storing/ managing source documents |  |  |  |  |  |
| **Randomisation** | | | | | |
| Randomising a participant onto the trial |  |  |  |  |  |
| Managing paper CRF data entry |  |  |  |  |  |
| Managing eCRF data entry |  |  |  |  |  |
| Storing essential documents at the SWSLHD site |  |  |  |  |  |
| **Participant Study Involvement at the SWSLHD Site** | | | | | |
| Scheduling of next visit |  |  |  |  |  |
| Notifying participant of next visit |  |  |  |  |  |
| Scheduling of study tests/ procedures |  |  |  |  |  |
| Booking of study test/ procedures with relevant departments |  |  |  |  |  |
| Managing trial visit requirements (e.g. Physical exams, tests, processing samples for shipping etc.) |  |  |  |  |  |
| Conducting clinical trials consultations and assessment as per protocol |  |  |  |  |  |
| **Safety Reporting Occurring at the SWSLHD Site** | | | | | |
| Reporting safety events to Sponsor |  |  |  |  |  |
| Reporting safety events to the SWSLHD site RGO |  |  |  |  |  |
| Reporting safety to the HREC (if required) |  |  |  |  |  |
| Deviation & Serious Breach at the SWSLHD Site |  |  |  |  |  |
| Reporting protocol deviations to the Sponsor |  |  |  |  |  |
| **Managing serious breaches occurring at the SWSLHD site** | | | | | |
| Research Governance at the SWSLHD Site: Amendments |  |  |  |  |  |
| **Managing amendments of site-specific documentation** | | | | | |
| Obtaining local site HOD sign-off (if required) |  |  |  |  |  |
| Submitting to the local site RGO |  |  |  |  |  |
| Responding to local site RGO queries |  |  |  |  |  |
| **Study Close-Out at the SWSLHD Site** | | | | | |
| SWSLHD site close-out visit |  |  |  |  |  |
| SWSLHD site close-out visit (Pharmacy) |  |  |  |  |  |
| SWSLHD site close-out visit (Pathology) |  |  |  |  |  |
| SWSLHD site close-out visit (imaging) |  |  |  |  |  |
| Managing satellite site archiving of trial documentations |  |  |  |  |  |

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| **Investigator Signature:** |  | **Date:** |  |