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| --- | --- |
| **CRC** | Clinical Research Coordinator |
| **CRO** | Clinical Research Organisation |
| **HREC** | Human Research Ethics Committee |
| **IMP** | Investigational Medicinal Product  |
| **PS** | Primary Site |
| **RCCC** | Regional Clinical trial Coordinating Centre |
| **Rep** | Representative |
| **RGO** | Research Governance Office |
| **SS** | Satellite Site |
| **TH** | Telehealth |

#  Location

Abbreviation

|  |  |
| --- | --- |
| **SS option** | This activity may be conducted at the SS |
| **SS location only**  | This activity will only be conducted at the SS |
| **PS location only** | This activity will not be conducted at the SS |
| **Not applicable**  | This activity is listed in the protocol but not applicable to PS or SS |

# Supervision

Definitions

|  |  |
| --- | --- |
| **SS staff conduct independently with supervision via regular communication** | SS staff supervised by regular meetings with PS  |
| **SS staff conduct with TH support from PS staff** | PS accessible by videocall during the conduct of the activity  |
| **SS delegate to third-party provider** | Note: written agreement required to utilise third-party |
| **PS staff conduct via TH with SS face to face facilitation** | SS staff located with the participant while the PS staff conduct activity via telehealth |
| **PS staff conduct via TH direct to patient** | PS staff will conduct this activity via telehealth and share relevant participant records with SS |
| **PS conduct only** | This activity will only be conducted at the PS location |
| **PS delegate to third party provider** | PS will delegate this activity to a third-party provider as agreed |
| **Other, describe** | Provide any further detail in the comments column |
| **Not applicable** | Supervision not required as this activity is not applicable to the PS or SS |



The drop-down menus are consistent across all topics for ease of use.
Where a drop-down option is not applicable please do not select it.

Clinical Trial and Site Details

|  |  |
| --- | --- |
| **Clinical Trial Name** | 🛈 Full name from trial protocol +/- protocol number |
| **HREC Reference Number** | 🛈 Enter HREC reference +/- local identifier |
| **Primary Site (PS)** | 🛈 Primary Site Name and Health Service Name |
| **PS Principal Investigator** | 🛈 Primary Site Principal Investigator Name |
| **Satellite Site (SS)** | 🛈 Satellite Site Name and Health Service Name |
| **SS Associate Investigator** | 🛈 Main Satellite Site Associate Investigator Name  |
| **Contact Person** | 🛈 Person coordinating Supervision Plan e.g. PS CRC or RCCC staff  |

Allocation of Activities to the Satellite Site

# Protocol Specific Activities

🛈 List trial activities defined in the protocol Suggestions:

* copy and paste list of headings only from schedule of assessment table e.g. medical history, physical exam, blood pressure, dispensing etc, or
* summarise activities into key headings e.g. blood testing, questionnaires, vitals etc, or
* copy and paste protocol specific activities from budget spreadsheet
* explain alternate approach in second box e.g. only vitals will be performed at the SS

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity**  | ****Location**** | ****Supervision**** | ****Comments (optional)**** |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. | 🛈 copy and paste additional rows as required |

**🛈 If table above is not suitable, enter an alternative approach here:**

|  |
| --- |
|  |

# Routine Clinical Trial Activities

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity**  | ****Location**** | ****Supervision**** | ****Comments (optional)**** |
| **Recruitment and Consent** |
| Participant identification | Choose an item. | Choose an item. |  |
| Initial participant contact  | Choose an item. | Choose an item. |  |
| Trial consent  | Choose an item. | Choose an item. |  |
| Teletrial consent (Stand-alone) | Choose an item. | Choose an item. |  |
| Reconsent | Choose an item. | Choose an item. |  |
| Withdrawal of Consent  | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| General comments or management summary (optional): |
| **Randomisation** |
| Registration | Choose an item. | Choose an item. |  |
| Randomisation  | Choose an item. | Choose an item. |  |
| Emergency Unblinding | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| General comments or management summary (optional): |
| **Clinical care** |
| Clinical care  | Choose an item. | Choose an item. |  |
| Clinical decision making  | Choose an item. | Choose an item. |  |
| Clinical documentation  | Choose an item. | Choose an item. |  |
| Add headings as required | Choose an item. | Choose an item. |  |
| General comments or management summary (optional): |
| **Investigational Medicinal Product*** Does this trial involve IMP? Yes / No (if “No” go to next section)
* Will the SS handle IMP? Yes / No (if “No” go to next section)
 |
| Storage  | Choose an item. | Choose an item. |  |
| Dispensing  | Choose an item. | Choose an item. |  |
| Administration/Dosing | Choose an item. | Choose an item. |  |
| Returns  | Choose an item. | Choose an item. |  |
| Accountability  | Choose an item. | Choose an item. |  |
| Destruction  | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Biospecimens*** Does this trial involve biospecimens? Yes / No (if “No” go to next section)
* Will the SS handle biospecimens? Yes / No (if “No” go to next section)
 |
| Sample collection  | Choose an item. | Choose an item. |  |
| Processing | Choose an item. | Choose an item. |  |
| Analysis  | Choose an item. | Choose an item. |  |
| Shipping | Choose an item. | Choose an item. |  |
| Storage | Choose an item. | Choose an item. |  |
| Reporting  | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |  |
| **Imaging*** Does this trial involve imaging? Yes / No (if “No” go to next section)
* Will the SS handle imaging? Yes / No (if “No” go to next section)
 |
| Image acquisition | Choose an item. | Choose an item. |  |
| Uploading | Choose an item. | Choose an item. |  |
| Reporting | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Medical Devices** * Is this a trial of a medical device? Yes / No (if “No” go to next section)
* Will the SS handle the medical device? Yes / No (if “No” go to next section)
 |
| Shipment  | Choose an item. | Choose an item. |  |
| Storage | Choose an item. | Choose an item. |  |
| Allocation | Choose an item. | Choose an item. |  |
| Disposal | Choose an item. | Choose an item. |  |
| Specialised training | Choose an item. | Choose an item. |  |
| Sponsor Rep on site  | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Other Intervention*** Is this a trial of an intervention other than IMP or medical device? Yes / No (if “No” go to next section)
* Will the SS be involved in the intervention? Yes / No (if “No” go to next section)

🛈 e.g. psychotherapy, physiotherapy, surgery, education etc |
| Add headings as required | Choose an item. | Choose an item. |  |
| General comments or management summary (optional): |
| **Training** |
| Trial training delivery  | Choose an item. | Choose an item. |  |
| Training documentation | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Communication** |
| Sponsor / CRO | Choose an item. | Choose an item. |  |
| RGO | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| Communication plan between PS and SS (detail meeting frequency and attendees):  |
| SS staff cover plan: |
| General comments or management summary (optional): |
| **Reporting and Safety Management** |
| Reporting to Sponsor | Choose an item. | Choose an item. |  |
| Reporting to HREC | Choose an item. | Choose an item. |  |
| Reporting to RGO | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Data and Documentation** |
| Monitoring  | Choose an item. | Choose an item. |  |
| Source data verification | Choose an item. | Choose an item. |  |
| Data entry | Choose an item. | Choose an item. |  |
| Data queries | Choose an item. | Choose an item. |  |
| Investigator Site File | Choose an item. | Choose an item. |  |
| Archiving | Choose an item. | Choose an item. |  |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |
| **Other** |
| *Add headings as required* | *Choose an item.* | *Choose an item.* |  |
| General comments or management summary (optional): |

# ****Endorsement****

|  |  |
| --- | --- |
| ****PS Principal Investigator**** **Name, Signature, Date** |  |
| ****SS Associate Investigator**** **Name, Signature, Date** |  |

