UoL remote monitoring report

This report is to be used for Sponsor remote monitoring visits as per SOP S-1007 UoL, Sponsor Monitoring.

**Completion of the report:**

* Sponsor will complete ***Part A*** of the report prior to issuing to the study site.
* Study site staff are to work through ***Part B*** of the report, confirming the presence of the listed documents in the site file and providing additional information/documents where required.
* The completed report and additional information/documents should be returned to Sponsor by the date stipulated in ***Part A***.
* Any report sections marked **NA** do not require completing and can be left blank.
* If there are specific documents missing from the site file indicate in the report and Sponsor will forward copies.
* All sponsor SOPs and associated documents can be accessed via our [website](https://le.ac.uk/research/regi/standard-operating-procedures).

**Review and response:**

* Sponsor will review the completed report and additional information/documents within 21 days of receipt. Findings will be detailed in the format of a ‘Corrective Action Preventative Action’ (CAPA) plan on ***Part C*** of the report.
* Findings from the monitoring visit will be categorised as ‘Critical’, ‘Major’ or ‘Other’ as per SOP S-1016 UoL, ‘Procedure in the event of non-compliance in clinical research’.
* Sponsor will issue the CAPA on ***Part C*** of the report to the study site.
* Site staff should address all findings, explaining what action(s) they will take in the first instance to correct the issue(s) and in the future to ensure that the issue(s) does not recur.
* Unless specified, site staff must return the completed CAPA to Sponsor within 28 days of issue. Sponsor will follow up the CAPA until completion/closure.

Part A should be completed by RGO. Text in blue should be actioned and deleted prior to issuing the report to the study team.

This report is designed to be adaptable to each study, sections headings can be marked not applicable and content deleted if they are not required to be completed.

# Part A:

## 1.0 Visit information

### 1.1 Remote monitoring report details

| Details required | Study specific information  |
| --- | --- |
| Sponsor reference: |  |
| Study title: |  |
| Site name: |  |
| Principal investigator:  |  |
| Site contact(s): |  |
| Monitoring visit number & date: |  |
| Monitoring visit type | [ ]  routine[ ]  triggered  |
| Version and date report issued: |  |
| Report issued by: |  |
| Date responses due: |  |

### 1.2 Overview of remote monitoring visit

| Add Sponsor comments including reason for visit and outstanding actions from previous monitoring visits |
| --- |
|  |

# Part B:

## 1.0 Site status [ ]  N/A

| Question | Answer | Site Comments  | Sponsor comments |
| --- | --- | --- | --- |
| Current status: | [ ]  open to recruitment[ ]  in follow up [ ]  closed  |  |  |
| Current end date: |  |  |  |
| Is an extension required: | [ ]  yes[ ]  no[ ]  unsure |  |  |
| Planned patient number: |  |  |  |
| Planned recruitment timescale: |  |  |  |
| Number of patients consented: |  |  |  |
| Number of patients on going: |  |  |  |
| Number of patients completed: |  |  |  |
| Number of patients withdrawn: |  |  |  |
| Number of patients ineligible: |  |  |  |
| Number of patients lost to follow up: |  |  |  |
| Are there any issues with recruitment or retention of participants?  | [ ]  yes, *provide detail*[ ]  no |  |  |

## 2.0 Essential document review [ ]  N/A

### 2.1 Trial master file/ investigator site file [ ]  N/A

| Question | Answer | Site comments: | Sponsor comments: |
| --- | --- | --- | --- |
| Does your site have a TMF, an ISF or both? | [ ]  TMF[ ]  ISF[ ]  Both |   |  |
| Confirm the location of TMF/ISF |  |  |  |
| Is this a secure, restricted access area? | [ ]  yes[ ]  no |  |  |
| Is there a current study contact list in the site file? | [ ]  yes[ ]  no |  |  |

### 2.2 Protocol [ ]  N/A

Confirm the following protocols are present in the site file:

| Document | Version and date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| Current approved protocol | vx.x; date |[ ] [ ] [ ]   |  |
| Superseded protocol | vx.x; date |[ ] [ ] [ ]   |  |
| Superseded protocol | vx.x; date |[ ] [ ] [ ]   |  |

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Has the signature page in the current approved protocol been completed by the CI, PI and Sponsor? RGO to request copy if not present in sponsor records |[ ] [ ] [ ]   |  |
| Are the above listed superseded protocols **all** marked as superseded? *To* ***supersede*** *a document strike a diagonal line across the front page and write “superseded by vx.x (dated dd/mm/yyyy) on dd/mm/yyyy” (inserting the version and date of the new document and the date of sponsor green light for this amendment, respectively), then initial and date this statement.* |[ ] [ ] [ ]   |  |
| Is there a completed [protocol deviation log](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 2; SOP-1013) on file? *If no;* confirm how protocol deviations are being recorded (e.g. Q-pulse)***.*** **Please forward a copy of the protocol deviation log/list to Sponsor with this report.** |[ ] [ ] [ ]   |  |

### 2.3 Initial study approvals [ ]  N/A

Are the following initial submission documents present in the site file:

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| IRAS application | date |[ ] [ ] [ ]   |  |
| REC valid application | date |[ ] [ ] [ ]   |  |
| REC provisional opinion | date |[ ] [ ] [ ]   |  |
| REC response | date |[ ] [ ] [ ]   |  |
| REC favourable opinion | date |[ ] [ ] [ ]   |  |
| HRA initial assessment | date |[ ] [ ] [ ]   |  |
| HRA response | date |[ ] [ ] [ ]   |  |
| HRA approval | date |[ ] [ ] [ ]   |  |
| MHRA valid application | date |[ ] [ ] [ ]   |  |
| MHRA GNA | date |[ ] [ ] [ ]   |  |
| MHRA response | date |[ ] [ ] [ ]   |  |
| MHRA approval | date |[ ] [ ] [ ]   |  |
| NHS trust capacity and capability | date |[ ] [ ] [ ]   |  |
| Sponsor green light | date |[ ] [ ] [ ]   |  |

### 2.4 Protocol amendments [ ]  N/A

Are the following **substantial amendment** documents present in the site file?

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| SA01 amendment tool | date |[ ] [ ] [ ]   |  |
| SA01 REC valid application | date |[ ] [ ] [ ]   |  |
| SA01 REC favourable opinion | date |[ ] [ ] [ ]   |  |
| SA01 HRA approval | date |[ ] [ ] [ ]   |  |
| SA01 MHRA annex 2 | date |[ ] [ ] [ ]   |  |
| SA01 MHRA valid application | date |[ ] [ ] [ ]   |  |
| SA01 MHRA GNA | date |[ ] [ ] [ ]   |  |
| SA01 MHRA approval | date |[ ] [ ] [ ]   |  |
| SA01 NHS trust capacity and capability | date |[ ] [ ] [ ]   |  |
| SA01 Sponsor green light | date |[ ] [ ] [ ]   |  |
| Repeat for additional SA |  |  |  |  |  |  |

Are the following **non-substantial amendment** documents present in the site file?

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| NSA01 amendment tool | date |[ ] [ ] [ ]   |  |
| NSA01 REC valid application | date |[ ] [ ] [ ]   |  |
| NSA01 REC favourable opinion | date |[ ] [ ] [ ]   |  |
| NSA01 HRA approval | date |[ ] [ ] [ ]   |  |
| NSA01 NHS trust capacity and capability | date |[ ] [ ] [ ]   |  |
| NSA01 Sponsor green light | date |[ ] [ ] [ ]   |  |
| Repeat for additional NSA |  |  |  |  |  |  |

Are the following **no study-wide review amendment** documents present in the site file?

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| NSWR01 amendment tool | date |[ ] [ ] [ ]   |  |
| NSWR01 NHS trust capacity and capability | date |[ ] [ ] [ ]   |  |
| Repeat for additional NSWR |  |  |  |  |  |  |

### 2.5 Site personnel [ ]  N/A

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Is the [delegation of authority and signature log](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 2: SOP-1010) present in the site file and complete? ***Forward a copy of this to sponsor with this report.*** |[ ] [ ] [ ]   |  |
| Have end dates been added for any personnel no longer working on the study? |[ ] [ ] [ ]   |  |

Are the following documents present for **all** personnel listed on the delegation log for their full duration of work on the study?

| Document | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Signed and dated 2 page [research CV](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/); *wet ink signed,* *no more than 3 years old* |[ ] [ ] [ ]   |  |
| Valid [GCP certificate](https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm) |[ ] [ ] [ ]   |  |
| Evidence of [protocol training](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 1: SOP-1020, including following substantial amendments where applicable |[ ] [ ] [ ]   |  |
| Consent training certificate for all non-medics delegated consent, available from the [UHL for UHL/UoL staff](https://www.leicestersresearch.nhs.uk/training/informed-consent-training/), and from the [NIHR for all staff](https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm) |[ ] [ ] [ ]   |  |
| UoL [SOP read logs](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 3; SOP-1011)*Note that staff are only required to read the sops that are relevant to their role on the study; there is no requirement to read all of the sops listed* |[ ] [ ] [ ]   |  |
| RGO to check PI CV and GCP on file and request updated copies if required |[ ] [ ] [ ]   |  |

### 2.6 Standard operating procedures [ ]  N/A

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Are the current [University of Leicester SOPs](https://le.ac.uk/research/regi/standard-operating-procedures) or a file note directing to them present in the site file?  |[ ] [ ] [ ]   |  |
| Provide details of any study specific SOPs present in the site file. |[ ] [ ] [ ]   |  |

### 2.7 Study documentation [ ]  N/A

Are the **current approved** study documents present in the site file?

| Document | Version & date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| Participant information sheet | vx.x; date |[ ] [ ] [ ]   |  |
| Consent form | vx.x; date |[ ] [ ] [ ]   |  |
| List all current documents | vx.x; date |[ ] [ ] [ ]   |  |
|  |  |[ ] [ ] [ ]   |  |
|  |  |[ ] [ ] [ ]   |  |

Are the **previously approved** versions of study documents present in the site file and marked as superseded?

| Document | Version & date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| Participant information sheet | vx.x; date |[ ] [ ] [ ]   |  |
| Consent form | vx.x; date |[ ] [ ] [ ]   |  |
| List all superseded documents | vx.x; date |[ ] [ ] [ ]   |  |
|  |  |[ ] [ ] [ ]   |  |
|  |  |[ ] [ ] [ ]   |  |

### 2.8 Participant documentation [ ]  N/A

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Is the [screening log](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 5: SOP-1011) up to date and present in the site file? |[ ] [ ] [ ]   |  |
| Is the [enrolment log](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 5: SOP-1011) up to date and present in the site file? |[ ] [ ] [ ]   |  |
| Are all participants listed on the enrolment log also present on the screening log? |[ ] [ ] [ ]   |  |
| How many participants are listed on the enrolment log? |[ ] [ ] [ ]   |  |
| Have outcomes been recorded on the enrolment log for participants that were not eligible following consent, have withdrawn or have completed the study? |[ ] [ ] [ ]   |  |
| Is there a completed consent form present for each participant listed on the enrolment log? |[ ] [ ] [ ]   |  |
| If the PIS has been updated during the study have participants been re-consented on the new version? |[ ] [ ] [ ]   |  |

A consent audit should be completed and documented in section 5.0 of this report *RGO to delete if not applicable*

### 2.9 Randomisation [ ]  N/A

*If the study is not randomised then RGO to mark section as NA*

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Is there documentation detailing the randomisation process in the site file? |[ ] [ ] [ ]   |  |
| Where is the master randomisation list held? |[ ] [ ] [ ]   |  |
| Have there been any errors with the randomisation process? Have these been documented in the site file? |[ ] [ ] [ ]   |  |
| Are staff and/or participants blinded to treatment allocation? |[ ] [ ] [ ]   |  |
| If yes; to your knowledge has the blind been maintained throughout the study?  |[ ] [ ] [ ]   |  |

### 2.10 Safety reporting / pharmacovigilance [ ]  N/A

*If there is no safety reporting for this study then RGO to mark section as NA*

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Are the University of Leicester [SAE/SUSAR reporting guidelines / SOP](https://le.ac.uk/research/regi/standard-operating-procedures) (SOP-1009) or a site file note directing to the website in the site file?  |[ ] [ ] [ ]   |  |
| Is the current [SAE form template](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (SOP-1009) on file?  |[ ] [ ] [ ]   |  |
| Is an up to date [listing of all SAEs](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 2 / 3; SOP-1009) reported present in the site file? **Please forward this to sponsor with this report;** ensure this contains no participant identifiable information. |[ ] [ ] [ ]   |  |
| Are there copies of all SAE reports and associated correspondence / acknowledgements present in the site file? |[ ] [ ] [ ]   |  |

The next section is for CTIMP/devices studies only: RGO to delete this section for non-CTIMP studies

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Have all SAEs been reviewed against the current reference safety information (RSI) found in the current approved investigator brochure (IB) or summary of product characteristics (SMPC)?  |[ ] [ ] [ ]   |  |
| Have there been any SUSARS reported for this study? |[ ] [ ] [ ]   |  |
| *If yes;* are copies of all SUSAR reports, correspondence and acknowledgements present in the site file? |[ ] [ ] [ ]   |  |

Are copies of the following IB(s) or SmPC(s) present in the site file:

| Document | Version & date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| Current IB/SmPC | vx.x; date |[ ] [ ] [ ]   |  |
| Superseded IB/SmPC | vx.x; date |[ ] [ ] [ ]   |  |
| Repeat as necessary | vx.x; date |[ ] [ ] [ ]   |  |

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Has the current version of the IB or SMPC been signed and dated on the front cover by the PI and study pharmacist? **Forward the signed and dated front page with this report.** |[ ] [ ] [ ]   |  |
| Have the previously approved IB(s) or SMPC(s) present in the site file been marked as superseded?  |[ ] [ ] [ ]   |  |

Are copies of the following safety alert updates present in the site file:

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| List safety updates | date |[ ] [ ] [ ]   |  |
| List safety updates | date |[ ] [ ] [ ]   |  |
| List safety updates | date |[ ] [ ] [ ]   |  |

Are copies of the following development safety update reports (DSUR) and associated correspondence present in the site file:

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| DSUR  | date |[ ] [ ] [ ]   |  |
| DSUR  | date |[ ] [ ] [ ]   |  |
| DSUR  | date |[ ] [ ] [ ]   |  |

### 2.11 Monitoring and audit [ ]  N/A

Are copies of the following monitoring reports, CAPAs and associated correspondence present in the site file:

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| SIV | date |[ ] [ ] [ ]   |  |
| Monitoring visit | date |[ ] [ ] [ ]   |  |
| Monitoring visit | date |[ ] [ ] [ ]   |  |

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Have any additional monitoring visits or audits not listed in the table above been conducted?  |[ ] [ ] [ ]   |  |
| *If yes;* provide the date and name of organisation(s) conducting the visit(s) |[ ] [ ] [ ]   |  |
| Are there copies of these additional monitoring visits and audits present in the site file? |[ ] [ ] [ ]   |  |
| Is there a completed and signed [monitoring log](https://le.ac.uk/research/regi/standard-operating-procedures/appendices) (Appendix 3; SOP-1007) present in the site file? |[ ] [ ] [ ]   |  |
| Has this remote monitoring visits has been recorded on the monitoring log. |[ ] [ ] [ ]   |  |

### 2.12 Data management and case report forms [ ]  N/A

| Question | Answer | Site comments: | Sponsor comments: |
| --- | --- | --- | --- |
| How is study data being collected?  | [ ]  Paper CRF[ ]  Electronic CRF[ ]  Combination of paper and electronic CRFs |  |  |
| What database being used for this study? | [ ]  Excel[ ]  Access[ ]  Redcap[ ]  Macro[ ]  Other:\_\_\_\_\_\_\_\_\_ |  |  |
| Who is providing the database? |  |  |  |
| Who is responsible for inputting data in to the database? |  |  |  |

Are the **current** CRFs present in the site file? If any have been updated indicate and forward copies with this report.

| Document | Version & date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |

Are the following **previous** CRFs present in the site file and marked as superseded?

| Document | Version & date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |
| CRF title | vx.x; date |[ ] [ ] [ ]   |  |

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Is there a data management plan in place? **If yes; please provide a copy with this report** |[ ] [ ] [ ]   |  |
| Is data inputting up to date? |[ ] [ ] [ ]   |  |
| Do you complete data quality control checks? If yes; provide detail of the checks completed and on approximately what proportion of the data |[ ] [ ] [ ]   |  |
| Do you check/run reports for missing and spurious data? |[ ] [ ] [ ]   |  |
| How are missing and spurious data handled? |[ ] [ ] [ ]   |  |
| Do you think the collection of primary endpoint data will be achieved? |[ ] [ ] [ ]   |  |
| Do you have any concerns around data collection, storage or management? |[ ] [ ] [ ]   |  |

### 2.13 Sample Management [ ]  N/A

| Question | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- |
| Are clinical samples being used or collected as part of this study? *If no; move to section 2.14* |[ ] [ ] [ ]   |  |
| Are sampling and sample handling procedures documented / is there a lab manual on file? |[ ] [ ] [ ]   |  |
| Are central labs being used? (are samples from **all** study sites being sent to one single central laboratory?) *If yes; provide the name and location of the central lab.* |[ ] [ ] [ ]   |  |
| Are the current and previous central lab accreditations on file?  *If yes; provide details and date* |[ ] [ ] [ ]   |  |
| Is central lab normal reference ranges on file?  *If yes; provide details and date* |[ ] [ ] [ ]   |  |
| Are sample shipment / receipt tracking records on file? |[ ] [ ] [ ]   |  |
| Are local labs being used? (are samples being sent to a laboratory at the local site?) Provide the name and location of the local lab. |[ ] [ ] [ ]   |  |
| Are the local laboratory current and previous accreditation certificates on file? |[ ] [ ] [ ]   |  |
| Are the local lab normal reference ranges on file? |[ ] [ ] [ ]   |  |
| Is there evidence of maintenance and calibration of lab equipment on file? |[ ] [ ] [ ]   |  |
| Are lab kits available and in date? |[ ] [ ] [ ]   |  |
| Is there evidence of lab staff training on file? Including GCP certificates, study specific training and SOP read logs. |[ ] [ ] [ ]   |  |
| Are samples being stored for later analysis / use?  *If no; move to section 2.14* |[ ] [ ] [ ]   |  |
| Are all samples correctly stored in a suitable and secure environment? Confirm the storage location. |[ ] [ ] [ ]   |  |
| Are storage conditions monitored and recorded? Confirm the monitoring system in place (e.g. Tutela, min/max thermometer) |[ ] [ ] [ ]   |  |
| Is there a contingency plan in place for storage facility failure? Provide details of the plan. |[ ] [ ] [ ]   |  |
| Are sample logs / records maintained? Confirm location of sample logs. |[ ] [ ] [ ]   |  |

### 2.14 Legal agreements [ ]  N/A

Are copies of the following agreements / letters / certificates present in the site file? RGO to list details of all agreements including main, sub-contract, investigator, data and material transfer, MNCA and OIDs

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| University of Leicester letter of sponsorship | date |[ ] [ ] [ ]   |  |
| Confirmation of indemnity letter | date |[ ] [ ] [ ]   |  |
| Clinical trials insurance Repeat as required | 20xx to 20xx |[ ] [ ] [ ]   |  |
| Professional insurance Repeat as required | 20xx to 20xx |[ ] [ ] [ ]   |  |
|  | date |[ ] [ ] [ ]   |  |
|  | date |[ ] [ ] [ ]   |  |
|  | date |[ ] [ ] [ ]   |  |
|  | date |[ ] [ ] [ ]   |  |

### 2.15 Annual / final reports [ ]  N/A

Are copies of the following annual reports and associated correspondence / acknowledgements present in the site file?

| Document | Date | Yes | No | N/A | Site comments: | Sponsor comments: |
| --- | --- | --- | --- | --- | --- | --- |
| APR | date |[ ] [ ] [ ]   |  |
| APR | date |[ ] [ ] [ ]   |  |
| APR | date |[ ] [ ] [ ]   |  |

## 3.0 Remote consent audit [ ]  N/A

Complete the following table for all versions of consent forms present for the selected participants.

RGO to detail number of consent forms to be reviewed, suggested text: conduct an initial consent review of a minimum of 10 participants or 20% of total number recruited (whichever is the higher figure)

| Participant ID number | Consent form version and date  | PIS version and date  | All boxes completed / initialled by participant? | Date of consent of participant | Participant name and signature completed? | Date of researcher signature | Name of researcher obtaining consent  | Researcher signature completed? | Comments: |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |
|  |  |  | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No |  |  | [ ]  Yes[ ]  No |  |

## 4.0 Remote source data verification [ ]  N/A

### 4.1 Remote Monitoring

Remote source data verification will be conducted in accordance with host site procedures for remote monitoring.

Complete the following details at the start of the source data verification meeting

| Questions | Comments |
| --- | --- |
| Date of source data verification meeting |  |
| Name, role and organisation of monitor(s) |  |
| Location of monitor(s) for duration of meeting |  |
| Name, role and organisation of study staff  |  |
| Location of study staff for duration of meeting |  |
| Remote video conferencing platform used |  |
| Meeting start time |  |

### 4.2 Consent

The following questions relate to participant: <insert ID number> RGO to duplicate this table for each participant monitored

| Questions | Yes | No | N/A | Comments/Findings |
| --- | --- | --- | --- | --- |
| Are copies of the Patient Information Sheet and Consent present in the medical records and TMF/ISF? |[ ] [ ] [ ]   |
| Are the PIS and ICF present the current approved versions? |[ ] [ ] [ ]   |
| Is the ICF correctly completed |[ ] [ ] [ ]   |
| Is there evidence the participant has the appropriate time to consider participation |[ ] [ ] [ ]   |
| Is the person taking consent delegated to do so |[ ] [ ] [ ]   |
| Was consent recorded prior to any study related procedures being undertaken |[ ] [ ] [ ]   |
| Is informed consent process properly documented in the medical/study records? |[ ] [ ] [ ]   |
| Is there a sticker on the front of the notes to confirm participation in the study |[ ] [ ] [ ]   |

### 4.3 CRF and Source Document review

The following questions relate to participant: <insert ID number> RGO to duplicate this table for each participant monitored

| Questions | Yes | No | N/A | Comments/Findings |
| --- | --- | --- | --- | --- |
| List the source documents viewed during the visit for this participant |  |  |  |  |
| Are all source documents available to verify the data in the Case Report Form? |[ ] [ ] [ ]   |
| Is CRF completion timely and accurate? |[ ] [ ] [ ]   |
| Are the CRFs complete for each visit? |[ ] [ ] [ ]   |
| Is there evidence of an eligibility check being performed? |[ ] [ ] [ ]   |
| Was eligibility confirmed and documented in the notes by a delegated person (clinician)? |[ ] [ ] [ ]   |
| Have all visit dates been checked? |[ ] [ ] [ ]   |
| Are all study visits fully annotated in the medical/study records? |[ ] [ ] [ ]   |
| Are specimen results reviewed and signed and dated by the PI or delegated clinician? |[ ] [ ] [ ]   |
| Are specimen results that are out of range marked as clinically significant or not clinically significant? |[ ] [ ] [ ]   |
| Have all AE/SAE been recorded and reported appropriately? |[ ] [ ] [ ]   |
| Have concomitant medications been checked and recorded appropriately? |[ ] [ ] [ ]   |

| Source Data Verification | Comments |
| --- | --- |
| Participant Study ID and Visits verified |  |
| Participant Study ID and Visits verified |  |
| Participant Study ID and Visits verified |  |
| Participant Study ID and Visits verified |  |

| Questions | Comments |
| --- | --- |
| Meeting end time |  |

## 5.0 Additional information [ ]  N/A

| Questions | Answer | Site comments | Sponsor comments |
| --- | --- | --- | --- |
| Is there any additional information you would like to provide? | [ ]  yes[ ]  no |  |  |
| Do you require any support from sponsor on any study related issues? | [ ]  yes[ ]  no |  |  |
| Please ensure you send the listed documents with this report: RGO to add/delete as appropriate * Protocol deviation log
* Any updated CRFs
* Delegation of authority log
* SAE line listing
* Signed and dated front page of IB/SMPC
* Data management plan
 |  |  |  |

**\*\*Please ensure no participant identifiable information is sent with this report\*\***

## 6.0 Signatures

Remote monitoring report responses completed by:

| Details  | Completed by |
| --- | --- |
| Study staff name: |  |
| Study staff role: |  |
| Date: |  |

# Part C:

## Remote monitoring response document [ ]  N/A

Date response document issued:

Date response required:

| No | Category | Finding | Immediate/Corrective Action | Preventative Action  | Completed by Initials & Date |
| --- | --- | --- | --- | --- | --- |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |

## Signatures

Responses completed by:

| Details  | Completed by |
| --- | --- |
| Study staff name: |  |
| Study staff role: |  |
| Study staff signature: |  |
| Date: |  |

Remote monitoring report and CAPA reviewed and approved by PI:

| Details  | Approved by |
| --- | --- |
| PI Name: |  |
| PI Signature: |  |
| Date: |  |

Remote monitoring report and CAPA closed by sponsor:

| Details  | Closed by |
| --- | --- |
| Sponsor name: |  |
| Sponsor role: |  |
| Sponsor signature: |  |
| Date: |  |

Final Sponsor comments: