**REMOTE MONITORING VISIT FOLLOW-UP LETTER**

*<Insert Date>*

**Instructions:**

*Instructional text – requires you to complete the information. Remove the italics / brackets prior to finalising the checklist and ensure all text is black.*

Optional text – delete when not required as applicable to your trial. Ensure any blue text retained is changed to black text upon finalisation of form for your study.

Standard wording – not to be removed or changed without prior consultation with the Sponsor.

If sent as a letter, ensure use of appropriate institute letterhead. Option to send as the body of an email. Ensure either mode of communication is accurately filed in the sites Site Investigator File (SIF).

**DELETE THIS INSTRUCTION BOX UPON FINALISATION OF FORM**

*<Insert Site Name>*

*<Insert Name of Site PI>*

*<Insert Site Address>*

Dear *<Insert PI Name>* and the *<Insert Trial name>* Research Team

**RE: REMOTE MONITORING VISIT (RMV) FOLLOW-UP LETTER**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Site Name:** |  |
| **Site Code:** |  |
| **Site Principal Investigator:** |  |
| **Date of Visit:** |  |

This is a follow-up letter relating to the recent remote monitoring visit that took place at your site on *<insert date>.* I would like to thank you for your time in assisting with this visit.

During the monitoring visit, the following items were reviewed, and where applicable, discussed:

* + - Your eISF for completeness, accuracy, and regulatory compliance
* Patient Information and Consent Forms (PICFs) from the following participants:
* *<insert PID#s>*
* *<insert PID#s>*
* *<insert PID#s>*
* Ethics Committee (HREC) and Research Governance Office (RGO) approval letters for currency and to ensure all previous approvals are filed accordingly, as applicable
* Review of Signature and Delegation of Authority Logs to ensure current staff are listed and tasks delegated accordingly
* Review of current Site Staff CVs and GCP Training Certificates to ensure currency
* Review of Site Training Logs ensure any new staff have been trained accordingly
* Review of all Expedited Safety Event/SAE Report Forms reported to the Sponsor, if applicable
* Review of all Event of Non-Compliance/Protocol Deviation Report Forms reported to the Sponsor, if applicable
* Review of Pharmacy Accountability Logs, if applicable
* Review of central lab and biospecimen reconciliation, if applicable
* Review of all eLogs/Trackers for completeness and accuracy, if applicable
* Review of screening and enrolment rates, as applicable
* Review of data entry and outstanding query status to date
* <insert other items as applicable to your clinical monitoring plan>
* <insert other items as applicable to your clinical monitoring plan>
* <insert other items as applicable to your clinical monitoring plan>

The follow-on de-brief meeting was attended by:

|  |  |
| --- | --- |
| **Name of Attendee** | **Role** |
| *<insert name>* | Site Principal Investigator |
| *<insert name>* | *Site Study Coordinator / Site Research Nurse* |
| <insert name> | <insert other role, as applicable> |
| *<insert name>* | Monitor |
| *<insert name>* | Sponsor-Investigator/Coordinating Principal Investigator |

Please find below a list of any open Action Items that resulted from this visit and/or previously conducted monitoring visits if applicable at your site. Please make sure that the action items are resolved within the specified due date, by you and your team members accordingly.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item/Title** | **Open Date** | **Action Required by Site** | **Due Date** |
| *<insert issue identified>* | *<insert date>* | *<insert action to rectify issue>* | *<insert date>* |
| *<insert issue identified>* | *<insert date>* | *<insert action to rectify issue>* | *<insert date>* |
| *<insert issue identified>* | *<insert date>* | *<insert action to rectify issue>* | *<insert date>* |

The following issues were also identified during the RMV, however, have been addressed by the Monitor during the visit and no further action is required:

|  |  |  |
| --- | --- | --- |
| **Item/Title** | **Open Date** | **Action Required by Site** |
| *<insert issue identified>* | *<insert date>* | NA – Addressed by Monitor during Remote Monitoring Visit |
| *<insert issue identified>* | *<insert date>* | NA – Addressed by Monitor during Remote Monitoring Visit |

For your information, copies of the following documents were obtained from your Site File, as these were missing from the Sponsor’s files:

1. <insert document name, date and version (if applicable)>
2. <insert document name, date and version (if applicable)>

It was a pleasure to meet with you and your staff during the de-brief session. I ask that you please review and resolve any action items outlined above by the due date listed.

Lastly, please also file a copy of this letter in Section 15.2 “Monitoring Correspondence and Feedback” of your Investigator Site File in Florence eBinders™.

Thank you for your ongoing support and contribution to this promising study.

Please feel free to contact me on *<insert contact phone number and/or email>* should you have any questions.

Kind Regards,

***<Sign off>***