**REMOTE MONITORING VISIT CONFIRMATION LETTER**

**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 Date>*

*<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) CONFIRMATION LETTER**

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

This letter is to confirm that your site is scheduled for a Remote Monitoring Visit (RMV) for the *<insert trial name>* on the *<insert date>.*

This monitoring visit will be undertaken by the nominated Trial Monitor, *<insert name>* and will be completed remotely by accessing your electronic Investigator Site File (eISF) Binder that is maintained via the Sponsors approved eISF platform, Florence eBinders™, in order to verify the completeness and accuracy of the eISF.

As the site Principal Investigator, you will need to attend a de-brief meeting at the completion of the remote monitoring visit for approximately 30 minutes. It is also advisable that the study coordinator/research nurse, *<insert name>,* also attend this meeting. A separate meeting invite with video-conference details will be circulated shortly.

The purpose of the visit is to ensure that this study is being conducted in accordance with the protocol and to review your eISF for completeness and regulatory compliance, review study staff training documentation and appropriate delegation of authority; review pharmacy and perform drug accountability (as applicable), review of central lab and biospecimen reconciliation (as applicable), confirm any action items from previous visits have been resolved, as applicable; review of safety events and protocol deviations, as applicable; as well as any other relevant study updates at the time of the visit.

During the RMV the following items will be reviewed:

* + - Verify in total, the completeness and accuracy of your eISF
* Review the rate of recruitment at site, by reviewing the <insert name of trial> Screening Log and your Site Participant Randomisation Log
* Confirm that the site Principal Investigator is following the current Ethics Committee approved protocol and all approved amendment(s), if any
* Confirm any changes in Delegation at site, or new delegations, have been appropriately documented on the Signature and Delegation of Authority Log, and ensure it is complete, current and delegations are in accordance with qualifications and training
* Confirm that the site has appropriately documented all training of its site staff involved with the trial on the Training Log, and ensure it is complete and current
* Ensure all Florence eLogs/Trackers are up to date and are being maintained, if applicable
* Ensure that the correct versions of the Ethics Committee approved Patient Information and Consent Forms (PICFs) have been used. To facilitate this, can you please ensure that the following PICFs have been redacted/de-identified, and a copy uploaded into your Investigator Site File in Florence eBinders™:
* <insert PID#>
* <insert PID#>
* <insert PID#>
* Review of data entry and outstanding query status to date, as applicable
* <insert other items as applicable to your clinical monitoring plan>
* <insert other items as applicable to your clinical monitoring plan>

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>***