**FINAL SITE CLOSURE 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: FINAL SITE CLOSURE LETTER**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Site Name:** |  |
| **Site Code:** |  |
| **Site Principal Investigator:** |  |

Thank you for promptly attending to the action items identified during your recent Close-Out Visit for the *<insert Trial name>* clinical trial.

I confirm that I have reviewed all items arisings from your COV and that these matters are considered resolved; the *<insert Trial name>* is now closed. Please ensure you have filed all end-of-trial documentation in the Investigator Site File <insert Section number>. The Investigator Site File can then be archived.

Please notify your site’s Ethics Committee/Research Governance Office (RGO)/IRB/REB/IEC that the study is now closed.

As per regulations, it is the Site Principal Investigator’s responsibility to ensure essential trial documents are kept appropriately, and that they are complete, secure, and legible, as they may be required for audits or inspections of the trial in future.

Archiving should be carried out in accordance with your Institute’s archiving policy, noting that study documents including the Investigator Site File (ISF) must be archived for 25 years or [per local institutional requirements].

If your site maintained a copy of your Investigator Site File (ISF) via the Sponsor’s Florence eBinders™ platform, a zip file of your eISF has been provided to you along with this letter for archiving locally. Please sign and date the final page of this letter acknowledging receipt of your eISF zip file and return a counter-signed copy to my attention at the email address below.

Please note that the Sponsor should be informed before disposal of any trial documentation.

The delegated individual at your site for receiving data will receive/will have received an email giving instructions for restricted access to download the data from [insert IT system]. An audit trail showing all correction/changes to data will also be sent. Please ensure that this data download is securely stored with an appropriate level of confidentiality and that it is filed as part of your electronic Investigator Site File / that it is stored location is recorded in your Investigator Site File.

On behalf of the Sponsor-Investigator *<Insert Name>,* the extended *<Insert Trial name>* Teamand the Sponsor, the Murdoch Children's Research Institute, we would like to thank you for your participation in the *<insert Trial name>* study. It has been a pleasure working with your entire team and we appreciate all the hard work and dedication that was put toward the study.

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

Kind Regards,

***<Sign off>***

***<Email Address>***

***--------------------------------------------------------------------------------------------------------------***

**Study Closure Notification and Acknowledgement of Receipt (AoR)**

I hereby acknowledge notification of site closure for this study and agree to fulfill the above-mentioned obligations.

I also acknowledge receipt of a zip file containing my sites Investigator Site File (ISF) which I will archive locally for the minimum required archive period.

|  |  |
| --- | --- |
| **Principal Investigator Name** |  |
| **Signature** |  |
| **Date** |  |