**PRINCIPLE - Platform Randomised trIal of treatmeNts in the Community for epIdemic**

**and Pandemic iLlnEsses**

**Ethics ref:** 20/SC/0158 **EudraCT Number:** 2020-001209-22 **IRAS Project ID:** 281958

Dear Principal Investigator,

Thank you for acting as Principal Investigator for the PRINCIPLE trial at your site. We greatly appreciate your contribution to this important research. As the trial has now come to an end, we are closing all research sites. We now need you to confirm that you have received the following information and have completed all the tasks listed below.

Once you have sent us the necessary documentation and this completed checklist, we will issue you with a Research Site Closure Report which should be filed in your ISF.

**Site Name:**

**Site ODS Code:**

**PI Name:**

**Principal Investigators**

Please list all persons who have acted as Principal Investigator (PI) for the PRINCIPLE trial at the site in the table below. Please ensure you cover the period from the date of your Green Light letter to present.

|  |  |  |
| --- | --- | --- |
| **Name** | **Email address** | **Dates acting as PI** |
|  |  |  |
|  |  |  |
|  |  |  |

Please enter your initials to indicate your confirmation in the tables below.

I can confirm that I have received:

|  |  |  |
| --- | --- | --- |
|  |  | GP Confirmation (initials) |
| 1 | The Site Agreement. |  |
| 2 | The Greenlight letter/email. |  |

I confirm that I have supplied the following to the PC-CTU PRINCIPLE Trial Team:

|  |  |  |
| --- | --- | --- |
|  |  | GP Confirmation (initials) |
| 1 | Up to date CVs for all PIs (signed and dated within the 3 years) |  |
| 2 | Up to date GCP certificate all PIs (dated within the last 3 years) |  |
| 3 | Up to date and completed delegation log letter |  |
| 4 | Up to date and completed training log  |  |
| 5 | Completed Hydroxychloroquine accountability log (if applicable) |  |
| 6 | Completed Hydroxychloroquine destruction log (if applicable) |  |

I confirm that I understand:

|  |  |  |
| --- | --- | --- |
|  |  | GP Confirmation (initials) |
| 1 | The ongoing requirements of the trial:* Site trial documentation retention as detailed in the Site Agreement.
* Audit procedure as detailed in the Site Agreement.
* Resolving any outstanding data queries and any follow-up questions regarding any hospitalisations recorded in the Notes Reviews.
 |  |
| 2 | The trial publication policy as documented in the site agreement.  |  |
| 3 | That the retention period for the study documentation is 20 years. |  |

I can confirm that:

|  |  |  |
| --- | --- | --- |
|  |  | GP Confirmation (initials) |
| 1 | All payments as per site agreement schedule (Appendix 2) have been made or have been scheduled to be made. |  |
| 2 | Appropriate plans have been made for the retention of trial data (including source data and any electronic data). |  |
| 3 | The completeness of the essential documents has been checked and all essential documents are present in the ISF. Please see the ISF Contents document for a complete list of essential documentation.  |  |

Print Name: …………………………………………………………………

Signature: …………………………………………………………………….

Date: …………………………………………………………………………….

Please scan and email this document to principle@phc.ox.ac.uk and then save a copy in your Investigator Site File.