|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **53.004H** | Version  | **5.0** |
| Title | **Preliminary Follow Up letter / Follow Up letter** |

|  |  |  |
| --- | --- | --- |
| NHSGG&C%20Black_th | Research & Innovation Research GovernanceGartnavel Hospital  | Governance DepartmentResearch and InnovationAdmin BuildingLevel 2Gartnavel Royal Hospital1055 Great Western RoadGlasgowG12 0XH |
| *<<Site/Investigator address>>* | Enquiries to: <<Name>>Mob Number Of Monitor: <<Number>> email: RandD.MonitoringGroup@nhs.scot Date: <<Date>> |

Dear <<Contact Name>>

Subject: <<Subject>>

Title: <<Trial Name >>

R&D Number: <<Trial ID>>

INTRODUCTION

I would be very grateful if you would pass on my thanks to <<Site Contacts>> for all their help and being so accommodating for the recent (remote) monitoring visit for the <<Trial Name>> trial, it was much appreciated.

<<The following titles are points of discussion for the follow up letter, complete as appropriate and remove if applicable>>

INVESTIGATOR SITE FILE (ISF)

<<Enter details or delete if applicable>>

Include details such as good filing, missing documents, storage suitability/space etc.

ESSENTIAL DOCUMENTS

<<Enter details or delete if applicable>>

Include details such as expired GCPs/CVs, training logs, missing documents i.e. protocol, approvals and missing signatures, delegation log issues etc.

TRIAL PROCESS

<<Enter details or delete if applicable>>

Include details such as processes working well including PI oversight or issues discovered i.e. bloods, visit planning/windows and review of the Source Data plan is consistent with the source found at site etc.

INFORMED CONSENT

<<Enter details or delete if applicable>>

Include details such as the number of consents reviewed and when they were reviewed i.e. prior to visit (participant number which was SDV’d), issues, version control etc.

STUDY VISITS

<<Enter details or delete if applicable>>

Include details such as the number of participants SDV’d and list the participant ID, protocol deviations etc

SAFETY REPORTING

<<Enter details or delete if applicable>>

Include details such as any SAE reports which were SDV’d, unreported SAEs found, issues with documenting AEs, MHRA reportable events linked to device deficiencies, SADEs etc.

NON-COMPLIANCES

<<Enter details or delete if applicable>>

Include details such as protocol deviations, GCP non-compliances etc.

ARCHIVING

Archiving arrangements still valid, ensure site is still able to meet requirements and knows how the archiving process.

PHARMACY FILE

<<Enter details or delete if applicable>>

Include details such as issues with expiration, stock and storage issues, PSF documents missing, delegation logs issues etc.

IMP ACCOUNTABILITY

<<Enter details or delete if applicable>>

Include details such as the number of participants reviewed, list pt ID, wrong kit dispensed etc.

DEVICE ACCOUNTABILITY

<<Enter details or delete if applicable>>

Include details such as device review, labelling, device storage issues, device deficiencies reported/unreported, issues with documentation

ACTIONS RESOLUTION DOCUMENT

<<Enter details or delete if applicable>>

Include details on what the timeline is for resolution etc.

Kind regards

Clinical Trials Monitor

NHS Greater Glasgow and Clyde

Research and Innovation Department

**SIGNATURES**

Name(s) of Monitor: <<Name>>

Signature: <<Signature>>

cc: *Research Governance Manager*

*Lead Clinical Trial Monitor, Sponsor Stakeholders etc with names*

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website. Any copy reproduced from the website may not, at time of reading, be the current version. |