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| Form number | **56.004A** | Version | **2.0** |
| Title | **Site Close Out Checklist Template** | | |

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|  | **Insert study title**  **SITE CLOSE OUT CHECKLIST** | Insert study logo |

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| **SUBJECT:** | SITE CLOSE OUT CHECKLIST |
| **SITE:** | STATE NUMBER AND SITE NUMBER |
| **PRINCIPAL INVESTIGATOR:** | STATE PI |
| **STUDY:** |  |
| **EUDRACT:** |  |
| **CHIEF INVESTIGATOR:** |  |

Dear insert name of local PI

Many thanks for your participation in the state name study. You have advised that patient visit activity has completed at your site and your site is now ready to be closed. This is an important last step in the process to ensure study data integrity but also to ensure that we close the study down conforming to GCP standards. Formal closure of the site will be confirmed upon completion of this close-out checklist.

**Please complete and return a signed and dated (PI Signature) copy of this checklist as this will act as confirmation that your site is ready to be closed.**

Upon receipt of this completed checklist, and , if applicable, confirmation from Sponsor pharmacy and Governance teams that all study actions are complete; I will forward an email to your site confirming that all necessary arrangements are in place and your site can officially close.

Kind regards

Insert name of PM and contact details

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| **TO BE COMPLETED BY STUDY TEAM / POINT OF CONTACT** |

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| **Has the study been monitored by NHS GG&C?** | Yes: if yes, site should skip straight to section 2  No: if no, site should complete all sections | | | | |
| **SECTION 1** | | | | | |
| **E-CASE REPORT FORM (eCRF)** | | | | | |
| Is the eCRF fully completed for all study participants? |  | | Yes |  | No\* |
| Completed Protocol Deviation Forms are inserted in Investigator Site File? |  | | Yes |  | No\* |
| Are all Data Query Forms resolved? |  | | Yes |  | No\* |
| **STUDY DOCUMENTS / LOGS** | | | | | |
| Is the staff delegation log complete and all corresponding CVs / GCP certificates filed? |  | Yes | |  | No\* |
| Are all participant logs complete (e.g. screening, enrolment, randomisation, as applicable)? |  | Yes | |  | No\* |
| **SERIOUS ADVERSE EVENT / SUSAR FORMS** | | | | | |
| All SAEs followed up to conclusion (as per communication with Sponsor Pharmacovigilance team)? |  | Yes | |  | No\* |
| Copies of completed SAE forms are inserted in Investigator Site File? |  | Yes | |  | No\* |
| **SECTION 2** | | | | | |
| **Study specific Samples (If applicable)** | | | | | |
| Have all samples been stored / shipped as per protocol and sample handling manual requirements? |  | Yes | |  | No\* |
| Have you forwarded copies of completed sample logs to the Project Manager? |  | Yes | |  | No\* |
| Completed filenotes and/or protocol deviation forms for missing samples are inserted in Investigator Site File? |  | Yes | |  | No\* |
| **Investigator Site File (ISF)** | | | | | |
| Have all study documents (current and superseded), and study correspondence/ other relevant documents been filed in the ISF in accordance with the index provided? |  | Yes | |  | No\* |
| Will the ISF be archived in accordance with local R&D arrangements? |  | Yes | |  | No\* |
| Where will ISF be archived? (State): |  | | | | |
| Name of contact person should access be needed to the ISF (Full contact details): |  | | | | |

**ACTIONS\*:**

* **Please ensure that all questions have been answered as yes prior to sign off by local PI. Any marked as ‘no’ should be resolved prior to signing off and returning.**

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| **CLOSE OUT SIGN OFF SHEET.** | | |
| Point of Contact at Site / person completing this checklist | Name:  Signature:  Date: | |
| **PRINCIPAL INVESTIGATOR SIGN OFF**  **BY SIGNING AND RETURNING A COPY OF THE SITE CLOSE OUT CHECKLIST YOU CONFIRM THAT ALL ACTIONS IN RELATION TO THE *INSERT STUDY NAME* STUDY HAVE BEEN UNDERTAKEN AT YOUR SITE.**  **\*\*\*COPY OF COMPLETED DOCUMENT TO BE FORWARDED TO STUDY PROJECT MANAGER\*\*\*** | | |
| Principal Investigator | | Name:  Signature:  Date: |
| **Please:**   * **Retain 1 copy and insert in Section 2 of the Site File, Study correspondence; and** * **Forward 1 copy to:** FAO Insert name of Project Manager   Email: insert email address of PM | | |

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