|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sponsor Number : EDGE** | | | | | |
| **Study Name:** | | | | | |
| **Site:** | | | | | |
| **Principal Investigator Name:** | | | | | |
| **Actions to be verified**  Please confirm the following: YES NO | | | | | |
| End of study Declaration and acknowledgement from REC, MHRA (where applicable) and sponsor confirmed filed in the Trial Master File. |  | |  | | |
| Final report and Acknowledgement from HRA and sponsor confirmed filed in Investigators site file |  | |  | | |
| Please confirm that the Investigator site file has been updated to reflect study closure |  | |  | | |
| **CTIMP Studies Only**  Please confirm that the Pharmacy folder has been updated to reflect study closure and that any IMP has been returned/destroyed as appropriate. |  | |  | | |
| Please confirm that all personal identifiable data not held as an essential document i.e. enrolment log/consent forms) within the Trial Master File, has been removed from:  Paper documents  Electronic documents |  | |  | | |
| Please confirm that all study participants have been thanked for their participation |  | |  | | |
| Please confirm that all study participants have been given a copy of/access to the final study results/invited to study result dissemination event as per your REC application |  | |  | | |
| Please confirm relevant contact details and location of paper/electronic Trial Master File and Pharmacy records (CTIMP studies only). | | | | | |
| Contact Details:  Location: | | | | | |
| Please confirm all study specific equipment/supplies (electronic/software) have been returned/disabled | YES | NO | | N/A | |
| Have all support services /third party vendors been notified of study closure | YES | NO | | | N/A |

**RETENTION/DESTRUCTION of SAMPLES**

|  |  |  |
| --- | --- | --- |
| Please confirm if any samples are to be held at your site for future research? | **YES** | **NO** |
| If **NO**  Where consent for future research is NOT in place samples MUST be destroyed as detailed in IRAS application.  Confirm destruction process and file records in the Trial Master File | | **YES** |
| If **YES**  Please confirm that ALL consent forms have been reviewed and it has been confirmed that consent for future research for retention of samples is in place.  Where it is identified on consent review that consent for future research is not in place for all participants. The relevant participant’s samples MUST be destroyed. A record of destruction should be filed in the Trial Master File. | | **YES** |

**DATA FOR FUTURE RESEARCH**

|  |  |  |
| --- | --- | --- |
| Please confirm if any data is to be retained for future research as per your regulatory application? | YES | NO |
| If YES  Please confirm that all the consent forms have been reviewed and it has been confirmed that consent for future research is in place for all participants?  Where it is found that participants have not given consent for future research the data will need to be destroyed. A record of destruction should be filed in the Trial Master File. |  |  |
| If NO  Confirm destruction of all records and file details in the Trial Master File. |  |  |

**MEDICAL DEVICE STUDIES ONLY**

|  |  |  |
| --- | --- | --- |
| Confirm that all devices have been returned by the participants where applicable | YES | N/A |
| Please confirm that all devices have been returned/ destroyed as per the device manufacturer/sponsor requirements. Filed relevant return/destruction record in Trial Master File | YES |  |

|  |  |
| --- | --- |
| PI sign off: | |
| I confirm that I have reviewed the checklist and that the information provided is to accurate | |
| Name of Principal Investigator |  |
| PI signature |  |
| Date |  |

|  |  |
| --- | --- |
| CI sign off: | |
| I confirm that I have reviewed the checklist and that the information provided is accurate and complete | |
| Name of Chief Investigator |  |
| CI signature |  |
| Date |  |

**For Multi Centre studies only\***

**Completed copies of Appendix 1B SOP S-1045 for all collaborating**

**sites to be submitted with this form**