|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Closure Checklist (site to complete)** | | | | | | | |
| *This form is to be completed by a site on closure to a study conducted by ITCC.* | | | | | | | |
| **Study** | |  | | | | | |
| **Site** | |  | | | | | |
|  | | | | | | | |
| **Activity** | | **Detail** | | **Yes** | | **No** | **N/A** |
| **Final pharmacy monitoring** | | Has the monitoring been undertaken by the contracted company? | |  | |  |  |
| Has the report been provided to pharmacy? | |  | |  |  |
| Has the Investigational Product been destroyed in accordance with the applicable regulations? | |  | |  |  |
| Has the completed Pharmacy folder been provided to site coordinator? | |  | |  |  |
| **Comments** | |  | |  | |  |  |
| **All invoices and payments have been raised and finalised** | | Has an Invoice been raised for the last patients and related activities? | |  | |  |  |
| Has payment been received? | |  | |  |  |
| **Comments** | |  | | | | | |
| **Final report sent to HREC** | | Has the report been submitted using the approving HREC standard format? | |  | |  |  |
| Has the closure letter been attached, with results publication and any appropriate participant correspondence? | |  | |  |  |
| Has an acknowledgement letter been received and filed, with a copy to ITCC? | |  | |  |  |
| Has a copy of the report and acknowledgement letter been submitted to the RGO? | |  | |  |  |
| **Comments** | |  | | | | | |
| **Study Closure Checklist (cont.)** | | | | | | | | |
| **Activity** | | **Detail** | | **Yes** | | **No** | **N/A** |
| **Letter sent to participants** | | Have the allocation codes been received from coordinating site? | |  | |  |  |
| Has a letter been written addressed to each participant or their remaining family, with the appropriate allocation inserted? | |  | |  |  |
| Have the letters for all participants been forwarded to clinical team to send to patients or remaining family?  *Note:* Instruct the clinical team to post out. | |  | |  |  |
| **Comments** | |  | | | | | |
| **Essential documents finalised** | | Has all correspondence been included in the investigator folder/file? | |  | |  | |  |
| Are all HREC and RGO letters included? | |  | |  | |  |
| Are all reports for monitoring and follow-up included in the folder/file? | |  | |  | |  |
| Check that the Staff Signatures and Delegation Log has completed including a cease date for each delegated person on the sheet? | |  | |  | |  |
| Insert a copy of results publication | |  | |  | |  |
| **Comments** | |  | | | | | | |
| **Copy of this checklist to ITCC** | | Send a copy of this final checklist to ITCC | |  | |  | |  |
| **Comments** | |  | | | | | | |
| **Name** | |  | | | | | | |
| **Signature** | |  | | | | | | |
| **Date completed** | |  | | | | | | |