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| **End-of-Study Documentation Checklist** | Version 1.0 | Effective Date: XX/XX/XX |

GENERAL INFORMATION

Principal Investigator (PI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

JeffTrial# or iRIS#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*This document is arranged chronologically from top to bottom. Please try to complete following that order.*

RECEIPT OF INTENT TO CLOSE

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| --- | --- | --- |
| **NCTN EARLY CLOSURE ONLY:**  Submit and receive approval “Request for LPO Approval of Early Closure Form" to/from sponsor study team before notifying stakeholders | | ☐ |
| **SPONSOR or IIT ONLY:**  PM and/or RC receives email notification of the intent to close from sponsor or internal PI. Upon receipt, the PM or RC will notify the following stakeholders: | | ☐ |
| All persons on the Delegation of Authority Log (DOAL) | ☐ | |
| JCRI Contracts and Budget team | ☐ | |
| Investigational Drug Service (IDS) | ☐ | |
| Quality Assurance and Education team (QAE) | ☐ | |
| Regulatory Operations team | ☐ | |
| CCRO/EPRO Director/s | ☐ | |
| Sponsor, if applicable | ☐ | |
| **NCTN ROUTINE CLOSURE**:  Submit *“Study Closure or Transfer of Study Review Responsibility”* worksheet to CIRB | | ☐ |

PRIOR TO FINAL REPORT SUBMISSION TO THE IRB (Project Manager’s Tasks)

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| Confirm the following have been completed: | |  |
| Close Out Visit is scheduled, as applicable | | ☐ |
| All outstanding data queries are resolved | | ☐ |
| All study data has been monitored | | ☐ |
| Visit payment tracker is updated and complete | | ☐ |
| All monitoring findings/action items are resolved | | ☐ |
| All pending biological specimens have been shipped to the **<<study designated lab>>** | | ☐ |
| NCTN trials only:  All bio-specimen collection dates have been entered in OPEN Funding system | | ☐ |
| **N/A ☐** | |  |
| After all protocol-specified laboratory testing is completed, confirm archival or destruction of all remaining stored specimens as specified in the Protocol (specimens obtained from participants who did not provide Informed Consent for post-study specimen storage and possible future research testing must be destroyed) *Confirm with PK/PD lab manager* | | ☐ |
|  | |  |
| In accordance with instructions provided by the Sponsor/CRO and as specified in the Protocol: | | ☐ |
| Confirm with IDS that IP records have been reconciled in Vestigo | YES ☐ NO ☐ | |
| Confirm that all Investigational Device Supplies have been destroyed or returned, as applicable | YES ☐ NO ☐ | |
| Confirm all destruction and/or shipping documentation completed and filed | YES ☐ NO ☐ | |

PRIOR TO FINAL REPORT SUBMISSION TO THE IRB (Regulatory Coordinator’s Tasks)

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| --- | --- | --- | --- |
| Confirm monitor/sponsor representative/s has eBinder access to all study close-out documents | | ☐ | |
| Final confirmation before IRB close-out submission | | | ☐ |
| All study-related activities have been completed | YES ☐ NO ☐ | | |
| The visit payment tracker is updated and complete | YES ☐ NO ☐ | | |
| Ensure all monitoring findings/action items have been resolved | YES ☐ NO ☐ | | |
| All invoices and payments have been rectified | YES ☐ NO ☐ | | |

SUBMISSION OF FINAL REPORT TO IRB(S) OF RECORD (Regulatory Coordinator’s Tasks)

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| Receive the final confirmation (after close-out visit) from the relevant team, according to the type of trial: |  |  |
| **Sponsor Trial**  Study monitor  **N/A ☐** | ☐ |  |
| **Investigator Initiated Trial (IIT) (TJU Center City only)**  QAE – *All regulatory documents have been reviewed*  **N/A ☐** | ☐ |  |
| **Multisite IIT (If any sites other than TJU Center city)**  QAE Multisite PM – *After all sub-sites are closed*  **N/A ☐** | ☐ |  |
| **NCTN Trials**  CIRB approved *Study Closure or Transfer of Study Review Responsibility worksheet*  **N/A ☐** | ☐ |  |
| Notify the IRB(s) of record of closure  (Local, central, and applicable reliance agreements IRBs) | ☐ |  |

LONG-TERM STORAGE GUIDANCE

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| Confirm you have followed the long-term archival guidance document  *Additional guidance for long-term archival storage requirements is pending* | ☐ |
| To the extent possible, organize and categorize all study documentation according to ICH GCP guidelines (ICH E6, Section 8.4). Prepare a written inventory of all documentation and storage locations. Documents must be stored securely and with adequate protection of participant confidentiality for the number of years agreed upon in the Clinical Trials Agreement. The date of destruction should be confirmed with a Senior Director or JCRI contract team. Always check contract and closeout letter for storage/destruction requirements.  *Additional guidance for long-term archival storage requirements is pending.* | ☐ |
| Confirm the following have been completed: |  |
| Administrative and regulatory documentation ☐ |  |
| Updated financial disclosure – *as requested or if applicable* ☐ |  |
| Final report by investigator to IRB/IEC where required, and where applicable  to the regulatory authority(ies) ☐ |  |
| IRB letter of termination received ☐ |  |
| Electronic study record received – *PM to confirm* ☐ |  |
| Final Clinical Study report received – *PM to confirm* ☐ |  |

PROCESSING FINAL IRB REPORTS (Regulatory Coordinator’s Tasks)

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| --- | --- |
| Prepare for and take part in a study close-out visit and file all visit documentation | ☐ |
| After receiving the IRB acknowledgment of study termination: |  |
| Enter the final report submission in JeffTrial and upload a copy of the IRB acknowledgement letter to the IRB transaction. | ☐ |
| If the study involves an external IRB, submit a final report via iRIS to the Jefferson IRB | ☐ |
| Add the termination end date to the following: |  |
| Delegation of Authority Log (DOAL) ☐ |  |
| Clinicaltrials.gov, if applicable ☐ |  |
| Update the study status in JeffTrial ☐ |  |

PROCESSING FDA IND/IDE WITHDRAWALS If not applicable, N/A ☐

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| --- | --- | --- |
| Verify if IND is associated with more than one TJU protocol or study\*  *\*note that you cannot withdraw an IND with the FDA if there are other active TJU studies* | | ☐ |
| Submit the following documents to the FDA to withdraw the IND or IDE: | | ☐ |
| IND/IDE Closure Cover Letter | ☐ | |
| Final Study Report | ☐ | |
| Letter of Authorization (LOA) | ☐ | |
| Form FDA 1571 | ☐ | |

REQUIRED SIGNATURES *(Electronic signature is acceptable)*

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| --- | --- | --- | --- |
| **Project Manager** | | | |
| Printed name: |  |  | |
| Signature: |  | Date: |  |
|  | | | |
| **Regulatory Representative** | | | |
| Printed name: |  |  | |
| Signature: |  | Date: |  |