**Checklist for Study CLOSURE**

Protocol TITLE/NUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| Complete the following checklist prior to archiving your clinical research project. | |
| 1. **FINAL PARTICIPANT VISITS**   *Have all final participant visits been conducted?*  *Have all adverse events (where applicable) resolved or been followed to stabilisation?* | YES  YES |
| 1. **STUDY DOCUMENTATION**   *In readiness for archiving\*, ensure you have:*   * *All STUDY LEVEL documents (“Essential Documents”) available for archive* * *All PARTICIPANT-LEVEL documents available for archive (e.g. data collection forms, questionnaires, study records)*   *\*Archiving can be in hard copy or electronic format (or a mixture). For electronic archiving, ensure documents are in appropriate format for long-term durability (contact CRDO at* [*crdo.info@mcri.edu.au*](mailto:crdo.info@mcri.edu.au) *for current guidance)* | YES  YES |
| 1. **NOTIFY ETHICS COMMITTEE & RESEARCH GOVERNANCE OFFICE**   *Submit a final report.*  *Submit to HREC for approval a thank you letter to send to participants (with a lay summary of study results).* | YES  YES |
| 1. **NOTIFY SUPPORTING DEPARTMENTS & EXTERNAL SERVICE PROVIDERS**   *If the study involved the services or support of other departments, research enablers or external service providers, have you notified them of study completion?* | YES  N/A |
| 1. **RETURN STUDY-SPECIFIC EQUIPMENT & SUPPLIES (where applicable)** | YES  N/A |
| 1. **SEND THE HREC-APPROVED THANK YOU LETTER TO STUDY PARTICIPANTS** | YES |
| 1. **DISSEMINATE STUDY RESULTS**   *Provide this to HREC as well as to stakeholders and all other relevant groups.* | YES |
| **DRUG/DEVICE TRIALS ONLY** |  |
| 1. **Clinical trials notification TO TGA – study completion IN AUSTRALIA (regulatory)**   *This should be undertaken by the Sponsor. Where the sponsor is MCRI/RCH, notify MCTC at* [*mctc@mcri.edu.au*](mailto:mctc@mcri.edu.au) *and MCTC will undertake the trial closure on-line. Where the CTN covers multiple sites, the notification should not be submitted until the final site listed has completed the study.* | YES |
| 1. **Investigational drug/device: return OR destrOY**   *Have the trial drugs/devices been returned to the Sponsor or destroyed (where applicable)?*  *Retain documentation of returns or destruction.* | YES |
| 1. **UPDATE THE CLINICAL TRIAL REGISTRY**   *A requirement of HREC approval is that all clinical trials be registered on a public trial register. The registry should now be updated to indicate study (or site) closure.* | YES |
| *ADDITIONAL NOTES FOR PREMATURE TERMINATION OF A STUDY:*  *Promptly inform study participants and ensure appropriate follow-up; inform HREC, RGO and (where applicable) the sponsor. For drug/device trials: ensure appropriate therapy and follow-up; notify MCTC to submit notification of closure to TGA with reason for premature closure.* | |
| By signing below, you are indicating that the study is ready to archive.  **Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_  Name Signature Date | |