**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* *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* *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 |