Title	Study Closure
SOP Code	2R2 SOP21_01Sep2022
Effective Date	26Sep2022

1.0 Objective(s)

The objective of this standard operating procedure (SOP) is to guide the research team during the closing of the research study $2R^2$.

2.0 Scope: Persons/Areas affected

This SOP concerns the Principal Investigator and the coordinating centre research team involved in conducting research with human participants for the study entitled – $2R^2$: *Higher dose Rifampin for 2 months vs Standard dose Rifampin for Latent TB: a 3-arm randomized trial.*

3.0 Responsibilities

The trial coordinating center is responsible for developing and maintaining this SOP and for adoption of the processes described in the SOP by the coordinating center research team.

4.0 Definition(s)

I. **Coordinating centre:** Research staff involved in running the $2R^2$ study who are based at the Research Institute of McGill University Health Centre (RI-MUHC)

5.0 Procedures

5.1 General information

- In this SOP, good practices relating to the closing of a study will be described, in a series of steps to be completed after the last participant participating in the study has completed his final follow-up visit/call for the study.
- It should be noted that in addition to the steps described, the budgets related to the research study should be verified and, if necessary, any further amounts owing to participating sites should be transferred. Payments for various contracts or agreements signed at the beginning of the study should also be completed.
- Before publication of the final results of the clinical research study is considered, it should first be verified that all participating sites are closed and all the data analyzed.

5.2 Conduct of Study closure

5.2.1 For Clinical Research Studies

For the closing of any study, the following steps should be completed:

- All adverse events/serious adverse events should be documented and reported to the Data Safety and Monitoring Committee (DSMB). They also should be recorded in the source documents as well as in the Case Report Forms (CRF) and recorded in the $2R^2$ website;

- All cases of active TB should be documented and reported to the ATB Clinical Panel for review. They also should be recorded in the source documents as well as in the Case Report Forms (CRF) and recorded in the $2R^2$ website;
- All cases of death should be documented and recorded on CRF and recorded in the $2R^2$ website;
- In compliance with the protocol and GCP, the Principal Investigator should inform the Funding agency, the Research Ethics Board (REB) and regulatory authorities, if applicable, of any unexpected SAEs following the study closure that can be reasonably associated with the study drug;
- All case report forms (CRF) should be completed in accordance with the data and source documents. All data should be entered into the study website;
- All necessary corrections to the data, the source documents or the CRFs should be carried out according to the correction procedures described in **SOP19** "Data Management";
- The process of request for data clarification should be completed and confirmed by the site investigator;
- All questions left outstanding from preceding monitoring, verification/audit or inspection visits should be resolved;
- Updating of the essential study documents should be finished; reference ICH section 8, Essential Documents for the Conduct of a Clinical Study.

5.3. Study-Related Material

- At the end of the study, accounting for all study drugs that were supplied by the coordinating centre, used and unused, should be recorded and this documentation retained with the essential documentation of the study;
- When accounting/reconciliation is finished, and following the coordinating centre's specifications, the study drug should be used by the study site team as appropriate or destroyed as per local regulations, as agreed with coordinating center;
- All unused CRFs and all used or unused study-related material should be destroyed on-site, in accordance with local procedures for destruction of confidential documents;
- PK samples, if not already done, should be shipped to the laboratory of Prof. Rovina Ruslami, at UNPAD University, Bandung, Indonesia (see **SOP24** "Sample shipping") or be destroyed as per agreement with the coordinating center.

5.4. Research Ethics Board and Regulatory Organizations

- Once sections 5.2 and 5.3 above are completed, the REB should be informed that the research study has ended, in agreement with section 4.13 of the ICH, which stipulates that the principal investigator should inform the institution, if applicable, of the end of a study. The principal investigator should also provide a summary of the study outcome to the REB. The Study Completion Report should be completed in the NAGANO system.

5.5. Study Completion communication

5.5.1 As this clinical trial application (CTA) was submitted to Health Canada, inform the agency that the study has ended.

5.5.2 Inform all members of the clinical research team and all relevant departments (e.g., pharmacy, laboratory) of the study closeout.

5.5.3 Inform all staff who participated in the study about study results and publications, once available.

5.5.4. A final study report, required for any study involving human participants (ICH E3), will be written once all the data are corrected and analyzed and the study is finished. NOTE: Reports for interim analyses will be produced at completion of the analyses and submitted to the DSMB.

5.5.5. The following elements will be listed in the report: information on the referenced protocol; the name of the Principal Investigator; the end date inclusion of participants; the total number of participants screened, enrolled, withdrew, and completed the study and all AEs; as appropriate.

5.6. Audit and inspection

An audit or inspection is possible even after a study is finished. An audit or inspection can be required by the funding agency (e.g. CIHR) or by another appropriately authorized authority. Coordinating center is responsible to prepare for an audit, before or after the study closure.

6.0. References

ICH E3: Guideline for Industry Structure and Content of Clinical Study Reports, 1996

Research Institute of McGill University Health Center, SOP-CR-016_07 Study Close-Out, 01-Sep-2018.

7.0 SOP Revision history

SOP code	Effective date	Summary of changes
SOP21_01Sep2022	26 Sep 2022	NA (original version)