Study Closure

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 $2R^2$

- 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 ithe

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.