Closing participant files

Title	**Closing participant files**
SOP Code	2R2 SOP17_01Sep2022
Effective Date	26 Sep 2022

1.0 Objective(s)

The objective of this standard operating procedure (SOP) is to ensure adequate closing of the study files of participant participating in $2R^2$ study at the end of follow-up period.

2.0 Scope: Persons/Areas affected

This SOP concerns the co-investigators (and their respective research teams) involved in conducting research with human participants for the study entitled – 2R2: *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 making it available at the clinical research site. At the clinical trial site, the site investigator is responsible for adoption of the processes described in the SOP.

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).

II. **Site Investigator**: A person responsible for the conduct of the research study at a study site. If a study is conducted by a team of investigators at the same study site, the Site Investigator is the responsible leader of the team.

III. **Case Report Form** (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the Sponsor on each participant in a clinical research study.

IV. **Data cleaning:** Process of detecting, diagnosing, and editing faulty data.

V. **Follow-up period**: This period comprises the treatment and post-treatment phase.

VI. **ID**: Unique participant identifier, de-identified and assigned to each participant by the 2R2 website at screening.

VII. **Source documents**: Original documents, data, and records (e.g. hospital health records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the study, and any other material applicable to the study).

VIII. **Participant file**: A participant file refers to all documents which purpose is to record specifically research-related information about a participant. These documents include case report forms (CRFs), as well as documents that are site-specific. A participant file does not include source documents that need to remain in a patient's chart after the conclusion of a study.

IX. **Participant file closure**: Participant file closure refers to the process by which a participant file is reviewed, cleaned, and archived once a participant has completed every phase of the study. Once closed, a participant file should not undergo any change.

5.0 Procedures

5.1 General information

- A participant file should be closed as soon as possible after follow-up period has been completed (i.e. when post-treatment follow-up is completed, 26 months post-randomisation);
- Study sites must develop operational and staffing plans for completion of all required procedures listed in this SOP;
- **The use of liquid corrector or correcting material is prohibited when making modifications to a participant file. Modification must be clearly visible, be dated and signed by the person doing the modification.**

5.2 Reviewing and cleaning the participant file

Once a participant's follow-up period is completed (i.e. 26 months post-randomisation), site investigator should ensure the integrity and coherence of the collected information by reviewing and cleaning the participant file:

- For each participant, an authorized person, as documented in the task delegation of responsibilities form (refer to **SOP1**), reviews the participant file by adhering to the following procedures:
  - **a)** If not already done, put all documents pertaining to a participant file into one file folder (except the participant identification form and the consent form);
  - **b)** Attach the applicable study file closure labels on the outside of the file folder. Note: all files will have **Label 1- FOR ALL FILES** (refer to **Appendix 1** for a sample of labels). Other labels (see **Appendix 1**), will be applied as needed, in particular: files of participants with Adverse events reports (CRF9, CRF10) will have also **Label 2- Adverse Events**; files of participants with active TB reports (CRF11-12) will have **Label 3-Active TB**, files of participants who died (at any point during the study), will have **Label 4-Death**; files of participants who participated in PK sampling (CRF13), will have **Label 5-PK**.
  - **c)** When a section of the participant file has been reviewed, indicate this on the appropriate area of the label (i.e. indicate YES/NO/NA);
  - **d)** For Indonesia and Vietnam sites: ensure that all necessary paper copies of Source Documents have been attached to the participant file (refer to **Appendix 2** for a list of required documents)

e) For Canadian sites, ensure that the source documents are available in the health care center electronic medical record system, they have been checked; and they will be available, if needed, for at least 15 years (as per Health Canada requirement of document storage).NOTE : if storage and access is not guaranteed for 15 years, please ensure necessary paper copies of Source Documents have been made and are in the participant file.

f) If it appears that there are some follow-up visits that were not attended by the study participant, review Source Documents to rule out the possibility that the study participant came to the clinic but the corresponding CRF was not completed;

g) As applicable use a Note to File, to be entered in the website, for required modifications to study data.

5.3 Anonymizing the participant file

Once a participant file has been reviewed and cleaned, it must be anonymized:

- The participant file should contain no directly identifiable information, such as name, initials, home address, or an Informed Consent/Assent Form;
- Steps should be taken by the Site Investigator or their delegate to mask all identifiable information in the participant file;
    a) When removing the personally identifying information, be sure:
        - to use a black sharpie pen and white out corrector. This way the name of the participant will be not visible.
        - the document is identified with the study participant ID (i.e. for source documents, remove the name and add the study participant ID);
    b) Documents that cannot be anonymized, such as the Informed Consent/Assent Form and the Identification form, must be stored separately from the participant file.

5.4 Archiving the participant file

Once a participant file has been reviewed, cleaned, and anonymized, it is ready to be archived by the Site Investigator with the rest of the Essential Study Documents (master binder). Archiving will be done at the time of site close-out using local archiving procedures. For this trial, documents must be stored for 25 years from trial completion.

6.0. References

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2), Current Step 4, version dated 9 November 2016.

Research Institute of McGill University Health Center SOP-CR-015_07 Investigator Study Files and Essential Documents; 01-Sept-2018.

7.0 SOP Revision history

SOP code	Effective date	Summary of changes

SOP017_01Sep2022	26Sep2022	NA (original version)

APPENDIX 1

LABELS FOR CLOSING STUDY PARTICIPANT FILES

(1) FOR ALL FILES

Reviewed: Screening & randomization CRF: ____ source doc: ____
Follow-up during treatment CRF: ____ source doc: ____
End of treatment CRF: ____
Follow-up post treatment CRF: ____ source doc: ____ NA:____
Adverse Events CRF:_____ NA: ____ source doc: ____ NA:____
Active TB CRF: _____ NA: ____ source doc: ____ NA:____
Subject file FULLY anonymized: _____
Consent stored separately: _____
Identification form stored separately: _____
Subject file ready for archiving: _____
Date of file closure ___ ___ /___ ___ ___ /___ ___ ___ ___

(2) FOR ADVERSE EVENTS

ADVERSE EVENT

Date of ADVERSE EVENT ___ ___ /___ ___ ___ /___ ___ ___ ___
TYPE: _____
GRADE: 1 2 3 4 5
RELATIONSHIP: Unlikely Possible Probable

(3) FOR ACTIVE TB (ATB)

Active TB Patient

Diagnosis: ATB Clinical ATB Microbiological Not TB

If ATB, Date of DIAGNOSIS ___ ___ /___ ___ ___ /___ ___ ___ ___

If ATB, Date of tx started ___ ___ /___ ___ ___ /___ ___ ___ ___

If ATB, Date of conversion ___ ___ /___ ___ ___ /___ ___ ___ ___or N/A

(4) FOR DEATH

DEATH

Date of death ___ ___ /___ ___ ___ /___ ___ ___ ___
Death in: treatment phase post-treatment phase
If in treatment phase, relationship: Unlikely Possible Probable
If in post-treatment phase: Unlikely ATB Possible ATB

(5) FOR PK

POPULATION PK

Date of PK sampling ___ ___ /___ ___ ___ /___ ___ ___ ___
Sample at : 2h 4h
Shipped on : ___ ___ /___ ___ ___ /___ ___ ___ ___

Closing participant files

Sample shipped: Box A only **All samples**

APPENDIX 2

LIST OF FIELDS THAT REQUIRE SOURCE DOCUMENTS

CRF-3: Evaluation & Randomization

In general, source documents are required to substantiate the eligibility of the study participant and as proof of any clinical test – bloodwork, CT scans, chest x-rays etc. Therefore, the following fields require source documents either electronically or paper copy:

- TST Injection / reading date & size
- Previous TST date & size (if appropriate)
- QFT date & results
- HIV status and therapy (if appropriate)
- Chest x-ray report date & results
- Other radiological tests date & results (if appropriate)
- Microbiology date & results (if appropriate)
- Bloodwork date & results

CRF-5: Follow-up during treatment

- Bloodwork date & results
- Other investigations, if applicable.

CRF-6: End of Treatment

None

CRF-7: Follow-up post treatment

- Applicable clinical, laboratory, treatment information, copies of relevant X-rays and any other test/results/documents as they relate to changes in health status.

CRF-8: End of post treatment follow-up

None

CRF-9 & CRF-10: Adverse event reporting

- Bloodwork date & results (if appropriate)
- Other relevant investigations, if applicable.

CRF-11 & CRF-12: Active TB reporting

- Chest x-ray report date & results
- Other radiological tests date & results
- Microbiology date & results
- Biopsy date & results

CRF-13: Population PK

None