Study site closure

Title	**Study Site Closure**
SOP Code	2R2 SOP18_27Jun2023

ensuring that all accounts payable and receivable have been dealt with. Lock of the trial database, final analysis of the data, and study report writing may occur after formal study closure. Study closure only occurs after all sites have been closed out (refer to **SOP21** Study closure).

5.0 Procedures

5.1 General information

A study site must be closed out as soon as it is practicable to do so:

- The coordinating centre will inform each study site of their respective projected date of close-out based on recruitment information;
- Study sites must develop operational and staffing plans for completion of all required close-out procedures as listed in this SOP;
- No study records are permitted to be destroyed without prior written authorization from the coordinating centre;
- If a study participant specifically requests for their samples to be removed from the study and destroyed, the coordinating centre must be notified.

5.2 Responsibilities of the site investigator prior to Site Close-Out Monitoring Visit

- Confirm that all Essential Study Documents and the study-related correspondence are in the Regulatory Binder (master binder);
- Ensure that all protocol-required data have been collected, entered in the website, and validated;
- All necessary corrections to the data should have been carried out, according to correspondence with coordinating center or note to file. Ensure that all participant files have been closed as per **SOP17** Closing participant files;
- Make sure that all adverse events have been properly reported and dealt with (refer to **SOP09** Adverse Event reporting & Management);
- Make sure that all Active TB cases have been properly reported and dealt with (refer to **SOP08** Active TB reporting);
- Make sure that all Death have been properly reported and dealt with (refer to **SOP07** Follow-up post treatment and **SOP09** Adverse Event reporting & Management);
- Make sure that: 1) All site samples for population PK (i.e. boxes A and B) have been shipped to : Montreal -for Canadian sites other than Montreal; to Ho Chi Minh City- for Vietnam sites in Ha Noi; 2) Boxes A have been shipped to Bandung, Indonesia for Montreal and Ho Chi Minh City sites;
- Make sure that all remaining study medications at site have been used or destroyed following communication from coordio.5linn3B8-45eeET % ResetTransform % SetTransform Q q % ResetTransforr

- Check that all issues from previous monitoring, auditing, or inspection visits have been resolved and were documented;
- Collect any outstanding required signatures;
- Confirm that all financial matters are in good standing;
    - For example, verify that all site payments have been processed as agreed in the study contracts.
- Read over the publication policy;
- Confirm archiving arrangements for at least one copy of the Essential Study Documents for a minimum of 15 years after publication, as calculated by the coordinating centre. In all cases:
    - A site's plan for archiving must meet all applicable regulations and standards – including *Good Clinical Practice;*
    - Storage should guarantee safety against disasters (e.g.: fire, floods) and confidentiality of the information contained in the participant file (i.e. it must be under lock);
    - All non-identifiable information regarding each individual participant in a study must be grouped together (**SOP17** "Closing participant files");
    - Data must be retrievable in such a fashion that all information regarding each individual participant in a study is attributable to that participant specifically;
    - The site investigator must make sure that the persons in charge of the archive understand that participant files must not be destroyed;
    - The plan must detail the transfer of responsibility for record retention in the event the investigator retires, dies, , or, for any other reac5 .00190hb.20-4ee.87sform34: Nea

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Plan for annual renewal of REB approval (if applicable at this site), until all analyses possible on the data collected are completed:
A)- People in charge of asking for annual REB's approval:

1. **Name:**_____

email address: _____

tel Number: _____

2. **Name:**_____

email address: _____

tel Number: _____

b) Place where the approvals will be stored once site is closed and master binder

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Full name: