|  |  |  |  |
| --- | --- | --- | --- |
| A Comparative Multicentric Non-Inferiority Clinical Trial of WHOMBMDT with a New Monthly Chemotherapy Regime containing Rifampicin, Moxifloxacin and Clarithromycin (RMC) on Multibacillary patients from IndiaStandard Operating Procedure 15Maintaining Training Records | | | |
| SOP Ref: TLMTI\_RMC -SOP-3 | | | |
| Version: Draft v | | | |
| Author: Joydeepa Darlong  Title: Maintaining Training Records | | | |
| Effective Date: |  | Review by: |  |
| Approved by: |  | Date: |  |
| Signature of Authorisor: |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **SOP Chronology** | | |  |
| **Version** | **Date** | **Reason for Change** | **Author** |
| 1.0 |  |  | JD |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| **Table of Contents** | **Page** |
| 1. Purpose | 3 |
| 2. Background | 3 |
| 3. Scope | 3 |
| 4. Procedure | 3-4 |
| 5. Appendices  Appendix 1 | 4  Separate document |

1. **PURPOSE**

This Standard Operating Procedure (SOP) describes the process of maintaining training records and what should be included in the employee’s training file.

**2. Background**

Research staff must be familiar with Good Clinical Practice (GCP) requirements and maintain their own training records. These records must demonstrate that all trial team members are qualified by education, training, and experience to perform their respective tasks. All training undertaken by staff within the RMC clinical trial must be in conjugation with the TLMTI policies and procedure.

**3. Scope**

This document applies to all staff involved in RMC clinical trial within TLMTI.

**4. Procedure**

**4.1 Creation of training record file**

**4.1.1** All staff members are required to maintain a Staff Training Record and folder. New employees will receive these from the trial co-ordinator during their Local Induction.

**4.1.2** The Staff Training Record will be labelled with the staff member's name and their start date.

**4.1.3** Based on the individual's role, the trial co-ordinator will provide guidance on the relevant Standard Operating Procedures (SOPs) and Working Instructions (WIs) required within the first week of employment. These documents must be signed off by the individual on the day of completion. The current RMC SOP reading log should be used to document completion of completion of SOPs and WIs

**4.1.4** The trial co-ordinator is responsible for informing the individual of any mandatory training/policies/procedures that need to be completed. The individual is responsible for completing all mandatory training as per TLMTI policy.

**4.1.5** The individual must keep their own log of any training/study/conference days that take place throughout their employment within the department.

**4.1.6** During the probation period the trial co-ordinator will identify any additional training required together with the individual.

**4.2 Updating of training record file**

**4.2.1** It is the responsibility of the individual employee to maintain their own training record and update it as and when appropriate.

**4.2.2** The training log should be updated with the name of the particular course, the date it took place, the provider, the duration and the location (Appendix 2).

**4.2.3** The training log should always be kept in a safe and secure place to be available for audit when required or review by the trial co-ordinator

**4.2.4** The Staff Training Record may be stored electronically by the individual but must be accessible as required.

**4.2.4** If an individual leaves their current employment, the training log will be taken with them and a copy kept by trial co-ordinator

**4.3 Review and Monitoring**

**4.3.1** The trial co-ordinator and individual are responsible for reviewing the training records/files annually during the appraisal process and the following documents should be checked for completeness:

* CV – up to date, signed
* GCP – up to date
* Job description
* Copies of certificates from training course undertaken during the year
* Up to date training log

**4.3.2** The trial co-ordinator will review their staff training records after the 6 month probationary period and then at yearly appraisals thereafter.

**5. References**

Integrated Addendum to Ich E6(R1): Guideline For Good Clinical Practice E6(R2)

**6. Appendices**

Appendix 1: Content of Training Record File

Appendix 2: Staff Training Record

**Appendix 1: Content of Training Record File**

* Current job description and any previous job descriptions which are relevant to the current post.
* Current CV demonstrating education, qualifications, training and experience
* Current GCP certificate
* Training log – both previous and current. These should list all the training an individual has received in their previous/current role, including mandatory training dates.
* Certificates of course attendance/study days
* SOP Reading Log

**Appendix 2: Staff Training Record**

|  |  |
| --- | --- |
| Name: |  |
| Date of employment: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of course/training | Course/training date | Course/Training provider | Course/Training location | Course/training duration |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |