

### Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

# MaPs in ENL

#### Session 2 – Training Log and Standard Operation Procedure

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The Leprosy Mission Trust India





ENLIST

The Leprosy Mission International Bangladesh Inclusion.rights



## Training Log and Standard Operation Procedures

### • Training log

- What is it
- How to use it
- Where to find it

### Standard Operational procedures (SOPs)

- What is it
- Importance
- Where to find it

## Training log

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	A	В	С	D	E	F G H	1	J K	
1	Centre		This log should be used to document any training you have completed or SOPs you have read that are relevant to your post. You must read and indicate on this log that you have understood all relevant LSHTM Standard Operating Procedures (SOPs) and any other applicable documents/procedures related to your post (As required by ICH GCP 5.1.1, 5.1.8, 5 and 5.1.9.1. You will be notified by email when a new version of an LSHTM SOP is released via the RGIO newsletter. It is your responsibility to ensure you have read and						
2	country		understood the new version within one month of notification (or sooner if required for your role/activities undertaken). If you need clarification about a SOP, please discuss with the senior member (s) of your daily working team / line manager as last resort.						
3	START DATE		You must add any relevant training you complete to the table below. The training and SOP logs should be printed and filed in the Personal Records TMF approximately every 4 months.						
4									
5	Date	SOP/ workshop/lecture	Subjects Covered	Trainer (if appropriate)	Research Staff who completed the training				
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## Standard Operational Procedures (SOPs)

- Screening
- Consent
- Enrolment
- Laboratory
- Severity scale
- First assessment
- Physical examination
- SF-36 and DLQI
- Follow up assessment

### • Flares

- Adverse Events
- Overdose
- Data entry and management
- Withdrawal
- End of study
- Unblinding
- Pregnancy
- Pharmacist

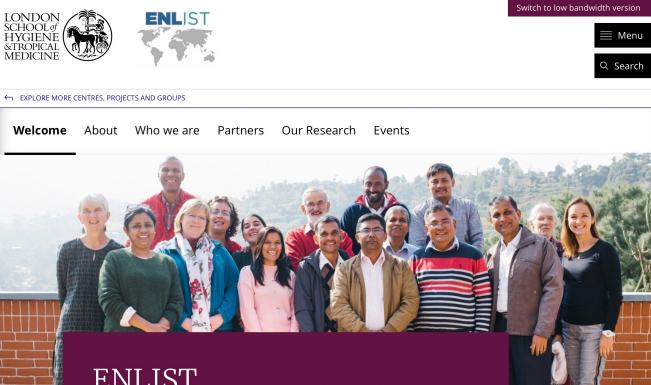
## SOPs

ENLI	ST		SCHOOL of HYGIENE &TROPICAL MEDICINE		
Methotrexate and Prednisolone studies in Erythema Nodosum <u>Leprosu</u> <u>MaPs</u> in ENL Standard Operating Procedure 1					
	Screening Log				
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SOP Ref:	Scree	ning Log			
SOP Ref: Version:		ning Log			
	LSHTM-SOP-1		creening		
Version:	LSHTM-SOP-1 Draft v 2		reening		
Version: Author:	LSHTM-SOP-1 Draft v 2	Title: So	creening		

SOP Chronol	logy					
Version	Date	Reason for Change	Author			
1	10/04/2018	Revision of procedures by the member of ENLIST	BB			

- In person training
- Online training
- Copies
- Storage

## Where to find it?



ENLIST

The Erythema Nodosum Leprosum International STudy (ENLIST) group is an international partnership between seven countries focused on improving the understanding and treatment of Erythema nodosum leprosum (ENL).

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https://www.lshtm.ac.uk/research/centres-projects-groups/enlist



- What is a SOP
- Trainings available to the research staff
- Videos
- Where to find it