LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

MaPs in ENL

Training session 6 – Consent

Dr. Barbara de Barros – MaPs study manager

ENLIST

Ahri Armauer Hansen Research Institute Since 1970

ALERT

BLP ESTD. 1978

The Leprosy Mission Trust India healing.inclusion.dignity

RUMAH SAKIT UMUM DAERAH DR. SOETOMO

The Leprosy Mission International Bangladesh dignity.inclusion.rights

The Leprosy Mission Nepal transforming individuals and communities

Consent process

- **When**
- **Consent Form**
- **How to get consent**
- **Documentation**

Consent process

- **Local language**
- **Before any study procedures**
  - **Prior to any blood tests collected for the study**
- **Informed consent**
  - **The study personnel will use a verbal informed consent review**
  - **Explain the study**
- **Two step consent form**
  - **If participant fulfills all inclusion and exclusion criteria the process continuous**
- **REDCap**

MaPs IN ENL: Study number: |_|_|_| Patient Initials: |_|_|_|

Study Center: _____

CONSENT FORM FOR PARTICIPATION IN METHOTREXATE AND PREDNISOLONE STUDIES IN ENL

A. I _____ understand that doctors at _____ and at the London School of Hygiene and Tropical Medicine are involved in research into alternative treatments for leprosy reactions. Erythema Nodosum Leprosum (ENL) is a recurrent condition which can affect patients for many years. This study will look at whether methotrexate and prednisolone is more efficacious than prednisolone alone in the management of acute, recurrent and chronic erythema nodosum leprosum. We are hoping to find a way of reducing the number of ENL attacks and the length of these attacks.

B. The study has been explained to me.

C. I confirm that I am 18 years old or above, and younger than 61 years old.

D. I shall be randomly assigned to a 48 weeks course of either Methotrexate and prednisolone (20 weeks only) or placebo and prednisolone. I agree to take all the tablets that I will be given.

D. I agree to regular review visits, at first fortnightly, then monthly for the duration of my treatment.

E. I also agree to return for follow-up during the course of this study.

F. I understand that I will have to have regular blood tests to monitor for any side effects as I may be at risk of picking up other infections. The maximum amount of blood drawn at any time will be 20ml (this is the equivalent of 4 teaspoons). It is possible that I may experience some side effects as explained on the information sheet and that I will be treated for these freely and appropriately.

G. Some of the samples taken (blood) may be kept in a laboratory for up to 5 years to allow future studies. Please tick the box if you agree to follow up studies to be conducted on stored materials.

□ Yes, I agree □ No, I don't agree

I. Women only: I agree to undergo a pregnancy test, to attend Family Planning and use family planning methods during the period of the study.

If I become pregnant I may be withdrawn from the study but will continue on the standard treatment used in pregnancy.
Men only: I agree to use effective contraception during the study and 6 months after study completion.

J. I agree to be tested for HIV via VCT (Voluntary Counselling and Testing). If I am HIV positive I will be excluded from the study but will still receive the standard treatment for leprosy and HIV. HIV testing may be repeated during the study period if clinically indicated.

K. I can decide to leave the study at any time for any reason and will still receive other treatment from the hospital for my disease.

L. I understand that my name will not be revealed in any published material concerning this study. I understand that my notes will be treated with maximum confidentiality and will only be accessed by staff directly involved in the Study or the monitors of the Study.

M. I have received enough information about the study in a language I understand. I had the opportunity to discuss it and ask questions, and my questions have been answered to my satisfaction. I understand that participation is voluntary and that I am free to withdraw my consent at any time. I freely consent to participate in this research study and to allow treatment and tests to be performed on me as explained.

N. I understand that I can be requested anytime to terminate my participation in the trial if the need arises. I will be given full explanation of the reason and will still receive standard treatment.

	Printed Name	Signature	Date
Patient	_____	_____	____/____/20___
Witness	_____	_____	____/____/20___
Doctor	_____	_____	____/____/20___

Two Steps consent process

- **Before any study procedure is done**
  - **Chest x-ray**
  - **Laboratory tests**
- **Explain that depending on the results of they may be eligible**
- **Explain that depending on the results they may be eligible in the future**
- **Be sure the participant understands he/she needs to commit to come to the following visits**
- **A witness needs to be present**

How to get consent

- **Two consent forms**
  - **One signed copy will be kept in the study file**
  - **One signed copy will be given to the participants**
- **Local language**
- **Informed consent is obtain in a setting free of coercion and undue influence**
- **Emphasize that the decision whether or not to participate is the participant's**
- **Emphasize that the participant's access to medical care and/or other services will not be affected by his/her decision whether or not to take part**
- **Read the "MaPs Participant Information Sheet" with the participant and clarify any question**
- **If the participant can NOT read an independent witness must be present**
- **Expenses will be reimbursed**

Documentation

Participants who can read

- Participant will print their name on the participant's name line
- Participant will sign on the signature line
- All entries will be completed in ink
- The witness will print their name on the witness name line and he/she will sign on the signature line
- The MaPs local researcher will complete his/her entry in ink on his/her respective lines (name, signature and date)

Participants who can NOT read

- The participant will place his/her thumbprint on the participant's signature line.
- The name and date lines of the participant will be left blank.
- The witness will print their name, sign and date on the witness lines.
- All entries will be completed in ink.
- The MaPs local researcher will write at the bottom of the signature page that "(Participant's name) is illiterate and consented to this form on DD MM YY" and he/she will initial and date this entry.
- The MaPs local researcher will document the process as specified for the literate participants.

Summary

- **Consent must be obtain before any study procedure is done**
- **Two consent forms must be signed**
- **Consent SOP**
- **REDCap**