

**ANANDABAN LEPROSY HOSPITAL/COLORADO STATE UNIVERSITY
TESTING NEW SKIN TEST ANTIGENS FOR LEPROSY (MLSA-LAM & MLCwA)
HUMAN SUBJECTS CONSENT FORM: Phase II, Parts A & B**

Subject's Name: _____ **Date:** _____

Purpose:

The purpose of this research study is to see how healthy people and leprosy patients react to two newly developed skin tests for detecting leprosy. This study will help us evaluate a tool (new skin test antigens) that may help us measure how many people are exposed to leprosy and enable us to diagnose and treat the disease at an earlier stage. Currently, there are no other diagnostic tests available for the detection of leprosy. A total of 100 volunteers will participate in Parts A and B of this study.

Procedures:

You will be asked some questions concerning your health and the doctor will need to physically examine you. Women will be asked to take a urine pregnancy test. Pregnant women will not be enrolled in the study. As a precaution, you will be examined for signs of leprosy. This will involve examining your skin and feeling your nerves.

You will receive 4 injections, two containing proteins of *M. leprae*, one containing proteins of *M. tuberculosis*, and one of saline (salt water). Two injections will be given on the forearm (below the elbow) of each arm. A small swelling will develop around some or all of these over the next 2-3 days. The swelling will be about the size of a mosquito bite. We will examine and measure the swelling 15 minutes after injection, after 3 days and after 7 days. If a swelling does develop in the first 3 days, we will examine the injection sites again after 28 days. If a swelling develops at any of the sites during the first seven days, your study/subject number will be posted on the College notice board to serve as a reminder for you to return at day 28 for a final reading. We may ask you to come in for additional visits as follow-up to any reaction you might have. Your total time involvement for this study will be approximately 5 hours spread out over a 1 month time period. By signing this form you agree to the injections and to attending the clinic for examination of the injections at the above times.

This is a research diagnostic test not approved for standard practice, and does not indicate that you have leprosy or that you are in danger of contracting leprosy. Also, you cannot contract leprosy from this test. At the commencement of the study, if it is found that you have leprosy, Anandaban Leprosy Hospital will provide free treatment. If it is found that you have tuberculosis, you will be referred to another hospital for treatment at your own expense.

Risks:

The risk to you from these injections is small. Areas of erythema and induration (redness and swelling) will occur in those responding to the antigen(s), but these are localized responses and, generally, do not cause any discomfort. However, some people may itch at the injection sites and others may react strongly to the injections and have a large swelling that may break open and ooze pus. If this happens, these areas will be examined daily to ensure that secondary infection does not occur and to confirm satisfactory healing. If necessary, you will be given antibiotics to keep an infection from starting.

There is a very small chance that some people may be hypersensitive to one or both of these antigens. If you are, within 30 minutes your throat may start to close and you may have trouble breathing, and you will immediately be given a drug injection to keep your throat open and enable you to breathe.

If you experience any side effects at any time you should call the hospital at 290-545 and ask to speak to Dr. Mark Macdonald. If you are injured or have an adverse reaction or illness as a direct result of this research Anandaban Leprosy Hospital will provide you with emergency medical treatment. You will not have to pay for this treatment; however, you will not be compensated for lost wages, pain, or suffering. If you think you have been injured because of this research, please contact the Nepal Health Research Council at 254-220.

It is not possible to identify all potential risks in any experimental procedure, but reasonable safeguards have been taken to minimize both the known and the potential, but unknown, risks.

Benefits:

There are no direct benefits to you for participating in this research study. However, the information gained about the early detection of individuals infected with leprosy should be beneficial to others with leprosy or exposed to leprosy.

Compensation:

There will be no monetary payment for participation, but in return for your time and inconvenience, you will receive a small gift valued at approximately US\$11.

Confidentiality:

The results of this research study may be published, but your name or identity will not be revealed. Your records may be reviewed by Colorado State University, the United States Food and Drug Administration (FDA), the sponsor of this study, the National Institute of Allergy and Infectious Diseases, National Institutes of Health, and the Nepal Health Research Council.

Statement of Voluntary Participation:

Your participation in this research study is voluntary; you may withdraw from this study of your own free will at any time without penalty.

You agree to receive the injections as outlined above and to allow the examination of the injection site by the research staff.

You have read/had read to you the information above and sign this form willingly.

Problems or Questions:

Should any problems or questions arise about this study or your rights as a participant in this study, you should contact one of the following individuals:

For medical questions call:

Dr. Mark Macdonald at 290-545

For questions about the study call:

Dr. Murdo Macdonald at 290-545

For questions concerning your rights as a participant contact:
The Nepal Health Research Council at 254-220

Subject's Name

Subject's Signature

Date

Witness' Name

Witness' Signature

Date

Investigator's Name

Investigator's Signature

Date

I certify that I have read and explained the above to _____, that s/he indicated that s/he understood what I said and had the opportunity to ask questions, and s/he agreed to join the study. I certify that this is her/his signature/mark/thumbprint.

Fieldworker's name

Fieldworker's signature

Date

Volunteer's Signature, Mark or Thumbprint _____