

**ANANDABAN HOSPITAL/COLORADO STATE UNIVERSITY
TESTING NEW SKIN TEST ANTIGENS FOR LEPROSY (MLSA-LAM & MLCwA)
HUMAN SUBJECTS CONSENT FORM: Phase II, Stage C1 (Controls, Contacts, TB)**

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. You are being asked to participate because you fulfill one of the following criteria: (i) you do not show any clinical signs of leprosy, nor have you been in contact with anyone known to have leprosy, (ii) you do not have clinical signs of leprosy, but you have been in contact with someone known to have leprosy, or (iii) you have tuberculosis. A total of 425 volunteers will participate in Stage C of this study, 90 of whom fit criteria (i), 140 of whom fit criteria (ii), and 48 of whom fit criteria (iii). Stage C1 is a sub-set of Stage C and will enroll 20 from each criteria mentioned above.

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. Women who are breast feeding their baby also cannot participate. As a precaution, you will be physically examined for signs of leprosy. This will involve examining your skin and feeling your nerves. Also, if you have tuberculosis your medical records will be examined by study personnel to determine the type of tuberculosis and treatment you received for this disease.

You will receive 3 injections in your forearm below the elbow. Two are research skin tests for leprosy and the third is the usual skin test for TB. A small swelling may develop around some or all of these over the next 2-3 days. In most people the swelling will be about the size of a mosquito bite, but can be larger in some people. 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 3-7 days we will examine the injection sites again after 28 days. We will remind you one week before the set date of day 28 for you. We will also ask you to give us 12 ml of your blood, about 2½ teaspoons, to test for the presence or absence of germ fighters in your blood that can limit or destroy the leprosy germ (leprosy-specific antibodies) and to measure in the laboratory how your body responds to the new tests. There will be some slight pain during the needle puncture. There may be some small amount of bleeding on the site upon withdrawal of the needle, but direct pressure on the site using a cotton swab saturated with spirit will stop this. Afterwards the site will be covered with a small dressing.

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.

The leprosy skin test 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 Hospital will provide free treatment. If it is found that you have tuberculosis, you will be referred to another hospital for treatment. Drugs for direct treatment for tuberculosis are free in all government health service centers. Other

direct expenses relating to TB treatment will be at your own cost.

Risks:

The risk to you from these injections is small. Areas of redness and swelling will occur in those responding to the tests, but these are just around where the needle went in and, generally, do not cause any discomfort. However, some people may itch at the needle 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 and treated 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 the leprosy skin tests. 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.

The risk to you from the blood extraction is small. In some instances, some blood may leak into the surrounding tissue, causing some skin discoloration around the puncture site. This is temporary and will fade after several days.

If you experience any side effects at any time you should call the hospital at 429-0545 and ask to speak to Dr. Rachel Hawksworth. If you are injured or have an adverse reaction or illness as a direct result of this research Anandaban 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 425-4220.

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.

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 give some blood and 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, have had your questions answered 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. Rachel Hawksworth at Anandaban Hospital, Tika Bhairab, Lalitpur on 429-0545

For questions about the study call:

Dr. Murdo Macdonald at 429-0545

For questions concerning your rights as a participant contact:
The Nepal Health Research Council at 425-4220

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 _____

**ANANDABAN HOSPITAL/COLORADO STATE UNIVERSITY
TESTING NEW SKIN TEST ANTIGENS FOR LEPROSY (MLSA-LAM & MLCwA)
HUMAN SUBJECTS CONSENT FORM: Phase II, Stage C1 (Leprosy Patients)**

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. You are being asked to participate in this study because either you have leprosy and are being treated, or you had leprosy but have been treated for leprosy. A total of 425 volunteers will participate in Stage C of this study, 147 of whom have, or have had, leprosy. Stage C1 is a sub-set of Stage C and will enroll 40 of the 147 leprosy patients.

Procedures:

You will be asked some questions concerning your health. The doctor will need to physically examine you to observe the extent of your leprosy and look for signs of any other diseases. Women will be asked to take a urine pregnancy test. Pregnant women will not be enrolled in the study. Women who are breast feeding their baby also cannot participate. Your medical records will be reviewed by study personnel to determine the type of leprosy and treatment you have received for this disease.

You will receive 3 injections in your forearm below the elbow. Two are research skin tests for leprosy and the third is the usual skin test for TB. A small swelling may develop around some or all of these over the next 2-3 days. In most people the swelling will be about the size of a mosquito bite, but can be larger in some people. 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 3-7 days we will examine the injection sites again after 28 days. We will also ask you to give us 12 ml of your blood, about 2½ teaspoons, to test for the presence or absence of germ fighters in your blood that can limit or destroy the leprosy germ (leprosy-specific antibodies) and to measure in the laboratory how your body responds to the new tests. There will be some slight pain during the needle puncture. There may be some small amount of bleeding on the site upon withdrawal of the needle, but direct pressure on the site using a cotton swab saturated with spirit will stop this. Afterwards the site will be covered with a small dressing.

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.

The leprosy skin test is a research diagnostic test not approved for standard practice. At the commencement of the study if it is found that you have tuberculosis, you will be referred to another hospital for treatment. Drugs for direct treatment for tuberculosis are free in all government health service centers. Other direct expenses relating to TB treatment will be at your own cost.

Risks:

The risk to you from these injections is small. Areas of redness and swelling will occur in those responding to the tests, but these are just around where the needle went in and, generally, do not cause any discomfort. However, some people may itch at the needle 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 and treated 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 the leprosy skin tests. 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.

The risk to you from the blood extraction is small. In some instances, some blood may leak into the surrounding tissue, causing some skin discoloration around the puncture site. This is temporary and will fade after several days.

If you experience any side effects at any time you should call the hospital at 429-0545 and ask to speak to Dr. Rachel Hawksworth. If you are injured or have an adverse reaction or illness as a direct result of this research Anandaban 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 425-4220.

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.

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 give some blood and receive the injections as outlined above and to allow the examination of the injection site by the research staff.

If you refuse to participate or if you withdraw from the study, you will continue to receive free treatment from Anandaban Hospital for leprosy.

You have read/had read to you the information above, have had your questions answered 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. Rachel Hawksworth at Anandaban Hospital, Tika Bhairab, Lalitpur on 429-0545

For questions about the study call:
Dr. Murdo Macdonald at 429-0545

For questions concerning your rights as a participant contact:
The Nepal Health Research Council at 425-4220

_____ 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 _____		

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

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.

One of the people who lives in the same house as you has been asked to participate in this study, so that we can examine their reaction to the skin test.

If they agree to participate, we will need to look at your medical records chart, to get some information about you.

Procedures:

We need your permission to look at your medical records chart, in order to get the following information:

1. hospital number
2. hospital where treated
3. leprosy type
4. initial skin smear
5. treatment history
6. months of treatment

We will also ask the person how long they have lived in the same house as you.

Risks:

There is a potential risk that information about you might be disclosed to others but study personnel will keep this information confidential as far as possible. While it is not possible to identify all potential risks in any experimental procedure, reasonable safeguards have been taken to minimize both the known and the 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.

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:

You are free to elect not to allow us to look at your medical records chart to obtain the above information.

You have read/had read to you the information above, have had your questions answered

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. Rachel Hawksworth at Anandaban Hospital, Tika Bhairab, Lalitpur on 429-0545

For questions about the study call:

Dr. Murdo Macdonald at 429-0545

For questions concerning your rights as a participant contact:

The Nepal Health Research Council at 425-4220

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 _____