**Annex A1: Information and consent sheet CL Cohort study – Adults**

***Title of Project: Improving experiences and outcomes for individuals with severe stigmatising skin diseases: Cutaneous Leishmaniasis Cohort Study in Ethiopia***

***Skin Health Africa Research Programme (SHARP) Ethiopia***

**Introduction**

We would like to invite you to participate in a research study focusing on people affected by cutaneous leishmaniasis. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. I will read and give you a copy of this information sheet and go through it with you and answer any questions you may have. If you agree to take part, we will then ask you to sign a consent form.

**What is research?**

Research is work designed to gather new information about a condition in order to answer questions which may lead to improvements in how we manage and treat the condition.

**Who are the researchers?**

Researchers from the Addis Ababa University, the Armauer Hansen Research Institute and ALERT hospital here in Ethiopia as well as from the London School of Hygiene & Tropical Medicine in the United Kingdom are conducting research into a skin disease known as cutaneous leishmaniasis (CL).

**What is cutaneous leishmaniasis?**

CL is caused by an infection transmitted after the bite of a sand-fly. We know CL affects many people in Ethiopia. CL causes scarring which may affect quality of life. CL may result in expenses for people and their families.

The infection causing CL is treatable and the different available treatments will be discussed with you by your doctor.

**What do we hope to learn from the research?**

1. How does CL affect people?
2. What are the best ways to measure the effects of CL?
3. What happens to CL during different treatments?
4. Which treatments do people prefer?
5. How do our bodies respond to infection and treatment?
6. What are the costs to people and their families of having CL?

Finding answers to these questions will improve the management of people affected by CL in Ethiopia.

**Why have you been asked to participate?**

You have been invited to participate in this study because you have been diagnosed with CL and are about to start treatment.

**Do you have to participate? Can you change your mind about taking part?**

It is up to you to decide whether to participate or not. You are free to stop participating in this study at any time for any reason. If you decide not to participate in this research, it will not influence your access to healthcare services now or in the future. If you withdraw from the study, we will keep any information you have provided to us confidential and exclude it from our analyses and publications.

**What will you have to do as a participant?**

Your doctor will discuss with you the treatment of your CL. The study will not influence the choice of treatment decided by you and your doctor. If you decide to participate in the study you will be asked some additional questions about your skin condition, general health and how you feel. We will take 15ml of blood in addition to the standard ones prior to your treatment and an additional small (3mm) piece of skin from the CL lesion. We will ask you questions about your skin, general health and how you feel during the treatment. We will take blood from you for the study on three further occasions. We would also like to take a small (3mm) additional piece of skin when you have the skin test to make sure the treatment has been successful. Any additional sample collected from you will only be used in related, ethically approved research.

**Will any pictures be taken of you?**

Photographs will be taken to follow the progress of healing in the skin lesions caused by CL, as treatment takes effect. Any photo will be taken based on your consent. We will take only the relevant part. Efforts will be made to remove any identifying features for publication.

**What are the possible risks and disadvantages?**

1. Interviews and completing questionnaires will take up some of your time. It is not anticipated this will make you feel uncomfortable please let us know if it does and we will stop talking about the particular issue/topic.
2. Participating in the CL Cohort study will mean providing blood for the research. Having blood taken involves a needle which may have mild pain. Occasionally bruising may occur at the site of the test. A skin biopsy will also be taken which is performed using local anaesthetic. The local anaesthetic is placed in the skin using a needle which can have mild pain. Removal of a small piece of skin will leave a small scar but this is unlikely to be more noticeable than the scar caused by CL. Occasionally wounds caused by skin biopsies may become infected which is amenable to antibiotics which will be provided by the study team.
3. All treatments may have adverse effects. The treatment prescribed for you is determined by your doctor following discussion with you and is **not** decided by the study team.

**What are the possible benefits?**

You will be closely monitored during treatment and afterwards. The information you provide will help us design and evaluate interventions aimed at improving experiences for people with these skin conditions in your community and in other countries.

**What will happen to information collected about you?**

All information collected about you will be kept private and it will not be shared with anyone else. Only a small number of researchers within the study team in Ethiopia and at the London School of Hygiene & Tropical Medicine will be allowed to look at information about you. At the end of the project, the anonymised study data will be kept in an online data repository. The data will be made available to other researchers worldwide for research and to improve medical knowledge and patient care. However, your personal information will not be included and there is no way that you can be identified.

**What will happen to the results of this study?**

The study results will be shared with you and people studying the disease and those responsible for decisions about treatment. The results will be published in scientific journals so that other researchers can learn from them. Your personal information will not be included in the study reports.

**Who has reviewed this study?**

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect the participant. This study has been reviewed and approved by The London School of Hygiene & Tropical Medicine’s Research Ethics Committee. The Ethiopian National Research Ethics Review Committee, the Amhara regional state Public Health Institute research ethics review committee and the AHRI/ALERT ethics committee has reviewed the study and have agreed that it is okay to ask people to take part.

**Will there be any payment?**

You will not receive any cash or other incentives for participating in this study. However, you will be reimbursed for costs incurred to travel during the study period. Participants coming from distant area may get covered for their accommodation cost which is at the discretion of the principal investigator: Dr Endalamaw Gadisa.

**What happens when the research study stops?**

Your doctor will discuss with you arrangements for any further visits to the hospital.

**What will happen to the samples you give?**

After investigations are done on the laboratory samples collected, they will be stored for a maximum of 5 years then destroyed following standard laboratory procedures.

**Further information and contact details**

Thank you for taking time to read this information sheet. If you would like to participate in the study please read and sign the consent form. If you have any questions or concerns, you can ask the researchers who will do their best to answer your questions. You may also contact any of the Study Investigators listed below[[1]](#footnote-1):

|  |  |  |  |
| --- | --- | --- | --- |
| **Investigator** | **Title** | **Institution**  | **Telephone Contact** |
| Exxxxxxxx Gxxxxxx | Senior NTD Researcher and study co-PI | Armauer Hansen Research Institute | xxxxxxxxxx |
| MxxxxxxxxKxxxxx | Lecturer | Addis Ababa University | xxxxxxxxxxx  |
| Sxxxxxx Wxxxxxx | Consultant Dermatologist Associate Professor and study co-PI | The London School of Hygiene & Tropical Medicine | xxxxxxxxxxx |

If you wish to complain formally, you can do this by contacting Patricia Henley (Head of Research Governance and Integrity at the London School of Hygiene & Tropical Medicine) at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626 and AHRI/ALERT ethics review office at 0118962183.

**Participant Consent Form**

**Title of Project: Improving experiences and outcomes for individuals with severe stigmatising skin diseases: Cutaneous Leishmaniasis Cohort Study in Ethiopia**

 ***Skin Health Africa Research Programme (SHARP) Ethiopia***

***Name of PI/Researcher responsible for project:*** *Prof. Steve Walker / Dr Endalamaw Gadisa*

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| --- | --- |
| Statement  | Please initial or thumbprint\* each box |
| I confirm that I have read the information sheet for the above-named study OR I have had the information explained to by study personnel in a language that I understand.  |  |
| I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.  |  |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. |  |
| I understand that relevant sections of my medical notes and data collected during the study may be looked at by authorised individuals from the research team. I give permission for these individuals to have access to my records. |  |
| I understand that data about/from me/the participant may be shared via a public data repository or by sharing directly with other researchers to support other research in the future, and that I will not be identifiable from this information. |  |
| I agree to answer health related questionnaires as well as a questionnaire of how my finances may be affected by this skin condition. |  |
| I agree to have additional laboratory investigations consisting of blood samples and skin biopsies |  |
| I have been asked for long term storage (maximum of 5 years) of my samples I agree with long term storage of my samples and for these be used for related, ethically approved research.  |  |
| I consent to photographs being taken and used for the research assessments  |  |
| OPTIONALI hereby confirm that I give consent for the photographs to be taken of me. I understand the material has educational value. I consent to the material being shown to appropriate professional staff and used in educational publications, journals, textbooks and used in any other form or medium including all forms of electronic publication or distribution anywhere in the world. As a result, I understand that the material may be seen by the general public. All or part of the material may be used in conjunction with other photographs, drawings, videotape images, sound recordings or other forms of illustration. Efforts will be made to conceal my identity, but full confidentiality is not guaranteed. |  |
| I agree to take part in the above-named study |  |

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|  |  |  |

 Name of participant Signature of participant Date

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 Name of impartial witness\* Signature of impartial witness\* Date

I attest that I have explained the study information accurately in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and was understood to the best of my

knowledge by the participant and that he/she has freely given their consent to participate in the presence of the above named impartial

witness (where applicable)

|  |  |  |
| --- | --- | --- |
|  |  |  |

 Name of person obtaining consent Signature of person obtaining consent Date

[\*Only required if the participant is unable to read or write.]

**One copy of this signed informed consent document to be kept to the participant and one copy to be filed securely**

1. Contact details of the research focal person in the study site will provided as soon as he/she is recruited. [↑](#footnote-ref-1)