**This Informed Consent Form is for patients with cutaneous leishmaniasis attending a MENTOR-supported health facility or mobile clinic who we are invited to participate in a research study on thermotherapy treatment versus meglumine antimoniate treatment. The title of our research project is ‘Randomised controlled trial to determine the efficacy of thermotherapy in comparison with intralesional meglumine antimoniate to treat cutaneous leishmaniasis in an operational setting in Syria’**

**Name of Principal Investigator**

Hendrik Sauskojus

**Name of Organization**

The MENTOR Initiative

**Name of Sponsor**

The MENTOR Initiative

**Name of Proposal and version**

‘Randomised controlled trial to determine the efficacy of thermotherapy in comparison with intralesional meglumine antimoniate to treat cutaneous leishmaniasis in an operational setting in Syria’

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the research with you)**
* **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form.**

**Information Sheet**

**Introduction**

The MENTOR Initiative is an international organisation that has been working to provide treatment for cutaneous leishmaniasis in North West Syria for 6 years. We are now doing research on different treatment options for cutaneous leishmaniasis which is a very common infection in this part of Syria. Cutaneous leishmaniasis is a type of disease which causes skin lesions like the one that you are presenting with today. We are inviting a little under 600 patients with cutaneous leishmaniasis to take part in the research study which we are doing.

You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

**Purpose of the research**

Cutaneous leishmaniasis, or Aleppo boil, is one of the most common infections in this region. The drugs that are currently used to help people with cutaneous leishmaniasis need to be given twice a week by injection for 3 – 4 weeks. There is another treatment called thermotherapy that only requires 1 treatment and it may work just as well as the injections. The reason we are doing this research is to find out if thermotherapy is as good as injections of the drug glucantime, which is currently the treatment most often used.

**Type of Research Intervention**

If you take part in this study, you will be randomly assigned to one of the two treatments. Randomly means it is like tossing a coin so it is by chance which treatment will be given to you.

**Participant selection**

We are inviting all people with leishmaniasis of the ages 5 and above and who have lesions in locations that are easy to be treated by both of the study treatments to participate in this study.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for leishmaniasis, and we will tell you more about it later. You are also free to change your mind later on and stop participating even if you agreed earlier.

**Information on the Trial Treatments**

The 2 treatments that are offered in this study are both proven to be safe and effective for treatment of cutaneous leishmaniasis.

Meglumine Antimoniate has few side effects when given by injection into skin lesions. The most common side effects that are experienced with this treatment are redness around the lesion, itching, swelling, pain where the needle is injected, and infection of the surrounding skin that needs treatment with an antibiotic. These side effects are rare.

The thermotherapy device is made by the ThermoMed company and also does not commonly cause side effects. The most common side effects associated with thermotherapy are pain over the lesion during and after the treatment, redness and some oozing of fluid from the lesion.

If you choose to participate in the study, you will be treated with one of these treatments.

**Procedures and Protocol**

Because we do not know if thermotherapy works better than injections for treating cutaneous leishmaniasis, we need to compare the two. To do this, we will put people taking part in this research into two groups.

For patients who are assigned to receive injections, they will need to attend the clinic twice a week for 3-4 weeks to have the lesion injected at each visit.

For patients assigned to receive thermotherapy treatment, they will have just 1 treatment session today.

Both patients will be asked to attend a follow-up appointment 3 months after their treatment has finished. For patients receiving their treatment at a health facility (HF), they will be given an appointment to return to the HF 3 months after their last treatment appointment. For patients receiving their treatment at a mobile clinic (MC), MENTOR’s medical officer will conduct the follow-up appointment at your house.

We will also do the following:

* Ask you some basic questions about your/your child’s leishmaniasis and how it is affecting you
* Measure and photograph the lesions and
* Take a skin scrape sample from the lesion to make a diagnosis using a microscope
* Take swab samples so we can analyse in more detail the parasite that is causing you/your child’s disease. This analysis will take place in a suitable laboratory outside of Syria.

**Duration**

The research will take place over 3-5 months.

Patients who are assigned to receive injections will attend appointments for treatment twice a week for 3-4 weeks. They will also have a follow up appointment 3 months after their last treatment. The duration of the study for these participants will be about 5 months.

Patients who are assigned to receive thermotherapy treatment will have only 1 treatment session done today. They will also have a follow up appointment 3 months later. The duration of the study for these participants will be 3 months.

**Risks**

We do not think that you will be at any extra risk compared to standard treatment by participating in this study.

**Benefits**

There may not be any additional benefit to you over and above standard treatment by participating in this study. However, there may be a benefit to future patients in the community because the study will give us information about thermotherapy and how good an alternative it might be compared to the injections.

**Confidentiality**

The information and photos that we collect from this research project will be kept confidential.

Your name will not appear on any study document or electronic database except for the list of patients who agree to join the study. Only the researchers will know what your number is and all study documents will be locked away safely with a lock and key. It will not be shared with or given to anyone except MENTOR’s research team and our colleagues at Oxford University.

**Data protection**

The MENTOR Initiative is responsible for ensuring the safe and proper use of any personal information you provide, solely for research purposes.

**Sharing the Results**

We may publish the results of this study, including some photographs of skin lesions, in order that other interested people may learn from our research; however, confidential information will not be shared about any of the participants at any point. No one will be able to identify you from these research publications.

**Right to Refuse or Withdraw**

You/your child do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your/your child’s treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You/your child may stop

participating in the research at any time that you wish without losing any of your rights as a patient here. Your/your child’s treatment at this clinic will not be affected in any way.

**Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

[MENTOR’s research medical officer – Dr xxxx, telephone number/e-mail])

This proposal has been reviewed and approved by the Idleb Health Directorate, who are responsible for the provision of health services in Idleb governorate. It has also been reviewed by the Oxford Tropical Research Ethics Committee.

**Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**If illiterate**

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**If age of consent has not been reached**

**I, the guardian, have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. The information has also been read to the person I am the guardian to. This person has also had the opportunity to ask questions and agrees to consent voluntarily to participate as a participant in this research.**

**Print Name of Guardian\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant / the guardian and the person he/she represents, and to the best of my ability made sure that the participant understands that the following will be done:**

**1. If they choose to participate, they will be randomly assigned to either treatment group**

**2. They will be required to attend a follow-up appointment 3 months after their last treatment**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher****/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**