INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Laser Acupuncture Therapy for the Treatment of Addiction: A Pre-Clinical Trial Study

Participant: _____ **Date:** _____

Subject ID Number: _____

NATURE AND PURPOSE OF STUDY:

I have been asked to voluntarily participate in a research study involving a low level medical laser, Theralase TLC 1000 provided by Theralase Inc. The approximate number of participants involved in the study will be 5000 adults, male and female, 16 years of age or older (must provide signed parental consent for those less than 18 years of age).

The purpose of the study is to evaluate the safety and effectiveness of a low level laser instrument in the therapeutic treatment of addiction; specifically tobacco or food in origin. Low Level Laser Therapy (LLLT) is a noninvasive, non-surgical procedure allowing light to penetrate deeply beneath the skin. Supporters of this method believe stimulation of acupuncture points reduces the addiction to tobacco products or food consumption. Many studies have examined the safety of LLLT and no adverse effects have been observed. The effectiveness of the technology is under clinical evaluation.

I understand that my participation in this study is voluntary and that my refusal to participate or withdraw from participation at any time will in no way result in penalty or loss of care to which I am otherwise entitled. The Principal Investigator may, at his/her discretion, dismiss me from the study at any time.

Theralase Inc., in fulfilling its public responsibility, accepts professional liability and responsibility for physical injury as the result of laser equipment malfunction. It is not the policy of the Company or any governmental funding agency to compensate subjects for injury.

PROCEDURES TO BE FOLLOWED DURING THE STUDY:

I will be asked to expose the area of my body for the treatment with the low energy laser probe. The principal investigator or assistant may use a small amount of alcohol over the treatment area to remove skin lotions or other substances that could interfere with the transmission of light. The typical session consists of applying the low level laser probe(s) over acupuncture treatment points located on the ears and body.

FORSEEABLE RISKS:

The laser light should not be viewed directly or stared into for an extended period of time, as with any bright light. Discomfort may occur as well as possible eye damage. I will be required to wear protective eyewear during any treatment. No other known side effects to LLLT have been observed in previous clinical studies; however, an occasional temporary redness or tingling may accompany the treatment at the site of the treatment. Generally, this effect disappears soon after treatment without any medical intervention. I am mindful that a possibility also exists that unknown adverse effects may occur with the LLLT, which is true with any medical procedure or investigational device. There may be other risks not yet identified, however, at this time there are no foreseeable risks known with the use of LLLT.

POTENTIAL BENEFITS OF THE STUDY:

The possible benefits to me from participating in this study may be: the possibility of receiving a reduction in addiction to tobacco products or food consumption resulting in a reduction in smoking or weight loss, respectively, or the satisfaction of contributing to a research study. However, I may not receive any benefit from the LLLT investigational device.

ALTERNATIVE METHODS:

Alternative methods of treatment are available to treat my condition, if I choose not to participate in this research project. These treatments include, but are not limited to in the case of smoking: over-the-counter and prescription medicine, smoking cessation drugs, nicotine replacement therapies (patches, gum) and in the case of food: over-the-counter and prescription medicine, weight loss diets, weight loss meals, exercize programs or surgery. The principal investigator has explained these alternative methods to me.

COMPENSATION FOR RESEARCH RELATED INJURY:

I understand that if I am physically injured because of procedure properly performed on me under the plan for this study, I will be reimbursed for the reasonable medical expenses for the treatment of that injury that are not covered by my own insurance or health care program. No other compensation is available from the treating physician or clinic for any injury that may occur.

WHOM TO CONTACT:

For answers to questions relating to this research study, to report a research related injury, or for information regarding study procedures I may contact the project director:

Roger White
Theralase Inc.
1-866-843-5273

T.A.B.S. Research Review Committee, an independent review board, has reviewed this consent form and study protocol. Questions regarding my rights as a participant may be addressed to:

M. Joyce Heinrich, Chairperson
T.A.B.S Research Review Committee
1-713-734-4433

CONSENT:

My identity in this study will be coded for confidentiality. All personal information learned about me during this research will be kept strictly confidential and my records will be protected. The Institutional Review Board, the Food and Drug Administration (FDA) and a representative of the study sponsor, Theralase Inc., may inspect all records pertaining to the data from this study, including those identifying me as a voluntary participant. If so, this inspection will take place under conditions that protect the privacy of the individual to the fullest extent possible within the laws related to public disclosure of information and the law enforcement responsibilities. The results obtained from this research may be published in a medical or scientific journal or used in a Pre Market Notification to the FDA without disclosure of my identity.

The research procedure and treatment procedures associated with it have been fully explained to me. I understand that I am free to decide whether or not to participate, and free to withdraw from the study at any time, by simply notifying the investigator without jeopardizing my future health care. I further understand that the investigator may, if necessary, terminate my participation in the study without my consent. I understand that I will be charged a fee for the treatments. I also understand that I will not be compensated for my participation in this research study.

I have read this Consent Form. I agree that all my questions have been answered. All oral and written information and discussion about the study are in English, a language in which I am fluent.

Participant Signature	Date	Signature of Witness	Date
Print Name		Print Name	
Guardian Signature	Date	Signature of Witness	Date
Print Name		Print Name	

INVESTIGATOR'S STATEMENT

I, the undersigned, certify that to the best of my knowledge, the participant signing this consent form has had the study fully and carefully explained and clearly understands the nature, risks and benefits of his/her participating in this research project. I have provided the patient/participant a copy of this signed consent document.

Signature of Investigator / Assistant	Date
Principal Investigator / Assistant Name (Print)	

Patient Subjective Review - Tobacco

Name: _____ **Date of Birth: (mm/dd/yyyy)** _____

Address: _____

City: _____ **State:** _____ **Zipcode:** _____

Male: _____ **Female:** _____

1) Are you sixteen (16) years of age or older and fluent and literate in the English language at the fifth grade level? ____ Yes ____ No

2) Are you able to provide signed parental consent if you are less than 18 years of age? ____ Yes ____ No

3) Have you had a NSAID or steroidal pain injection in the last 5 days? ____ Yes ____ No

4) Are you able to attend all scheduled treatment sessions and be available for follow up by internet or telephone for up to 60 days after your last treatment? ____ Yes ____ No

5) Do you smoke or consume tobacco products? ____ Yes ____ No

6) Is your Body Mass Index for your age in excess of 25 as determined by the American Medical Association recommended guidelines? ____ Yes ____ No

7) Are you able to sign an informed consent? ____ Yes ____ No

8) Have you had surgery in the last 4 months or more and still have unhealed tissue? ____ Yes ____ No

9) Do you have any thyroid disorders? ____ Yes ____ No

10) Do you take experimental drugs or opioids? ____ Yes ____ No

11) Do you have or have you had any diagnosed cancers? (Malignant, active or benign tumors (metastatic or primary)) ____ Yes ____ No

12) Are you currently receiving treatment for any diagnosed cancers? ____ Yes ____ No

13) Do you have any severe co-existing disease? (i.e., Some condition that threatens your 6-month survival) ____ Yes ____ No

14) Are you currently or have you been involved in healthcare related litigation? ____ Yes ____ No

15) Do you have epilepsy and if so would you be willing to wear additional eye protection precautions? ____ Yes ____ No

16) Are you currently being treatment with photo-dynamic therapy or immunosuppressant drugs? ____ Yes ____ No

17) Are you pregnant or are you suspected of being pregnant? ____ Yes ____ No

18) Do you have a history of severe psychological or psychiatric illness? ____ Yes ____ No

19) Are you light sensitive? ____ Yes ____ No

20) Have you participated in a similar study protocol in the last 5 years? ____ Yes ____ No

21) When did you last see a doctor? (mm/dd/yyyy) _____

22) What was the reason? _____

23) When was your last medical checkup? (mm/dd/yyyy) _____

24) Are you currently under medical care? _____ Yes _____ No By whom _____

25) For what conditions are you currently under medical care?

Describe: _____

_____

25) To determine your eligibility to participate in the IRB FDA study using Low Level Laser Therapy (LLLT), it is important to know if you currently suffer from any of the following medical conditions or are receiving certain treatments (Check yes or no)

	Yes	No		Yes	No
High Blood Pressure	_____	_____	Prone to Fainting	_____	_____
Chest Pain or Heart Condition	_____	_____	Diabetes, Gout	_____	_____
Rheumatic Scarlet Fever	_____	_____	Bowels, Liver, Gall Bladder	_____	_____
Indigestion, gastric	_____	_____	Arthritis	_____	_____
Glandular Fever or Hepatitis	_____	_____	Chemotherapy	_____	_____
Asthma or Tuberculosis	_____	_____	Radiation Treatment	_____	
Kidney or Bladder Disease including chronic pylitis or cystitis	_____	_____	Do you take pain killers, sedatives, sleeping pills	_____	

26) Do you take prescription medicine? _____ Yes _____ No

Describe: _____

_____

27) Do you take non-prescription medicine? (check all that apply)

_____ other medication _____ supplements _____ herbal formulas _____ vitamins

Describe: _____

_____

28) Do you have any other medical condition that has been diagnosed by a medical doctor?

Describe: _____

_____

29) Do you suffer from skin conditions? (check all that apply)

_____ Sensitive skin _____ Psoriasis _____ Cold Sores _____ Allergies _____ Eczema

30) Are you currently receiving laser therapy for any other condition? _____Yes _____ No

Describe: _____

_____

31) Are you using any medicinal lotions?: _____ Yes _____ No Describe _____

If you have any doubts that LLLT is appropriate for you, consult your physician before starting treatment.

Signature _____ **Date** _____

Staff Notes

_____

_____

_____

_____

Principal Investigator / Assistant Signature _____ **Date** _____

Subject ID#: _____ **Height:** _____ **Weight:** _____

Blood Pressure: _____ _____ **Heart rate:** _____

Patient Data Sheet

Name: _____ **Subject ID#: S-**_____

Date of Birth (mm/dd/yyyy): _____ _____ **Male** _____ **Female**

1) Is this your first time in this treatment program, if yes what were you treated for? _____ Yes _____ No

_____

2) How much do you weigh in pounds? (Skip question if smoker) _____ pounds

3) What is the size of your waist in inches? (Skip question if smoker) _____ inches

4) What is your height in inches? (Skip question if smoker) _____ inches

5) What is the size of your hips in inches? (Skip question if smoker) _____ inches

6) Which number best describes the number of cigarettes you currently consume on a daily basis? (circle correct number): (Skip question, if non smoker)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42		
43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62		
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82		
83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100				

7) On a rating from the most pleasurable taste imaginable to the most undesirable taste imaginable, please rate how your cigarette(s) or food currently taste? (Please mark your choice with a single vertical line on the scale below)

_____

Most Pleasurable Taste Imaginable

Most Unpleasurable Taste Imaginable

I agree that the information I have supplied is true to the best of my knowledge.

Signature _____ **Date** _____

Staff Notes

_____

_____

_____

Principal Investigator / Assistant Signature _____ **Date** _____

Laser Treatment Data – Tobacco

Name: _____ **Subject ID#:** _____

Principal Investigator: _____ **Site Location:** _____

Treatment Number:										
Date:										
Laser Power		**mW**		**mW**		**mW**		**mW**		**mW**
Ear / Side	**Left (sec)**	**Right (sec)**	**Left (sec)**	**Right (sec)**	**Left (sec)**	**Right (sec)**	**Left (sec)**	**Right (sec)**	**Left (sec)**	**Right (sec)**
Laser Points (enter time)										
Shen Men										
Lung 1										
Lung 2										
Mouth										
Liver										
Kidney										
Sympathetic Autonomic										
Nicotine										
Point Zero										
Master Sensory										
Allergy										
Master Omega										
Brain C										
Anti-depressant										
Aggression										
HE7										
LU7										
ST36										
LIV3										
LI4										
Total Points Treated										
Total Treatment Time										