Treatment Consent Form

A. Background & Purpose

The ToeFX Therapy Light is an antifungal therapy device designed for patients with onychomycosis (nail fungus). The complete course of treatment ranges from 10-12 treatments with an initial screening session.

Procedures

Prior to beginning treatment, the clinician will take a photograph of your toenail and take a nail sample via clipping. The clinician will also be taking pictures of your toenails at the start of each treatment visit to maintain records of your progress.

During your treatments, you will be using the ToeFX Light Therapy Device which consists of an LED-based light source and a blue serum. During the treatments, a clinician will file the surface of all nails on the infected foot, paint the formulation onto the nails, and allow it to penetrate for about 5 minutes. The clinician will then place the affected foot under a light source for another 12 minutes. This will be repeated for each infected foot.

The clinician may take a nail sample via clipping to evaluate the severity of the infection and make any adjustments to your treatments at their discretion.

B. Risks

There are no known risks associated with the use of the ToeFX Light Therapy system. This is a non-invasive procedure.

C. Benefits

The ToeFX Light Therapy system has been shown to be highly effective in a controlled environment. However, we cannot guarantee results from this treatment.

D. Duration

After your initial screening visit, patients often have a total of 10-12 treatments at 2-week intervals. Each visit will take approximately 30 minutes.

E. Termination

Your participation in this treatment is voluntary. You may refuse treatment at any time.

F. Pregnancy

The effects of the treatment on fetuses and infants are unknown, and women who think they might be pregnant, are planning to become pregnant, or are nursing a child are excluded from participating.

G. Statement of Consent

The purpose of this treatment, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have been given enough time to read this consent form and to consider whether to participate.

I understand that by signing this consent form, I have not waived any of my legal rights.

_____

Patients' Full Name (Please Print)

_____ _____

Patient Signature Date Signed (DD/MM/YYYY)

STAFF ONLY

I confirm that I have explained the purpose of this treatment, the treatment procedures, the possible risks and discomforts, as well as the potential benefits and have answered any questions regarding the study.

_____

Full Name of Individual Obtaining Consent (Please Print)

_____ _____

Signature of Individual Obtaining Consent Date Signed (DD/MM/YYYY)