TippingPoint4Cancer BV
Licensed Clinic

INFORMED CONSENT FOR LIGHT THERAPY

Summary

The purpose of this document is to confirm that the patient has understood and consented to the light therapy. The therapy is delivered in discrete cycles that consist of the application of a sensitiser and the subsequent application of light. Patients can ask questions and subsequently are given time to consider. Patients discuss the experimental nature of our light therapy and understand that previously unknown side effects may occur. Patients need to be aware that the monitoring of their progress is important. We are a learning organisation and take care that side effects do not recur in future patients.

The treatment takes several months and may be entirely at the patients' home or in combination with a clinic. We only provide the core treatment and not the ancillary support. Patients rely on their GP and their medical specialists for additional medication, emergency care, laboratory testing and imaging.

Only when the patient has taken all the time needed will he sign this document.

Contents

Introduction

Signing this informed consent is a step towards treatment. It confirms consent to all steps as seen in the Treatment Process Overview table below. There are three steps prior to treatment: (1) determining the patient's eligibility for the light therapy, (2) the acceptance of the anonymous use of their dossier and (3) the signing of this informed consent form. Each cycle of treatment consists of two further steps (4 and 5). The informed consent is for all cycles.

Treatment Process Overview		
Step Name	**Objective**	**Description**
1. Eligibly	Inclusion/Exclusion	Reviewing documentation defining the cancer
2. Dossier	Establishing a Dossier	Understanding the purpose of the dossier
3. Agreement	Informed Consent	Careful consideration before signing
4. Planning	Logistics	Meeting individual requirements
5. Delivery	Cycles of Therapy	Patients understand their role

Eligibility

Patients confirm their cancer diagnosis with a letter from a medical specialist and/or a copy of their scan. We consider patients eligible when standard treatments have a low chance of cure. Patients may consider themselves eligible when they accept their role in the experimental nature of the treatment. The patient is expected to provide feedback. Especially, so that together we can identify serious side effects and suppress them. Patients remain reliant on their GP and their medical specialists for additional medication, laboratory testing and imaging. Although unexpected, a medical emergency could occur. In such a case a patient will rely on nearby hospitals. Patients need to understand that this may involve additional costs. For example, if a patient needs special transportation to return home.

Dossier

The patient agrees to the anonymous use of the dossier for science, negotiations with healthcare insurance companies and legalities with the authorities. Occasionally the authorities may require information of a named patient.

Agreement

By signing this consent document, the patient agrees to be treated. The informed consent is a legally binding agreement between the patient and the provider of medicine. It confirms that questions raised by the patient have been discussed and that he is informed.

Planning

Planning is required because the treatment takes several months and may be entirely at the patients' home or in combination with a clinic. We offer cycles of light therapy. Our package does not include management of other medical specialists, additional medication, laboratory testing and imaging. The patient needs to discuss his requirements very carefully to ensure they match his situation.

Delivery

In the any cycle the delivery starts with the application of a sensitiser. Non-uptake of the sensitiser by cancer has been reported in Russian literature in less than 10% of patients. The known side effects of each of our sensitisers are listed in the relevant product leaflets. One of the sensitisers is used to prevent recurrence requires chelation after treatment Patients confirm that they have read these leaflets and realise that sunlight can cause serious side effects.

The day after the application of the sensitiser the light is given. As soon as light is given its effects set in and continue for months. Further cycles of light have cumulative effects. The product leaflets for the

sensitisers explain the known side effects caused by the interaction with light. Patients should be aware that too much light may cause reaction of the skin, known as dermatitis or eczema. Sometimes a reaction is observed of other parts of the body where the light has passed through. Serious side effects must be controlled with regulated drugs such as prednisone that suppress the immune reaction.

The proxy measure of the effect is cancer fever. Cancer fever will appear in minutes and might become painful. Flue like symptoms may appear. Patients require strong painkillers such as short and long acting morphine derivatives, e.g. generic Oxycodone 5 mg direct release to be used after the light has been applied and generic Oxycontin 10 mg extended release twice daily. Nausea may occur when cancer is present in the abdominal cavity. This should be treated with strong anti-emetic drugs such as ondansetron 8 mg twice daily. When nausea persists a feeding tube or a parenteral line may be indicated.

The immune reaction of the body against the cancer may become too strong when too much light has been given. Too much light causes too much oedema of the cancer. When this is in an area of the body, where it may become dangerous, such as the brain, the lung, or the liver high doses of prednisolone are urgently required. Ideally the patient is treated in a specialist clinic. A specialist may also be required when extensive lung metastasis causes asthma or pneumonia. With liver metastasis obstructive liver disease may also require specialist care. When liver obstruction persists, the patient may require a stent to create a bypass. Jaundice especially requires immediate decompression.

Confidentiality

This consent and details of the treatment are confidential. The patient may always report to the authorities anything that he/she believes should be reported.

Complaint Handling

TippingPoint4Cancer has an independent complaints procedure, a trusted representative. Contact information can be found on the TippingPoint4Cancer website.

Authorisation Patient

I have read the information on the light therapy. I could ask additional questions. My questions have been answered sufficiently. I took the time to decide. I consent to this experimental treatment for myself. I know that it is not a regular, standard treatment. I can decide to stop at any time without a requirement to provide reasons, although I understand that this may be dangerous due to the long lasting cumulative effects of the therapy.

I give permission to use my anonymous data and share that information with its partners and the authorities when requested.

I understand that I will get a copy of the signed consent form. I took plenty of time to decide and confirm that I sign voluntarily sign to agree to the treatment.

	Patient	**Provider of Medicine**
Date:	.....	.....
Place:	.....	.....
Name in Full:	.....	.....
Signature:	.....	.....