

**HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE  
DE SÃO PAULO – HCFMUSP  
INFORMED CONSENT FORM**

**RESEARCH INFORMATION**

Study title – “Impact of partial body stereotactic radiotherapy on hypoxic segments of large-volume and unresectable tumors (SBRT-LATTICE-PATHY) – a prospective phase II study”

Principal investigator – Prof. Dr. Heloísa de Andrade Carvalho

Department/Institute – Radiology and Oncology / Institute of Radiology – Radiotherapy Service

According to Resolution 466/2012, the following content must be part of the explanations about the research.

**Invitation to participate:**

You are being invited to participate in this research because you have been diagnosed with cancer and currently have a large tumor for which surgery or another type of treatment, such as chemotherapy, is not possible at this time. For this reason, you were referred for evaluation for radiotherapy.

This document is called the **Informed Consent Form** and has this name because you should decide whether to participate in this research only after carefully reading and understanding this entire document. Please ask the researcher responsible for this study any questions you may have to ensure that you make an informed decision about whether or not to participate. You are under no obligation to agree to participate in this research, and if you decide not to participate, none of your treatment will be affected. If you agree to participate, you may withdraw your decision and leave the study at any time without stating the reason, and this decision will also not affect your future treatment or its continuation. If you agree to participate in this research, you will be asked to sign this Informed Consent Form.

**Rationale and objectives of the study:**

Cancer is a very challenging disease, even with the development of new technologies for diagnosis and treatment.

There are situations in which cancer may be at a more advanced stage, with tumor disease appearing in several regions of the body or when the tumor is very large. In these cases, surgery to remove the tumor may no longer be possible, and chemotherapy may no longer work as we would like. Sometimes the patient

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Researcher’s name: Heloísa de Andrade Carvalho Hospital Das Clínicas Da Faculdade De Medicina Da USP	<div style="display: flex; justify-content: space-between;"> <div> Initials of the Research Participant / Legal Representative </div> <div> Initials of the Principal Investigator </div> </div>

is referred for radiotherapy only for palliative treatment (to try to keep the tumor stable or to improve pain or bleeding). However, there are situations in which, when the tumor is very large, normal (standard) radiotherapy may not be indicated because there is a high chance of affecting the organs around the tumor and harming them.

There are international studies that have evaluated delivering radiotherapy with a high dose of radiation to only a few small areas within the tumor. According to these studies, this treatment may “awaken” the patient’s immune system, allowing the patient’s own defense cells to fight the harmful tumor cells. Patients who underwent this treatment achieved good results, with a reduction in tumor mass size and few side effects.

For this reason, through this study, we are evaluating in this radiotherapy service this new radiotherapy technique, which we already perform at the Institute of Radiology (InRad), for cases of very large tumors. We will assess tumor reduction after treatment and also administer questionnaires to evaluate your quality of life (improvement or worsening of symptoms, for example) before treatment and at scheduled follow-up visits.

#### **Procedures that will be performed and methods that will be used:**

- a) You were referred from ICESP (Cancer Institute of the State of São Paulo) to our radiotherapy service at the Institute of Radiology (InRad) for this outpatient consultation, with the objective of verifying whether you meet the necessary criteria for our treatment;
- b) If you are eligible and agree to participate in our research, you must sign this Informed Consent Form (ICF);
- c) The quality-of-life assessment questionnaire (EORTC QLC-C30) will be administered and the planning computed tomography (CT) scan will be scheduled;
- d) A planning computed tomography (CT) scan will be performed, with and without contrast, according to the study procedures protocol; accessories will be used for your positioning and immobilization to ensure treatment precision, in the same way that we already do for all other treatments;
- e) While you wait at home, all planning for your treatment will be done on the computer;
- f) When the treatment plan is ready, you will be contacted and a staff member from the department will get in touch to schedule your treatment;
- g) Treatment will be performed on the radiotherapy machine, called a linear accelerator, in only 1 (one) day and will last approximately 30 minutes to 1 hour. You must remain positioned in the same way as during the computed tomography (CT) stage, using the same positioning and immobilization accessories. You must cooperate and remain still throughout the treatment time, but if there is any discomfort, we may interrupt the treatment and resume it after the problem is resolved;

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- h) At discharge, a treatment report will be provided and the first outpatient follow-up visit will be scheduled in 15 days. After that, outpatient follow-up visits with control computed tomography scans (of the regions known to be affected by disease at the start of the study) will be scheduled at 1 month, 3 months, 6 months, 9 months, and 12 months after the end of treatment.
- i) At follow-up visits, we will analyze the images and you will be clinically evaluated. The quality-of-life assessment questionnaire (EORTC QLC-C30) will also be administered.

### Explanation of possible discomforts and risks resulting from participation in the research –

The risk of the study for you is low, according to international studies already conducted. However, we can list below some possible effects, according to the probability of occurrence and the treatment location:

1. Common side effects (>10% of cases):
  - nausea/vomiting
  - diarrhea
  - fatigue/tiredness
  - pain
  - mild or moderate urinary burning / increased urinary frequency
  - anxiety
  - skin inflammation / redness due to radiation / burning sensation.
2. Uncommon side effects (1–10% of cases)
  - mild/moderate shortness of breath due to lung inflammation
  - dry or moist skin peeling / skin wound
3. Rare side effects (<1% of cases)
  - severe urinary burning / urinary bleeding / weakened urine stream
  - severe shortness of breath due to lung inflammation
  - decreased kidney function
  - decreased liver function
  - severe nausea/vomiting
  - severe and prolonged diarrhea
  - severe fatigue
  - severe pain
  - prolonged urinary bleeding

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- prolonged bleeding in the stool
4. Side effects not described in the literature, but with a very rare potential to occur (<0.1% of cases)
- perforation, necrosis (tissue death), intestinal fistula
  - rupture of large arterial and/or venous blood vessels
  - necrosis of healthy skin and/or muscle, causing long-lasting open wounds
  - bone necrosis
  - joint alteration/dysfunction (movement restriction, fibrosis, necrosis)
  - pneumothorax (air between the lung and the chest wall) due to airway perforation
  - changes to spinal cord nerves and/or other nerves (causing changes in sensation and/or muscle paralysis)
  - death

Note: please remember that the possible side effects depend on the treatment region; therefore, not all of the effects mentioned above apply to your case.

#### **Expected benefits for the participant:**

The expected benefits, according to international studies, are a reduction in tumor size, or at least a halt in its growth, leading to improved quality of life. In the event of a major reduction in the tumor, surgery to remove the residual tumor may even become possible, depending, of course, on the surgical team's assessment and on specific treatment protocol criteria.

There are situations in which the treatment may not result in any benefit. This may occur due to the specific characteristics of each tumor, which can vary from patient to patient. Some tumors are very resistant to the effects of radiation and, therefore, the tumor mass may not decrease. Even so, negative results help contribute to future adjustments regarding treatment indication, radiation dose, treatment region, and irradiated volume.

At outpatient follow-up visits 15 days and 1, 3, 6, 9, and 12 months after treatment, we will ask about side effects and, if they occur, we will provide the necessary guidance to minimize them.

In the event of mild or moderate symptoms after treatment, the patient or caregiver should contact us by telephone (during business hours, from 8 a.m. to 6 p.m.) or by email, both listed below, to receive the necessary guidance.

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In the event of severe and disabling symptoms, the patient must immediately seek the emergency care service at ICESP (Cancer Institute of the State of São Paulo), known as CAIO (Center for Oncologic Complication Care), which operates 24 hours a day.

**Guarantees of the participant's full freedom to refuse participation or withdraw consent at any stage of the research without any penalty, and guarantees of confidentiality and privacy:**

We guarantee you full freedom to refuse participation or withdraw your consent at any stage of the research without any penalty, as well as confidentiality and privacy.

**Guarantee that the participant will receive a copy of the consent form:**

This informed consent form will be printed in two copies, and the principal investigator and the participant will initial all copies. One copy of this form will remain in your possession.

**Clarification of guarantees for reimbursement of expenses resulting from the research and clarification of the guarantee of compensation for any damages resulting from the research:**

The treatment will be carried out according to the institution's routine (InRad/ICESP). Therefore, there are no additional personal expenses for the participant at any stage of the study, including tests and consultations. There is also no financial compensation related to your participation. If any additional expense arises, it will be covered by the institution, as will compensation for any damages resulting from the research that are different from the effects already expected.

At any stage of the study, you will have access to the professionals responsible for the research to clarify any questions. The principal investigator is Dr. Heloísa de Andrade Carvalho, who can be found at the following address: Rua Ovídio Pires de Campos, 75 – InRad – Gate 3. Telephone: (11) 2661-6722, email: [heloisacarvalho@hc.fm.usp.br](mailto:heloisacarvalho@hc.fm.usp.br). If you have any concerns or questions about research ethics, contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 225 – 6th floor – telephone: (11) 2661-7585, (11) 2661-1548, from 7 a.m. to 4 p.m., Monday through Friday, or by email: [cappesq.adm@hc.fm.usp.br](mailto:cappesq.adm@hc.fm.usp.br)

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I have been sufficiently informed about the study “Impact of partial body stereotactic radiotherapy on hypoxic segments of large-volume and unresectable tumors (SBRT-LATTICE-PATHY) – a prospective phase II study”

I discussed the information above with the Principal Investigator (Dr. Heloísa de Andrade Carvalho) or person(s) delegated by her (Dr. Thiago Brasileiro de Freitas or Dr. Silvio Thiago Pereira Vasconcelos) regarding my decision to participate in this study. The objectives, procedures, potential discomforts and risks, and guarantees were clear to me. I voluntarily agree to participate in this study, I sign this consent form, and I receive a copy initialed by the researcher.

\_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of participant / legal representative

\_\_\_\_\_

Name of participant / legal representative

\_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of the person responsible for the study

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