Informed Consent Mr.

I, Mr. born on the 1973 (Personal ID in Iceland:), and resident in Reykjavik, Iceland, patient from the Department of ENT of the Karolinska Hospital in Huddinge declare voluntarily that:

I have been extensively informed by Prof. Paolo Macchiarini about the possibility of a complete resection of my primary malignant tracheal tumor and its reconstruction with a synthetic polymer-based and completely biocompatible tracheal scaffold reseeded *ex vivo* with autologous mesenchymal stem cells and *in vivo* with upper respiratory cells. I understand that I have currently shortness of breath and was found to have a primary carcinoma (a mucoepidermoid carcinoma) of the trachea, judged inoperable with traditional airway surgery. The tracheal tumor extends across the right tracheobronchial angle over a length of 5 cm, confirmed by CT and PET scans. The PET-CT shows no distant spread.

I have read as well the protocol of the transplant procedure, written in English, and understand that this represents the only chance of survival I have. A trachea of corresponding length and size will be custom-made at the University College in London by Prof. Seifalian and that Prof. Macchiarini will take the scaffold to Stockholm. I would then undergo a redo median sternotomy (re-opening of the chest) to take of the tracheal tumor using classic surgical airway principles. Before surgery (on June 7th), 200 to 300 mL of bone marrow would be aspirated from my left or right iliac crest and processed by Prof. LeBlanc K so that undifferentiated mesenchymal stem cells would be used for the reseeding process (48-72 hrs) using the bioreactor described in the Protocol.

At the time of transplantation, islands of respiratory cells will be taken from the right and left nose, and used to resurface the internal layer of the graft to promote re-epithelialization. Once the primary tracheal tumor has been resected, the tracheal scaffold will be reseeded with the above mentioned cells (respiratory cells on the internal) within the native tracheal bed of my body. Once the reseeding has been made, the tracheal graft will be anastomosed proximally and distally to recreate a trachea and tracheobronchial bifurcation, and wrapped with the *omentus major* (vascularised fat from the big stomach curve) to provide vascularisation and protect against radiation therapy (usual manoeuvres in lung transplantation). To boost the regeneration process, a perioperative treatment with local injection of transforming growth factor-B1 (50µg) (transforms mesenchymal stem cells into chondrocytes), granulocyte-coloning stimulating factor (10 mg/kg) (recruits progenitor endothelial cells) and erythropoietin (10.000UI) (reduces apoptosis) will be given for 2 weeks only. These drugs will be given at "regenerative" doses and have no side-effects. I have also been informed that tissue engineered graft will not require any immunosuppression at any time, and especially its side-effects.

Anaesthesia will be general and through selective orotracheal tube, using arterial monitoring lines, urinary bladder catheter, epidural analgesia and cardiopulmonary by-pass stand-by. Complications from this transplant could be postoperative bleeding, left recurrent nerve palsy, respiratory infections, anastomotic complications, wound infections, respiratory insufficiency and requirement of mechanical ventilation.

I have been informed clearly about every single details, and my questions and doubts have been clarified without any restrictions. It is therefore that I liberally take the decision to authorize the above mentioned procedure with the understanding that I could retract this consent at any time. As proof of willingness, I sign this document.

Huddinge, 26 the June 2011

Doctor Signature

Prof. .....

Signature of the patient

Mr .....