# Non Interventional Prospective Study ”CALM”: Collaboration to collect Autologous transplant outcomes in Lymphoma and Myeloma

## 1.1.1 INFORMATION FOR THE PATIENT

### *Introduction*

This non-interventional prospective study is conducted by the European Blood and Marrow Stem Cell Transplantation Group (EBMT).

The study will collect details about the treatment you receive for lymphoma or myeloma. In particular the effects of mobilising the cells with plerixafor or another method before transplantation will be studied. Your participation in this non-interventional prospective study does not influence the choice of the treatment you will receive; you will get exactly the same treatment as you would have otherwise received. The only difference is that your doctor provides some additional data to the EBMT.

When mobilising stem cells there is a slight possibility of mobilising tumour cells as well. To minimize this risk, your doctor will take measures to optimize the method of mobilising stem cells. The information obtained from your treatment and many others will be used to achieve more standardized methods for stem cell mobilisation.

***Personal Data Privacy Protection***

Your data collected during the treatment of your disease will be filed non-identifiably. Only authorized and qualified collaborators of the government bodies and of the hospital have been allowed access to the data of this study.

A unique code number will protect all medical data collected during the study; we never use the full name of the patient. No personal data will be used in any study documentation, in reports or publications.

### 1.1.2 PATIENT CONSENT

| **Patient's Initials and Date of Birth (or patient's label)** | **Study number** (provided by data office) |
|---|---|
| Initials: .....……..(first name(s)-surname(s))<br>Date of birth: ..... ..... - ..... ..... - ..... ..... ..... .....<br>*dd mm yyyy* | |

I ……(Patient, Parent, Guardian) have been informed to my satisfaction regarding data collection for the “CALM” Non-Interventional Prospective Study and I consent to non-identifiable data about my transplant and follow up being reported to the EBMT.

Signed ……..

Date ……

(Witness ……)

Patient Information and Informed Consent

I confirm that I have explained the aim of monitoring the outcome of lymphoma and myeloma patients transplanted with plerixafor-mobilised cells and comparing these to equivalent patients transplanted without the use of plerixafor; and the process regarding the collection and storage of data to this patient, who appears to have fully understood them.

Signed ……

Date ……..