



**Registro nazionale Italiano Donatori Midollo Osseo**  
Italian Bone Marrow Donor Registry



Content of Form CD 101 - Donor Consent Form

at recruitment *(V14 feb. 2017)*

This document is not intended in substitution of form CD 101 (Donor's consent at recruitment) but as a possible support. **It is reminded that under Italian current legislation the potential blood stem cell donor must be able to understand (including forms) and communicate in Italian.**

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I hereby (last name and first name): .....

Gender: M F

Birth place: .....Country: ..... date of born: (dd/mm/yy)

Social security number

Address: : .....City:.....Country.....

Zip code:.....home phone number:.....

Work phone number:.....

Mobile phone number:.....E-mail:.....

I hereby declare that I have read the information regarding the scientific basis and the aims of haematopoietic stem cell (HSC) transplantation. I have also read about the methods for withdrawing marrow or peripheral blood, about the main exclusion criteria for enrolment- Attachment A, C and H- and about donors' rights and obligations, as stated in Law 52/2001 and Decree 196/03. Furthermore, I declare that I have spoken to the Donor Center (DC) health care personnel and that I understand the information I have been given.

I have read the enclosed statements and I know that a biological sample ( blood/ saliva/ buccal swab) will be collected in order to determine the allelic tissue typing (HLA typing). I understand that the examination results are not usually given to the donor, although the specific rights stated in article 7 Decree 196/03 are applicable. I know, moreover, that my personal data are stored in the computer database of the Italian national bone marrow donor registry (IBMDR) and will only be used for the above-mentioned data processing purposes.

I know that I may be contacted in the future in order to carry out further tests, so as to ascertain more closely my compatibility with candidates (Italian or not) for an HSC transplant. I may also be contacted for other non-commercial research projects related to either HSCT or IBMDR purposes or for extended HLA genetic investigation. I am aware that I am free to withdraw consent, which I am providing herein, at any time, and that however, my enrolment in the Registry will cease to be effective when I am 55 years of age.

I have completed and returned the pre enrolment health questionnaire and consequently, by placing my signature below, I declare that I would like to become a possible HSC donor from:

Bone Marrow

PBSC

**I am aware that donation is anonymous, voluntary and unpaid:**

**In faith:** ..... **Date and place:** .....

Personal data of the health care professional who provided the donor with information and who accepted his/her consent form:

**Name and surname:** ..... **Position:** .....

**Signature:** ..... **Date and place:** .....

*INFORMATION AS PER LAW 675, 31<sup>st</sup> DECEMBER 1996, AND  
DECREE 196, 30<sup>th</sup> JUNE 2003*

**PREMISE**

Laws 675/96 and 196/03 state that registration and processing of any type of personal data in databases, be they electronic or on paper, must be carried out while fully respecting the individual's fundamental rights and freedom, as well as their dignity. This especially refers to personal identity, to secrecy, and to the right to protection of one's personal data.

Furthermore, the data may only be processed after providing the person whose data are being collected with the appropriate information.

We hereby inform you that, on the basis of Decree 196/03, article 94, Comma 1 § d), the data you have provided and in particular, any sensitive information, including anything that may be revealed by our genetic investigation, will be treated on the basis of the above mentioned law, on the other currently existing Laws and on the obligation to secrecy that our policy is based on.

On the basis of article 4, Comma 1,a) of Decree 196/03, any operation or group of operations related to the registration, communication, cancellation or destruction of data, including anything that is not registered in a database, may be considered personal data processing.

According to article 4, Comma 1,d) of Decree 196/03, sensitive data may be defined as any information that might reveal race or ethnic origin, religious, philosophical or any other beliefs, political opinions, affiliation with political parties, unions, religious, philosophical or union associations or organisations, as well as any personal data that might reveal health status or sexual lifestyle.

**RESPONSIBILITY FOR DATA PROCESSING**

The HOLDER is the local National Health Service branch:

\_\_\_\_\_, located in: \_\_\_\_\_ Street address \_\_\_\_\_

The ORGANISATION ( if designated ) that is responsible for data processing is included in a list which contains names of all people who, or organisations that, are responsible for data processing. The list is routinely up-dated, and is available at the designated office to whoever is interested.

**PURPOSE OF DATA PROCESSING:**

The information that is provided may only be used for enrolment into the Italian National Bone Marrow Registry, which the E.O. Ospedali Galliera established in 1989, and has since managed. The purpose of the registry is to find volunteer donors who are compatible with haematological patients requiring an HSCT.

The Guarantor authorizes the release of personal data, (authorisation 258, 24/06/2011– G.U. 159, 11/07/2011) including any that may reveal health status, as well as the acquisition of other sensitive data. However, the need to know about and to manage genetic data, even though limited to the tissue typing required to reach the aims of data collection, make it mandatory to obtain the subject's consent.

Total or partial refusal to provide personal data, the request to stop or cancel information, or any attempt to limit consent render it impossible to establish or to continue the relationship between the IBMDR and the subject concerned.

**DISCLOSING PERSONAL DATA:**

Only those who have been authorized by the HOLDER or by the ORGANISATION that is responsible for data processing, have full access to information regarding potential donors (personal, genetic and health data). Thus, disclosure of personal data, which must be strictly related to the obligations, duties and purposes of data management, must be limited to:

- IBMDR;
- public bodies ( transplant centres and IBMDR ) identified by the qualified health authorities;
- other international registries identified by IBMDR;

Personal data are replaced by an identification code and health data are summarized in a report of eligibility or ineligibility to donate HSC.

## DATA PROCESSING

With regards to the above-mentioned purposes, personal data are processed by manual and/or computer procedures and are strictly related to the specific purposes of the collection, so as to guarantee the security and the privacy of the data.

## RIGHTS OF THE CONCERNED PARTY

List processing :

- Art. 7. the right to access one's own personal data and other rights (full text below);
- Art. 8. exercising one's rights;
- Art. 9. ways of exercising one's rights;
- Art. 10. acknowledgement of the concerned party.

From the Decree 30<sup>th</sup> June 2003, n.196 Published in the Gazzetta Ufficiale dated 29th July 2003, n. Ordinary supplement n. 123/L.