SUMMARY

1. INTRODUCTION

The Brazilian Registry of Voluntary Bone Marrow Donors (REDOME) started its activities in 1993 and, since 2000, has been part of the National Transplant Policy of the General Coordination of the National Transplant System (CGSNT) of the Ministry of Health (Law 9434/1997 and Law 211/2001), having as guidelines the gratuity of the donation, beneficence in relation to the recipients, and non-maleficence in relation to the living donors and is under the technical coordination and management of the National Cancer Institute (INCA).

REDOME's operational activities are performed by a team of collaborators located at the Instituto Nacional do Câncer (INCA) in Rio de Janeiro and among the actions related to this activity, focused on the assistance to voluntary donors and patients, the processes under INCA's direct management can be summarized as follows:

- Maintenance of a unified registry containing information on voluntary donors and candidate patients for unrelated hematopoietic stem cell transplantation;
- Selection and identification of compatible donors for Brazilian patients with indication for unrelated hematopoietic stem cell transplantation, which includes requesting laboratory and clinical procedures from international registries;
- Logistics of biological samples and voluntary donors for the collection of cellular products for transplantation.

REDOME's financial resources are the responsibility of the Ministry of Health and the Registry carries out its activities through public funding and resources from its own activity, considering good governance a fundamental aspect in the conduction of these actions and for good management.

This Donor Protection Policy establishes the principles of autonomy, equity, the right to privacy, information transparency of information, division of responsibility, and the technical, ethical, and humanization aspects in the processes involving voluntary donors.

2. PURPOSE AND SCOPE

This document aims to establish the principles, responsibilities and procedures related to the protection of REDOME's voluntary donors in the stages of registration, compatibility assessment and collection of hematopoietic progenitor cells (HPC) for unrelated transplantation purposes, and is aimed at all REDOME's collaborators, public servants of INCA and the Ministry of Health, donors and patients assisted by REDOME, health professionals and society in general.

3. PRINCIPLES

3.1. Autonomy

REDOME reiterates that the donation of Hematopoietic Progenitor Cells (HPC) is a voluntary act and that the donor, throughout the entire process involving registration, compatibility evaluation and donation of HPC for transplantation, will have their autonomy preserved, being allowed to request cancellation, interruption or exclusion from the registry at any of these stages.

REDOME also ensures the donor the right to obtain information about these processes and participate in decisions that involve their health, such as the source of collection of HPC for unrelated transplantation.

3.2. Equity

The REDOME team works to ensure that all voluntary donors have the same care throughout the registration process, compatibility assessment and donation of HPC for compatibility assessment, and donation of HPC for transplantation, without promoting any kind of discrimination or favoritism.

A nationwide information system (REDOMEWEB) ensures access to the registry for donors from all over the country, through the public blood centers, according to criteria established in the current legislation.

3.3. Privacy

The donors´ data privacy is a priority at REDOME which ensures it keeping these data bank on a specific and safe infrastructure environment, determined by INCA.

The process of registration, compatibility assessment, and collection of HPC for unrelated transplantation occurs anonymously and the donor, once registered, will not have his/her personal information disclosed without prior consultation, according to the institutional policy that regulates this activity.

Thus, REDOME ensures the privacy of donors and the sharing of personal information occurs in the context of registration processes, compatibility evaluation and collection of HPC for transplantation, for which it is intended, anonymously (using REDOME's identification code).

REDOME does not share or sell personal information of registered donors, and all staff with access to personal data of donors are trained and guided to maintain confidentiality and protection of these data, according to its Privacy Policy.

3.4. Transparency

REDOME guarantees registered voluntary donors access to information on the registration process, compatibility assessment and collection of HPC for unrelated transplantation, through statistical data and technical information available on its website (redome.inca.gov.br).

Information can also be obtained through telephone contact, email or electronic service (chatbot).

All information related to donor registration processes and donation of CPH for unrelated transplantation, including the related personal data, are recorded in REDOME's computerized systems or in INCA's secure digital storage environment, in order to ensure their traceability.

3.5. Division of Responsibilities

The blood center is responsible for receiving candidates for registration in REDOME, the inclusion of registration data and sending of donors' personal information, in addition to collecting and sending blood samples to the histocompatibility laboratory.

The histocompatibility laboratory is responsible for performing the HLA typing and sending the results to REDOME, to conclude the registration or, as demanded by REDOME, in the subsequent stages of compatibility evaluation.

The sending of personal data, including HLA typing, occurs through a computerized system (REDOMEWEB).

The collection centers (transplant centers and specialized hemotherapy services) are responsible for performing the clinical and laboratory evaluation of selected donors and the collection procedure of HPC for unrelated transplantation.

After registration, REDOME offers support to voluntary donors through several communication channels, and during the compatibility evaluation process and selection of donors for transplantation, it is responsible for contacting these donors, and may request support from blood centers.

3.6. Humanization

REDOME considers that the assistance and care of the donor must occur integrally, prioritizing technical quality, safety, and the relationship between the donor and the teams involved. For this reason, every donor is seen as a unique and complex human being, and respect and compassion are part of the entire donation process.

Every REDOME approach seeks to establish a link between transparency and trust, guaranteeing the donor an environment where he can be heard for the clarification of doubts, in order to make the donation of CPH a positive experience.

4. PROTECTION OF THE VOLUNTARY DONOR IN THE REGISTRATION, COMPATIBILITY EVALUATION AND COLLECTION OF HEMATOPOIETIC PROGENITOR CELLS

4.1. Registration of Voluntary Donors in REDOME

REDOME defines criteria and guides blood centers throughout the country in relation to the registration of voluntary donors. This activity consists in sending the donor's personal information to REDOME and in the collection of a blood sample (a 5 ml tube) to perform the HLA typing for the registration.

The eligibility criteria for the registration are determined by the current legislation and can be summarized as follows:

- Age from18 to 35 years;
- Good health condition;
- No previous history of blood transmissible infections - HIV, HBV (Hepatitis B), HCV (Hepatitis C), HTLV;
- No previous history of oncological disease and hematologic.

Other conditions must be evaluated by the blood center, according to the current legislation and the guidelines provided in the Manual for Blood Centers made available by REDOME. Information is also available on the REDOME site (redome.inca.gov.br).

When registering, donors are informed of the altruistic and voluntary nature of the donation, the steps that follow registration, and the potential risks of collecting HPC, as well as the maintenance of the registry until they reach the age of 60. He will also be enlightened about the flow of information between REDOME, transplant centers throughout the country, and international registries.

As part of the registration process, the donor will receive an Informed Consent Form (ICF) for registration in REDOME**,** in print or digital format, containing information about the registration and donation process, and contact channels with REDOME. After signing, a copy of the Informed Consent Form is filed in the blood center and another copy is made available to the donor.

4.2. Compatible Donor Selection

REDOME defines criteria for the selection of compatible donors according to scientific evidence that ensures the benefit of unrelated HPC transplantation for patients, in order to preserve voluntary donors.

The performance of an unrelated HPC transplant procedure for clinical conditions that have no clinical indication in current medical practice, must be evaluated within the scope of a scientific research project, with prior knowledge and approval of the donor involved.

4.2.1. REDOME donor contact

Donors who are potentially compatible with a patient are selected for further compatibility testing. At this stage, only REDOME's collaborators, properly trained, are authorized to contact the donor in order to assess their availability and health issues that

may lead to unsuitability - donors who present a condition associated with increased risk for the collection of HPC are temporarily or permanently removed and informed of this.

4.3. HPC Collection for Unrelated Transplantation

REDOME has a well-established procedure that guides the teams from transplant centers, collection centers, and specialized hemotherapy services during the voluntary donor's HPC collection stage. A specific document - the Collection Center Manual - was developed aiming to ensure donation safety and considering the needs of patients and donors.

A REDOME team member, properly trained, will keep in touch with the selected donor during the clinical and laboratory evaluation and the collection of HPC, through phone calls, messages and e-mails, in order to provide guidance and clarify any doubts about the subsequent steps.

The various steps for HPC collection may require the donor to travel to the indicated collection center when there is no alternative center available near his/her residence. In this case, REDOME is committed to offering the donor the best alternative for this displacement, including acquisition of airfare, ground transportation, accommodation, meals, and the presence of a companion selected by the donor.

After confirmation of compatibility with a patient, the scheduling of procedures related to the collection of HPC is conditioned to the sending of a prescription by an authorized transplant center.

All the information related to the work up process and HPC collection are monitored by REDOME, through specific forms sent by the collection centers, as a way to ensure the donor's safety and protection.

4.3.1. Donor clinical and laboratory evaluation (work up)

The clinical and laboratory evaluation, performed in a specialized collection center and known as work up, is an essential step for the collection of HPC.

This service involves qualified and trained professionals, with experience in the field of HPC transplantation and in the evaluation of donors, in centers authorized by the Ministry of Health for this activity. These professionals must not be involved with the patient or his treatment, as a way to ensure an impartial and safe evaluation for the donor.

Besides a clinical evaluation with health information, including previous diseases, use of medications, and life habits, the donor will be submitted to laboratory tests - blood count, biochemistry with liver and kidney function, and research for infectious disease markers (HIV, Hepatitis B, Hepatitis C, HTLV, Syphilis, Cytomegalovirus, Epstein Barr, Toxoplasmosis, Syphilis, Chagas' Disease). Depending on epidemiological factors or the donor's clinical history, other tests can be performed (for example, serology for Malaria in donors from endemic areas).

During the consultation, the donor will be able to clarify any questions about the collection procedure and participate in the decision about the cell source selected. An Informed Consent Form (ICF) for the HPC Donation will be presented by the collection center and must be signed by the donor and the professional responsible for the evaluation.

The results of the clinical and laboratory evaluations will be shared only with REDOME and with the patient's transplant center (anonymously, for the latter) and at the end of the evaluations, the donor can request the results of all tests performed.

4.3.2. Selection of the source of cells for transplantation

The transplant center will indicate in the prescription the preferred source for HPC transplantation - bone marrow or peripheral blood - but the final choice of the source of cells should consider the donor's clinical evaluation and the donor's preference regarding the main side effects and potential risks associated with each source.

During the evaluation at the collection center, the donor will be educated about bone marrow collection and peripheral blood donation and, according to evidence in the scientific literature, both are considered safe.

The characteristics of the two sources are summarized below, and more detailed information will be presented during the work-up process by the responsible medical team.

	Bone Marrow	Peripheral Blood
Collection Center	Transplant center	Transplant Center or Hemotherapy Service
Hospital Admission	Yes (2 days)	No. In case of catheter use, hospital admission will be necessary (2 days)
Prior Use of Drug	No	Yes (G-CSF/Filgrastim for 5 days)
Place of Procedure	Surgical center	Room or blood bank
Anesthesia	Yes	No
Side Effects	Pain at puncture site (hip bone), mild anemia and fatigue after donation	Body aches, headache and low-grade fever during the use of the medication. Arm pain after collection
Recovery Time (return to activities)	7 days after the collection	2 days after collection

4.4. Follow-up of Donors after HPC Collection

REDOME has a well-established procedure for the follow-up of donors after the collection of HPC in order to ensure their physical and emotional well-being. This follow-up is performed by a health professional, trained to identify complications to identify possible complications and act in the referral of these cases, and is done by telephone contact, by sending a phone message (WhatsApp) or by e-mail.

Post-collection evaluation should occur at least at the following intervals:

- 7 days;
- 30 days;
- 12 months;
- Annually, for a 10-year interval.

The 30-day evaluation foresees the performance of a complete blood count to evaluate the recovery of hematological levels and improvement of anemia (if any).

In the occurrence of adverse events, additional evaluations may be performed, and the adverse events must be reported to the competent health authority.

Events that may affect the recipient's health must be reported to the transplant center.

4.4.1. Post-Collection Complications

REDOME has a well-established procedure to identify and monitor the occurrence of adverse reactions or undesirable events associated with HPC donation. Depending on the severity of the event, the donor may be followed remotely and, in more severe or prolonged cases, he/she may be oriented to seek medical care at a health service near his/her residence or return to the collection center for reassessment.

In case of medical evaluation that requires displacement, REDOME will provide all the logistics and defray all related expenses.

4.5. Subsequent Donation

REDOME has well-defined criteria for the re-collection of HPC from voluntary donors who have already undergone the donation procedure:

- Minimum interval of 45 days between the two donation procedures;
- The donor should have the autonomy to refuse the second donation;
- Preference for collecting peripheral blood after a first bone marrow donation;
- The donor's clinical and laboratory evaluation must obey the parameters foreseen in the legislation, with special attention to alterations resulting from the first donation;
- After the third donation of HPC, regardless of the source, the donor will be permanently removed from REDOME.

Requests that do not meet the above criteria will be evaluated by REDOME's Technical Coordination.

4.6. Breaking Anonymity (Disclosure)

REDOME has a procedure to allow the break of anonymity between patient and donor, also called disclosure, after unrelated HPC transplantation, in order to protect the privacy of donors and respect their wishes regarding the eventual meeting with the recipient.

After six months from the date of the infusion, the donor may request information about the health status of the recipient, and eighteen months after the transplant, a breach of confidentiality between donor and recipient is authorized.

During the period of six to eighteen months, correspondence may be exchanged (without data allowing the identification of the donor or recipient), but REDOME does not allow the exchange of gifts.

The process of anonymity breaking and disclosure is voluntary and will be evaluated and conducted by REDOME. It must be approved by the donor and the recipient and, in the case of the recipient, it will still be necessary an evaluation from the responsible medical team authorizing the meeting.

4.7. Scientific Research with Voluntary Donors and Patients of REDOME

The performance of any research activity involving data from donors registered at REDOME is subject to project approval by the Research Ethics Board of INCA or the institution responsible for the project and further evaluation by REDOME's Technical Coordination.

Donor data may be used in a consolidated and anonymous (non-identifiable) form for statistical and epidemiological purposes, as a way to improve the voluntary donor registration process and the strategies for selection and identification of compatible donors.

REDOME does not share donors' or patients' personal data with research institutions without the prior consent of the donors or patients involved.

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