

Manual Blood Center



Brazilian Registry of Voluntary Bone Marrow Donors (REDOME)
Instituto Nacional de Câncer José Alencar Gomes da Silva (INCA)
MINISTRY OF HEALTH



GENERAL MANAGEMENT

MANUAL

REDOME

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Presentation

Created in 1993, REDOME (the Brazilian Registry of Voluntary Bone Marrow Donors) has consolidated its position as the third largest registry of voluntary bone marrow donors in the world and this success must be shared with the entire network that has worked to ensure access to potential donors and patients to the registry throughout the Brazilian territory.

However, maintaining a nationwide registry in a country the size of Brazil represents a major challenge, especially in the subsequent location of this donor and in the steps that involve complementary tests for identification and confirmation of compatibility, fundamental to the success of hematopoietic stem cell transplantation, highlighting the work of blood centers and histocompatibility laboratories. The displacement of selected donors to specialized collection centers and the assurance of a humanized and safe environment in the evaluation of these donors is also a result of REDOME's work with the various professionals who receive them.

Throughout its history, REDOME has endeavored to keep up with the technical and scientific changes that have promoted a significant improvement in transplant results for patients who find in the voluntary donors of our registry, the renewal of their hopes for a full and healthy life.

Guided by values such as ethics, transparency, cooperation, and innovation, we thank the successful partnership with blood centers, histocompatibility laboratories, transplant and collection centers, and present in this document some general guidelines that seek to strengthen this activity for the benefit of our donors and patients.

Dr. Danielli Oliveira
REDOME's Technical Coordinator



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Introduction

This manual was prepared with the objective of orienting blood centers, which are REDOME's partners and are part of the support network, in relation to the care, registration, and requests for collection of blood samples from voluntary bone marrow donors for confirmatory testing (CT), aiming to provide guidance on how requests should be conducted.

Bone marrow donation should be voluntary, anonymous, and altruistic. All information provided to the potential donor during the entire process must be preserved in accordance with REDOME's Data Protection Policy and other determinations set forth in the legislation in force.

Service should be humanized, cordial and empathetic. The registration of donors is the responsibility of blood centers qualified for this purpose and should follow procedures previously defined to ensure the traceability of records, in order to ensure protection to donors and the safety of the recipient.

Blood sample collection requests must be requested and managed through the REDOMEWEB system, which can be used both for National (for Brazilian patients) and International (for foreign patients) CT collection requests.



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1. Donor Care

The care provided to potential candidates for REDOME donors must occur in an appropriate place where they can receive informative material about the process of bone marrow and/or peripheral blood donation; basic conditions for donation; risks to the donor; purpose or use of cells and laboratory tests. This information is available on our website redome.inca.gov.br and the blood center may also use its own material.

The blood center should have professionals trained to answer all questions about the procedure and give the candidate the opportunity to ask any questions he/she may have.

It is important to inform donors that, in case of possible compatibility of the selected donors, REDOME can be contacted by phone or WhatsApp, and in situations of suspicion, we count on the partnership of the blood centers to clarify doubts and confirm the veracity of the information.

To facilitate related donation processes, when the donor or patient lives in another country, REDOME will inform the selected blood center and will be responsible for making the initial contact with the donor for clarifications and inclusion of the registration in the REDOMEWEB system. This donor will then be referred to the blood center to collect a blood sample for the HLA typing test.

2. Donor Registration

The registration is the responsibility of the blood centers and can only be carried out upon presentation of an identification document with photograph, issued by an official body, and a certified photocopy of the document or in a digital format with certification (e.g. digital driver's license) will be accepted.



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It is recommended that all fields in the REDOMEWEB system be filled out and checked with the donor to facilitate contact in case of a possible match. All the information that is not included in the donor's identification document must be asked.

2.1 Basic Data

- Full Name: Fill out according to the document presented, without abbreviations, including prepositions, and check with the donor before saving.
- Name changing: It should only be filled out if it appears on the identity card, remembering that in the name changing you can only change the first name (or the first two in case of a compound name).
- **Date of Birth**: Include date, month, and year with 4 digits in accordance with the submitted document.
- Date of collection and registration: It is recommended that the sampling date and the registration date occur on the same day through the system to ensure data traceability.
- Blood Center: Public institution that performs hemotherapy activities and is qualified to register bone marrow donors and collect blood samples for confirmatory testing.
- **Mother's Name**: Fill out the name that appears on the identity document presented, without abbreviations. In the case of an unknown mother, as this is a mandatory field, place an asterisk (*).
- Campaign: Routine (individual registration) or import (in case of a campaign).



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- Father's Name: It is recommended that you fill in the name on your ID card.
- Biological Gender: The options for this field are: MALE or FEMALE, corresponding to the sex at birth. It is important that REDOME knows the donor's genetic sex, since it is a criterion considered in the selection of unrelated donors. Candidates who have gone through the gender transition process and who do not agree with the inclusion or maintenance of this information in their registry will not be included as donors, at the risk of compromising the technical aspects of donor selection for transplantation.
- Gender: This field was created with the objective of ensuring respect for gender identity, according to the Charter of Rights and Duties of the National Brazilian Health Service (SUS) Users. The options to be filled in are Woman, Man, Agender (Identity that denotes the absence of gender, neutral gender, or absence of gender identity) and Others.
- Nationality: Brazilian citizens born in Brazilian Territory. Foreign citizens, and residents in Brazil, are allowed to be registered as REDOME donors.
- Blood Center Code: It is the donor's code/number at the Blood Center.
- Race: Asiatic, white, brown, indigenous, black, and not informed race.
- Ethnicity: fill in only in case of indigenous race and select ethnicity.
- Individual Taxpayer Registration Number: Extremely important information, as it helps locating the donor in case of a possible match.
- **Identity Card**: Number of the official identification document with photo submitted for registration.
- Place of birth: Fill in the donor's state and municipality of birth. In case of a foreign donor, this field should not be filled out.



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- CNS Brazilian Health Card: Fill in the identification document number of the SUS user, when available.
- Marital Status: The options are: legally separated, divorced, widowed, divorced, unknown, other, single, married, and separated.
- Weight: Very important information, which can be used as a criterion for donor selection.
- **Height:** Critical information used to calculate body mass index, in obesity assessment.
- ABO/Rh: Blood group (A, B, AB, O or NI) and Rh factor (+, or NI).
- **Smoker**: Record current use or smoking history.
- Education: Include the education level of the last grade attended or course completed.

2.2 Address

Include the type of address (residential or commercial), insert the zip code, street address, district, number, complement, state and city.

2.3 Telephones

Include all the possible phone numbers of the donor with area code and of people close to him for messages, including the name of the contact, so that when the call comes in, it will be possible to find the donor and avoid suspicions.

2.4 Email

Enter all e-mails used by the donor, including commercial ones.

3. Criteria for registration change

It is recommended that all registration changes related to the basic data, especially in the name and gender fields, be made by the blood center that made the registration, upon presentation of an official identification document with a photo. If this is not possible, it can be done by the REDOME service team and/or the contact center company designated for this purpose.



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4. Documents and records

The blood center must maintain proper control of the documents provided by REDOME - Informed Consent Form (ICF) and other documents requested by them, ensuring the use of the current versions of the models provided by REDOME. We recommend that REDOME's own versions of the documents should not be generated.

Records generated at the time of registration, such as the ICF, must be stored and identifiable by the responsible blood center for at least 20 years, according to current legislation.

5. Campaigns

The campaigns to attract new bone marrow donors must be carried out by the blood centers (which may partner with some NGOs or projects), taking into consideration that the flow of spontaneous donors will be maintained and that they must control the number of donors registered, considering the annual ceiling for each state, as determined by the Ministry of Health in Ordinance No. 1,229 of June 15th, 2021.

The blood center is responsible for organizing the campaigns, being responsible for evaluating the possibility of meeting this request, providing the collection material and the teams of professionals who will work in the collection and registration.

Campaigns that focus on a specific case of a patient should be carried out with care, emphasizing that donation is voluntary and anonymous, and once in the registry, the donor will be available to any patient.



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6. Provision of cadastral information

For cases of requests for copies of registration, according to the General Law of Protection of Personal Data (LGPD) - LAW No. 13,709, OF AUGUST 14TH, 2018, REDOME will provide by e-mail, to the blood centers, a document with the information contained in the registration to be delivered personally, in two copies and upon presentation of an official document with photo of the requesting donor - one of the copies will be signed, scanned and returned to REDOME and also stored by the blood center, and the other will be delivered to the donor.

7. Guidelines on scheduling and collecting confirmatory typing samples (CT)

The sample collection for confirmatory typing is a fundamental step in the process of identifying a compatible donor and usually occurs after previous direct contact with this donor by a REDOME representative, where explanations about the test to be performed and the possibility of donation are provided.

However, the success of this process depends on the agility of the tests and on the donor's availability and commitment. Thus, upon arrival at the blood center, the donor should have the opportunity to clarify any doubts about the donation process and may be provided with informative materials, such as those available on the REDOME site (redome.inca.gov.br).

If the blood center representative identifies any impeding condition for the donation, he/she should contact the REDOME team.



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If it is difficult to locate a selected donor, REDOME may also request the blood center to support the search for this donor by providing available data in its records and updating the REDOMEWEB system.

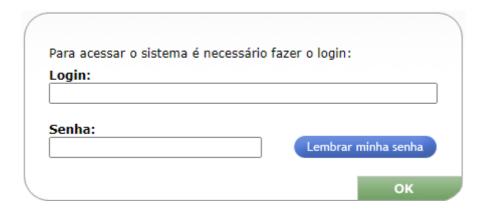
7.1 REDOMEWEB

REDOMEWEB is the system made available by REDOME and used by blood centers to consult, modify and create donor records, as well as to receive and manage calls for blood collection for confirmatory tests.

7.2 Sample Collection Request Acceptance

In order to inform REDOME of the acknowledgement of collection requests, the blood center should proceed as explained below:

Enter REDOMEWEB, Blood Center profile, through the link https://redomeweb.inca.gov.br/REDOMEWeb/CAUPrepararLogin.action



Access the list of "Awaiting acceptance" ("Aguardando aceite") requests.



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Accept the request by clicking on the icon , which will open the donor's record. At this point, note which are the tubes required for collection in "Collection Instructions" ("Instruções de coleta") and then click "OK".

At this moment the status of the request changes from "waiting for acceptance" ("aguardando aceite") to "not fulfilled" ("não atendida").

If the blood center does not have the tubes for collection, they must be requested by e-mail to the person responsible for REDOME.

7.3 Sample Collection Scheduling

After acceptance into the system, the blood center should contact the donor to schedule the collection date within 7 days. If the donor is unable to come within the established deadline, we request that REDOME be informed by e-mail immediately.

Then, the blood donor center responsible must enter on REDOMEWEB again and enter the scheduling date.

The scheduling of blood sample requests for International TC can only happen on the following days of the week - Mondays, Tuesdays, and Wednesdays in order to ensure the adequate transportation of the sample. The CT National samples can be collected from Monday to Friday.

On the homepage, in order to proceed, access the "**not fulfilled**"("não atendida") requests:



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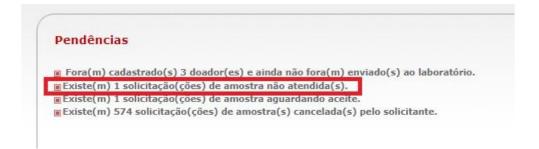
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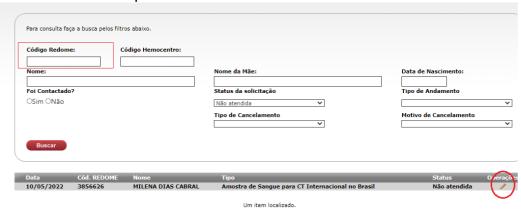
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Search for the donor by DMR (REDOME identification number) and then click on the pencil:



On the request progress tab, click on include progress and fill in the scheduling date, quantity of tubes and total volume, in milliliters. Also fill in your contact information, address, zip code, city and state, and to finish, click on the arrow.





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7.4 Sample Collection

After the collection is performed, the blood center will access the donor's REDOMEWEB record again and follow the steps below: Unmet sample requests, click on the pencil, Request progress tab, include progress, fill in with the date, number of tubes and total milliliters, finally click on the red arrow on the right.



After that, the blood center will not be able to change any other information, since the collection step for that donor has been closed until then.

If you have entered any incorrect information or need to make any changes, the blood center should notify the REDOME team.

7.5 Cancellation of Sample Collection request

If the donor informs that he/she will not be able to collect the sample, or if the blood center is unable to contact him/her after at least three attempts (WhatsApp, phone call, and e-mail), the request should be canceled in REDOMEWEB as follows: "not fulfilled" ("não atendida") sample requests;



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Click on the icon sand insert the justification for the cancellation:



To finish, click ok.

8. Sample Transportation Request

8.1 Receiving documents and identifying collection tubes

To request the removal of the sample to be delivered to the laboratory that will perform the test, a message should be sent to the e-mail address informed in the collection instructions.

Then, REDOME will request the transportation company to pick up the sample and, at this moment, the blood center will receive in its e-mail two PDF files

- Transport Declaration: print in two copies, sign and stamp (responsible for the blood center)
- Standard labels: to be used on the sample collected. only this identification is accepted by REDOME.

During sample collection, it is very important to ensure the proper identification of the tubes (using the labels provided by REDOME) and the completion of the forms, because failure in the identification may compromise the use of these samples, requiring new contact with the donor and sample collection, which will impact the selection process of a compatible donor with losses also for the patient.

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The responsible transporter will contact you by phone to confirm the date and time for pickup and without this confirmation, the pickup will not take place.

8.2 Tubes delivery to the carrier

The transportation company may send, at an earlier time, or by the representative who will pick up the samples, a box in which the tubes will be packed.

The blood center should not pack the tubes in their own box or close it before the pickup, as this makes it impossible for the transportation company to check the box.

If the company does not send the box in advance or the representative does not have the box at the time of withdrawal, REDOME should be informed of this fact before the samples are delivered.

If the pickup is the day after the collection, the samples must be kept refrigerated between 2°C and 8°C until the pickup and then can be kept at room temperature.

After the withdrawal of the sample, the request will have its status on REDOMEWEB changed to "fulfilled" as soon as the sample is delivered to the laboratory indicated.



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9. Privacy and Data Security

REDOME acts to ensure the privacy of all users of its computerized systems, patients and donors, and advises that all information made available, as part of the process of identifying a compatible donor for allogeneic transplantation, respects the privacy of patients and donors, according to REDOME's Privacy Policy and in accordance with the General Law of Data Protection (LGPD) - LAW No. 13,709, OF AUGUST 14TH, 2018.

All employees involved in this activity should be informed about the responsibility in this process.

Final Remarks

In case of doubts about how to use the system or other clarifications and functionalities, explanatory videos and manuals are available on REDOMEWEB through the link: https://redomeweb.inca.gov.br/REDOMEWeb/PrepararConsultarDocumentaca

In the blood center profile, access:

oHemocentro.action?initial=true, on the path described below.

- Donor:
- Documentation:
- Video lessons:
- Manual.

Additional information can also be obtained from the REDOME team through the following channels:

Email: redome.hemocentros@inca.gov.br

Phone: (21) 3207-4744



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