	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 1 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		


SUMMARY

1.	INTRODUCTION	1
2.	PURPOSE AND SCOPE	2
	2.1. Areas concened.....	2
3.	COLLECTION AND USE OF PERSONAL DATA.....	3
	3.1. What personal data is collected?	3
	3.1.1. The data collected from donors registered in REDOME are:.....	3
	3.1.2. The data collected from patients registered for the purpose of unrelated donor search are:	4
	3.1.3. The data collected from users who use the information systems made available by REDOME (REDOMEWEB and REDOMENET) include:	5
	3.2. How is personal data collected?	5
	3.3. How is personal data processed and shared?.....	6
	3.4. The personal data collected by REDOME are sent abroad?	7
	3.5. How REDOME guarantees the protection of personal data?	8
	3.6. How and for how long is personal data stored?.....	8
4.	USER RIGHTS	9
5.	COMMUNICATION	9
6.	AMENDMENT TO PRIVACY POLICY.....	10
7.	REFERENCES	10

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 no. 9434/1997 and Law no. 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 National Cancer Institute (INCA) in Rio de Janeiro and, besides having its own Information Technology team, REDOME is also supported by INCA's Information Technology Service.

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 2 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

REDOME respects the individual's right to personal data protection and clarifies that it processes personal data with care and confidentiality. The personal data collected are those necessary for the nature of the activities of registration, selection and identification of compatible donors in the process of unrelated allogeneic transplantation of hematopoietic stem cells (HSC). REDOME's employees and service providers are informed of this Policy and sign a Confidentiality Agreement.


The processing of personal data is essential for REDOME's operation and to disclose the aspects related to confidentiality and data protection is important to maintain transparency and trust with our employees, REDOME network users, service providers, as well as patients and donors benefited by this Program.

2. PURPOSE AND SCOPE

This document aims to establish the principles, limits, responsibilities, and procedures relating to confidentiality and protection of REDOME data and is intended to all employees, direct users of REDOME network (blood centers, histocompatibility laboratories and transplant centers), public servants of INCA and the Ministry of Health, donors and patients served by REDOME, health professionals and society in general.

2.1. Areas concerned

- REDOME Section Chief, responsible for REDOME's Technical Coordination and Management;
- REDOME Information Technology Area, responsible for REDOME operational processes;
- INCA's Information Technology Service, responsible for the infrastructure support of REDOME's systems;
- INCA's General Management.

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 3 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

3. COLLECTION AND USE OF PERSONAL DATA

3.1. What personal data is collected?


REDOME collects personal data from patients and donors for the purpose of registration in the respective registries. The objective of these registries is to identify compatible donors for the purpose of unrelated hematopoietic stem cell transplantation.

3.1.1. The data collected from donors registered in REDOME are:

- ✓ Full Name
- ✓ Mother's Name
- ✓ Date of birth
- ✓ Sex
- ✓ Gender
- ✓ Nationality
- ✓ Place of birth
- ✓ Race *
- ✓ Home address
- ✓ Telephone numbers
- ✓ E-mail
- ✓ HLA typing **

(*)The race information corresponds to the self-declared denomination, based on the categories used by IBGE (Brazilian Institute for Demographic Data) and aims to allow the comparison with other official demographic data, in terms of representativeness of the Brazilian population, and to optimize the use of available algorithms for the selection of compatible donors that also considers this characteristic.

(**) HLA typing represents the result of genetic compatibility tests.


	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 4 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

Some optional data that can be included in the registry are Individual Taxpayer Registration Number (for identification purposes), blood typing (as a secondary criterion of compatibility for transplantation).

During the donor matching process, some selected donors will also have health information collected, such as pre-existing medical conditions, number of pregnancies and abortions (for women), use of medications, risk factors for transmissible diseases (including sexually transmitted diseases), use of licit and illicit drugs.

3.1.2. The data collected from patients registered for the purpose of unrelated donor search are:

- ✓ Full Name
- ✓ Date of birth
- ✓ Individual Taxpayer Registration Number
- ✓ CNS (the Brazilian Health Card)
- ✓ Mother's name
- ✓ Sex
- ✓ Nationality
- ✓ Place of birth
- ✓ Blood type ABO
- ✓ Race *
- ✓ Address
- ✓ E-mail
- ✓ Contact telephone numbers
- ✓ Diagnosis
- ✓ Date of diagnosis
- ✓ HLA Typing **
- ✓ Medical Evolution ***

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 5 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

(*) The information on race corresponds to the self-declared denomination, based on the categories used by the IBGE (Brazilian Institute for Demographic Data) and aims to allow comparison with other official demographic data, in terms of representativeness of the Brazilian population, and to optimize the use of available algorithms for the selection of compatible donors that also consider this characteristic.

(**) HLA typing represents the result of genetic compatibility tests.

(***) Medical evolution includes data such as patient's weight and height, current disease stage and response to treatment, and patient's clinical condition in order of assessing the urgency of transplantation.

3.1.3. The data collected from users who use the information systems made available by REDOME (REDOMEWEB and REDOMENET) include:


- ✓ Full Name *
- ✓ Address
- ✓ Phone
- ✓ E-mail *
- ✓ CRM (Regional Medical Council) Registration **

(*) Required data.

(**) In case of access for medical professionals.

3.2. How is personal data collected?

Data from donors registered in REDOME are collected through a computerized system (REDOMEWEB) with the completion of information by the blood center responsible for the registration. Alternatively, registration data can be entered directly by the donor using the REDOME application. The collection of data from REDOME donors is conditional on the donor's consent, according to the consent form applied in the registration process.

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 6 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

Data from patients registered for the unrelated donor identification and selection process are collected through the REDOMENET system, filled out by the physician responsible for the patient. The physician responsible for the patient is responsible for informing the patient about his/her registration in REDOME's information system.

Data collection from system users (REDOMEWEB and REDOMENET) occurs when the user requests access to the systems.

3.3. How is personal data processed and shared?


All activities related to the collection, processing and sharing of REDOME's personal data follow the determinations of the Brazilian General Law of Data Protection (LGDP - Law No. 13,709/2018), the Brazilian Civil Rights Framework for the Internet (Law No. 12,965/2014) and other applicable laws.

The processing of data collected by REDOME is limited to what is necessary for REDOME's operational processes related to the registration, selection and identification of compatible voluntary donors and allogeneic transplantation with an unrelated donor. This processing involves blood centers, histocompatibility laboratories and transplant centers that integrate the REDOME network.

As part of the selection and identification process of compatible donors, some personal data of donors and patients are shared in an anonymized way, so that no personal identification is possible. Thus, the name of the patient or donor is replaced by an identification code.

Only during the clinical evaluation process of donors to collect cells for transplantation, the responsible collection center will receive the identification information from the selected donor and will be responsible for ensuring the confidentiality of this data.

The donation of unrelated stem cells and all activities related to this process are anonymous in nature and the patient as well as the medical team responsible for the patient does not know the identity of the donor, nor does the donor have personal information about the patient to whom they are donating.

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 7 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

Personal data of patients and voluntary donors may be used, also anonymously, in scientific research projects developed by REDOME and approved by the Research Ethics Board of INCA or other responsible institution.


In order to ensure good communication with professionals working in various services that integrate the REDOME network (blood centers, histocompatibility laboratories and transplant centers), the data from users of information systems REDOMEWEB and REDOMENET may be used to send notices and messages to ensure its proper functioning.

All activities related to data processing by REDOME prioritize the fundamental right of donors and patients to privacy.

REDOME does not sell or provide personal data from collaborators, voluntary donors, patients and users of its information systems to third parties, and the entire network of collaborators and service providers is guided to follow rules to prevent the unauthorized sharing of personal information.

3.4. The personal data collected by REDOME are sent abroad?

As part of the international network of voluntary bone marrow donor registries and a member of the World Marrow Donor Association (WMDA), REDOME shares personal data of registered voluntary donors and of patients in the process of matching and donor selection with other international registries. This process occurs anonymously, not allowing the disclosure of donor identity, and aims to increase the chances of a Brazilian patient to identify a compatible donor through international registries and ensure that Brazilian donors, registered in REDOME, are available to patients from other countries, in a large network of international collaboration.

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 8 of 11	DATE OF THIS VERSION: 07/04/2022
	PRIVACY POLICY		

3.5. How REDOME guarantees the protection of personal data?

Access to personal data of patients and donors is restricted to REDOME employees or professionals who work in REDOME network in activities that require this level of access, properly trained and informed about information security measures and data protection.

The use of information systems that ensure this access is protected through login and password for personal use.

Information shared on an international level with other registries occurs, preferably using encryption tools to keep data secure during transmission.


The sending of electronic messages and sharing of documents in digital media occurs through an institutional provider (@inca.gov.br) in accordance with security protocols.

Documents containing personal information on patients and donors are stored digitally in a secure area made available by INCA's Information Technology Service, and physical files are stored according to INCA's policy in an area designated by a provider contracted for this purpose.

3.6. How and for how long is personal data stored?

Databases containing personal information of voluntary donors and patients registered in REDOME are stored in servers designated by INCA's Information Technology Service, responsible for their safekeeping and protection. REDOME has a backup strategy to avoid loss or unavailability of information and ensure the maintenance of the operation.

Information related to clinical and/or laboratory procedures performed, registration data of volunteer donors and patients, as well as their digital records, are stored in REDOME's database in a server made available by INCA; however, the visualization by users and the possibility of using these data will depend on the status of the data; visualization by users and the possibility of using these data will depend on the registration status (active or inactive). Thus, upon request or impediment associated with death or disease condition, the donor's registration will suffer a logical exclusion

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 9 of 11	DATE OF THIS VERSION: 07/04/2022
			VERSION OF THIS DOCUMENT NO.: 00
PRIVACY POLICY			

and the information will no longer be available for the identification process of a compatible donor.

The voluntary donors will remain active in the registry, and their data will be available for eventual compatibility evaluation and selection for a patient, until the age of 60 - in case no ineligibility condition has been identified, before this term.

4. USER RIGHTS

The user shall have the right to obtain from the National Cancer Institute (INCA), free of charge, at any time and by means of a formal request by sending an electronic message (e-mail), the rights assured to them by article 18 of the General Data Protection Law, including confirmation, access and correction of the data used by the platform, elimination of data processed without consent, and revocation of the same.


Compliance with these rights may be requested through the Customer Service channels informed in this Privacy Policy.

INCA may adopt measures to validate the applicant's identity.

5. COMMUNICATION

INCA's General Ombudsman:

- Email: ouvidoria.geral@inca.gov.br
- Phones: (21) 3207-1399 / 3207-1420/ 3207-1613
- Message form: <https://www.inca.gov.br/ouvidoria#formul%C3%A1rio>

	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 10 of 11	DATE OF THIS VERSION: 07/04/2022
			VERSION OF THIS DOCUMENT NO.: 00
PRIVACY POLICY			

6. AMENDMENT TO PRIVACY POLICY

This Privacy Policy was published on 07/04/2022 and relevant amendments and/or reviews will be effective from the date of its publication in **REDOME** platform, in strict accordance with the Publicity Principle, established in Article 37, caput of the Federal Constitution, and should be fully complied with by users, regardless of prior or express notification.

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	GENERAL MANAGEMENT	No. 000.5980.002	DATE OF THE 1ST VERSION APPROVAL: 07/04/2022
	INSTITUTIONAL POLICY REDOME	Page 11 of 11	DATE OF THIS VERSION: 07/04/2022
			VERSION OF THIS DOCUMENT NO.: 00
PRIVACY POLICY			

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