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1. INTRODUCTION

The Brazilian Registry of Volunteer Bone Marrow Donors (REDOME) began its activities in 1993 and since 2000 is part of the National Transplant Policy of the General Coordination of the National Transplant System (CGSNT) of the Ministry of Health (Law No. 9,434/1997 and Law No. 10,211/2001) having as guidelines the gratuity of the donation, beneficence in relation to the recipients and non-maleficence in relation to living donors, and is under the technical coordination and management of the National Cancer Institute (INCA).

The processing of data collected by REDOME is limited to what is necessary to carry out the operational processes of the Registry, aimed at registering, selecting and identifying compatible voluntary donors and performing allogeneic transplantation with an

unrelated donor. This processing involves blood centers, histocompatibility laboratories and transplant centers that are part of the REDOME network.

Aiming at transparent access to REDOME data and with the objective of disseminating information and data of public interest, REDOME encourages and supports scientific research.

The disclosure of REDOME data in research projects (internal or external) must comply with the criteria determined by current legislation, as well as the Registry guidelines described in this Policy.

2. PURPOSE AND SCOPE

This Policy aims to establish the principles, responsibilities, criteria and procedures for requesting REDOME data for research projects.

DREDOME data requests are intended for scientific research projects, of a qualitative or quantitative nature, by internal collaborators or external researchers.

A research project is understood as the set of activities whose purpose is to seek information, knowledge and experiences, to present its conclusions and results through course completion works, master's dissertations, doctoral theses, scientific articles, presentations at congresses (regional, national and international), conferences, symposiums, seminars, colloquiums, round tables, forums, *workshop*, lectures and panels.

2.1. Involved areas

- Head of the REDOME Section, responsible for the Technical Coordination and Management of REDOME;
- REDOME Information Technology Area, responsible for REDOME data and operational processes;
- INCA's Information Technology Service, responsible for supporting the infrastructure of REDOME's systems;

- General Directorate of INCA.

3. PRINCIPLES

3.1. Privacy

REDOME respects the right of each individual to the protection of personal data and 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 allogeneic unrelated hematopoietic stem cell (HSC) transplantation

REDOME does not sell personal information of donors and patients. The personal data of patients and voluntary donors can only be used in scientific research projects anonymously (using the REDOME identification code).

REDOME's activities related to the collection, processing and sharing of personal data follow the provisions of the General Data Protection Law (LGPD - Law No. 13,709/2018), the Civil Rights Framework for the Internet (Law No. applicable laws.

The data information collected by REDOME is described in its Privacy Policy.

3.2. Ethics

Ethical guidelines must regulate the development of research throughout the process, from its conception to publication.

It is expected that the researcher in charge and his team (other researchers, fellows, students, specialists, technologists and technicians) comply with existing regulations regarding research ethics, be honest in the presentation of scientific evidence, in the description of methodologies and research procedures , in citations and interpretation of results, respecting the ethical principles of protection of human rights, beneficence, non-maleficence, autonomy, justice, confidentiality and privacy.

4. DATA REQUIREMENT FOR RESEARCH

4.1. External researchers

In order to request REDOME data, the researcher responsible for the research must have a formal link with INCA or with another institution on behalf of which the research is presented (Offering institution - co-responsible for the research and for the actions of the researcher).

To request the use of data, the responsible researcher must send an email to REDOME, containing the following documents:

- REDOME Data Request Form for research (ANNEX A) completed;
- Confidentiality Agreement for Researchers (ANNEX B) completed;
- Research project containing abstract, introduction, objective, methodology and main bibliographical references;
- Evidence of approval by the Research Ethics Committee (CEP) of INCA or the Offering Institution;
- Participant information document and informed consent form (when recommended by CEP).

The request and documentation must be sent initially to the following e-mail: redome@inca.gov.br

REDOME uses these forms and documentation only for internal management, organization and archiving purposes, and no evaluation of the scientific merit of the Project will be carried out.

4.2. REDOME collaborators

For an internal request for the use of data, the employee must send an email to the REDOME Coordination, with a copy for their supervision, containing the following documents:

- REDOME Data Request Form for research (ANNEX A) completed (ANNEX A) completed;

- Confidentiality Agreement for Researchers (ANNEX B) completed;
- Research project containing abstract, introduction, objective, methodology and main bibliographical references (if applicable);
- Evidence of approval by INCA's Research Ethics Committee (CEP) (if necessary);
- Participant information document and informed consent form (when recommended by CEP).

Internal collaborators are expected to develop their research with respect to REDOME's values and principles, with zeal for the institutional image and their own.

5. AVAILABILITY OF REQUESTED DATA

The REDOME Coordination, together with the relevant area(s), will analyze the research data requests received and the feasibility of providing the requested data.

REDOME will provide an opinion to the applicant, informing whether the request was accepted or not, within a maximum period of up to 30 (thirty) days. Depending on the type and volume of data requested, REDOME may accept the request with reservations.

The REDOME Coordination or person appointed by it may contact the responsible researcher or his team to request more information about the research and/or the requested data.

After acceptance, REDOME's Information Technology area will collect the requested data and make them available to the responsible researcher or member of his/her team by email, within a period of up to 30 (thirty) days.

The provision of data does not involve the analysis of these data by the REDOME team. The data will be made available in raw form, with anonymization of the names of donors and patients, and the researcher and his team will be responsible for the proper treatment of the data.

6. PUBLICATIONS WITH REDOME DATA

It is not necessary to establish scientific collaboration with REDOME for the use of data, but the applicant may request scientific collaboration if he so wishes.

The researcher in charge and his team must undertake to forward by email a copy (virtual) or *links* of all publications made using the REDOME data provided.

7. COMMUNICATION CHANNELS

7.1. Data Request

- Internal Request: E-mail to REDOME Supervision and Coordination;
- External Request: E-mail to redome@inca.gov.br or (21) 3207-4700.

7.2. Ombudsman

REDOME provides a channel for sending complaints, doubts or suggestions through the INCA Ombudsman service:

- E-mail: ouvidoria.geral@inca.gov.br
- Phone numbers: (21) 3207-1399 / 3207-1420/ 3207-1613
- Message form: https://www.inca.gov.br/ouvidoria#formul%C3%A1rio

8. ANNEXES:

8.1. ANNEX A - REQUEST FOR RESEARCH REDOME DATA

REDOME DATA REQUIREMENT FOR SEARCH

Dear Researcher,

The REDOME data request for research projects must comply with the criteria determined by current legislation, be approved by the Research Ethics Committee of INCA or the Offering Institution, as well as comply with the REDOME guidelines, described in our Research Data Policy and our Privacy Policy.

Every team of collaborating researchers must be properly oriented to comply with such norms.

In order to respond to your request, we request that you fill in the fields below and attach the following documents to this request:

- Research project containing the abstract, introduction, objective, methodology and main bibliographical references;
- Evidence of approval by the Research Ethics Committee (CEP) of INCA or the Offering Institution;
- Participant information document and informed consent form (when recommended by CEP).

Research Project			
Research Title			
Proponent Institution			
Lead Researcher			
Responsible Researcher			
Name			
CPF		Professional record	
E-mail		Cell phone	
Research team member(s) who will have access to REDOME data If there are more members, create new fields to enter the requested information			

Name			
CPF		Professional record	
E-mail		Cell phone	
Name			
CPF		Professional record	
E-mail		Cell phone	
Name			
CPF		Professional record	
E-mail		Cell phone	

Purpose(s) of the Research

☐ Final paper ☐ Masters dissertation ☐ Doctoral thesis ☐ Scientific article ☐ Congress* ☐ Conference* ☐ Symposium* ☐ Seminar*	☐ Colloquium* ☐ Round table* ☐ Forum* ☐ Workshop* ☐ Lecture* ☐ Panel* ☐ Others*	
*Event name	*Date	*Place

Estimated Research Time

Beginning (month and year)		End (month and year)	

Brief Presentation of the Research Project
Describe the purpose of using REDOME data

Research Ethics Committee Include information regarding the evaluation of the CEP	
CEP institution	
CEP assessment status ☐ Approved - Number: _____ ☐ Under evaluation - Forecast: _____ ☐ Disapproved	
Information about the Data Required	
Does the research project involve the use of personal data from donors or patients registered in REDOME? ☐ No ☐ Yes. Specify:	
Does the research project involve the use of sensitive personal data (such as racial origin, data referring to health or sex life, genetic or biometric data) of donors or patients registered in REDOME? ☐ No ☐ Yes. Specify:	
Does the research project involve making genetic data available, obtained from the testing of biological samples, from donors registered in REDOME? ☐ No ☐ Yes. Specify:	
List Required Data	

Statement of responsibility

Members of the Research Team assume the following responsibilities:

1. Conduct the Research in accordance with current Brazilian legislation, as well as applicable International Standards;
2. Obey, comply with and enforce the provisions of the General Data Protection Law (Law 13.709/2018), the REDOME Privacy Policy and the REDOME Research Data Policy, available at https://redome.inca.gov. br/institutional/documents/
3. Comply with the recommendations of the Research Ethics Committee/CEP of INCA or of the Offering Institution (when applicable);
4. Guarantee the secrecy and confidentiality of the identity of donors and patients, providing for the anonymization of data;
5. Guarantee access to data exclusively to members of the research team;
6. Ensure that the data provided by REDOME will not be used for any purpose other than the one proposed in the research. Not to use the confidential information to which you have access, to generate your own exclusive and/or unilateral benefit, present or future, or for the use of third parties. Likewise, not to commercialize any data provided by REDOME;
7. Not to appropriate for yourself or others confidential and/or confidential material of the technology that may be made available;
8. Not to pass on the knowledge of confidential information, being responsible for all people who may have access to the information, through it, and thus being obliged to reimburse the occurrence of any damage and/or loss arising from a possible breach confidentiality of the information provided;
9. Mention REDOME as a source of data used in all publications that used and/or mentioned the data;
10. Inform REDOME of all content published using the data provided.

As it is an expression of the truth and responsibility of the previously identified Research Team Members, they sign this instrument.

Date	
Responsible Researcher Signature	
Team Member Signature	

Team Member Signature	
Team Member Signature	
To be completed by REDOME	
☐ Request Accepted ☐ Request Not Accepted	
Reservations or Comments	
Date	
REDOME Coordination Signature	

8.2. ANNEX B - CONFIDENTIALITY AGREEMENT_RESEARCHERS

	DIREÇÃO GERAL	Nº 000.5980.805	APROVAÇÃO DA 1º VERSÃO DATA: 21/08/2022
	TERMO REDOME	FOLHA 1 de 1	APROVAÇÃO DESTA VERSÃO DATA: 21/08/2022
			VERSÃO DESTE DOCUMENTO NÚMERO: 01
	TERMO DE CONFIDENCIALIDADE PESQUISADORES		

The purpose of this Term is to highlight the rules established for the performance of scientific and research activities related to REDOME, by the researchers involved, with regard to privacy and data protection of patients, voluntary donors and users of the REDOME network.

By this term of confidentiality and secrecy I declare:

1. To be a qualified researcher and have received guidance for carrying out activities involving access and use of personal information from patients and voluntary donors registered at REDOME, as provided for in the General Data Protection Law (LGPD - Law No. 13,709/2018);
2. To maintain exclusive use of information from patients, voluntary donors and users for research, acting in an ethical and transparent manner;
3. To recognize my responsibility to guarantee the secrecy and confidentiality of patient and donor data to which I have access, in accordance with REDOME's Privacy Policy and current legislation;
4. To be aware that infractions involving the privacy and confidentiality of personal data obtained from REDOME's information systems are subject to administrative sanctions.

☐ **I have read and accept this REDOME/INCA Confidentiality Term;**

☐**By this Confidentiality Agreement, I undertake to ensure that personal information (whether confidential or not) to which I have access is restricted to the knowledge only of the people who are directly involved in activities related to REDOME, and must make them aware of the existence of this Agreement and the confidentiality of this information.**

Responsible Researcher's Full Name:
Email:
Telephone:

Project name:
Offering Institution:
Date:
Researcher Signature:

Receipt Date at REDOME:
Recipient's Name:

9. REFERENCES

BRASIL. Ministério da Saúde. National Health Council. National Committee of Ethics in Research. Available at: https://conselho.saude.gov.br/comissoes-cns/conep

BRASIL. Presidency of the Republic. General secretary. Deputy Director for Legal Affairs. **LAW NO. 13.709, OF AUGUST 14, 2018**. General Law for the Protection of Personal Data (LGPD). 2018. Available at: http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/L13709compilado.htm

BRASIL. Presidency of the Republic. General secretary. Deputy Director for Legal Affairs. **Internet Civil Framework**: LAW NO. 12.965, OF APRIL 23, 2014. It establishes principles, guarantees, rights and duties for the use of the Internet in Brazil. 2014. Available at: http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2014/lei/l12965.htm

INCA. Instituto Nacional de Câncer. Research. Available at: https://www.gov.br/inca/pt-br/assuntos/pesquisa

WMDA. World Marrow Donor Association. **International Standards for Unrelated Hematopoietic Stem Cell Donor Registries**. 2020. Available at: https://wmda.info/wp-content/uploads/2021/01/WMDA-2020-Standards_AM1_Jan2021-1.pdf

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Developer(s):
Natalia Daher Jaques

Reviewer:
Danielli Cristina Muniz de Oliveira

Approver:
Danielli Cristina Muniz de Oliveira