

# Implementation of the REDCap System for Data Management in Human Tissue Bank

Luiz Henrique de Freitas Filho<sup>1,\*</sup> , Cristina de Carvalho Silva Neves<sup>1</sup> , Gustavo Bregalda Mattos<sup>1</sup> ,  
Petrus de Paula Ribeiro<sup>1</sup> , Helga Caputo Nunes Holzhausen<sup>2</sup> , Maurício Etchebehere<sup>3</sup> ,  
Gustavo Constantino de Campos<sup>1</sup> 

1. Universidade Estadual de Campinas  – Hospital de Clínicas – Banco de Multitecidos Humanos – Campinas (SP) – Brazil.
2. Centro Nacional de Pesquisa em Energia e Materiais  – Laboratório Nacional de Biociências – Campinas (SP) – Brazil.
3. Universidade Estadual de Campinas  – Faculdade de Ciências Médicas – Departamento de Ortopedia e Traumatologia – Campinas (SP) – Brazil.

\*Corresponding author: [luizhff@unicamp.br](mailto:luizhff@unicamp.br)

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## ABSTRACT

**Introduction:** Regulations governing good practices in Human Tissue Banks (HTB) intended for therapeutic use stipulate that the electronic data management system must be secure, efficient, and traceable. In this context, Research Electronic Data Capture (REDCap) is an electronic data management system originally developed for the collection and management of data in clinical studies, offering a set of integrated functionalities. **Objective:** To describe the implementation and validation of REDCap as an electronic data management system in an HTB. **Methodology:** This is a descriptive validation study. Based on the criteria established by current legislation, a validation plan was developed to analyze the important functionalities aimed at ensuring the security and integrity of the data. The functions analyzed were (a) system access and user registration; (b) data export and backup; (c) report generation; (d) traceability; and (e) blocking against alterations. **Results:** During validation, it was possible to verify that the system has important access control mechanisms, activity logging, and providing complete traceability of entered and modified information. Furthermore, REDCap offers multiple export and backup options, ensuring continued access to information in contingency situations or operational failures. **Conclusion:** REDCap demonstrated satisfactory compliance with the security, integrity, and traceability criteria required by current regulations for HTBs. Moreover, its replicability may represent a viable alternative for managing electronic data in other healthcare services.

**Descriptors:** Tissue Banks; Tissue and Organ Procurement; Data Management; Data Warehousing; Data Systems.

## *Implementação do Sistema REDCap para Gerenciamento de Dados em Banco de Tecidos Humanos*

## RESUMO

**Introdução:** As normativas que regulamentam as boas práticas em Bancos de Tecidos Humanos (BTH) destinados ao uso terapêutico determinam que o sistema de gerenciamento dos dados eletrônicos seja seguro, eficiente e rastreável. Nesse contexto, o *Research Electronic Data Capture* (REDCap) é um sistema de gerenciamento de dados eletrônicos originalmente desenvolvido para a coleta e gestão de dados em estudos clínicos que oferece um conjunto de funcionalidades integradas. **Objetivo:** Descrever a implementação e validação do REDCap como sistema de gerenciamento de dados eletrônicos em um BTH. **Metodologia:** Trata-se de um estudo descritivo de validação. Com base nos critérios estabelecidos pela legislação vigente, foi desenvolvido um plano de validação para analisar as funcionalidades importantes que visam garantir a segurança e a integridade dos dados. Foram analisadas as funções para (a) acesso ao sistema e cadastro de usuário; (b) exportação e *backup* de dados; (c) elaboração de relatórios; (d) rastreabilidade; e (e) bloqueio contra alterações. **Resultados:** Durante a validação, foi possível verificar que o sistema possui mecanismos importantes de controle de acesso, registro de atividades, além de permitir total rastreabilidade das informações inseridas e alteradas. Além disso, o REDCap dispõe de múltiplas opções de exportação e *backup*, o que garante continuidade do acesso às informações em situações de contingência ou falhas operacionais. **Conclusão:** O REDCap demonstrou atender de forma satisfatória aos critérios de segurança, integridade e rastreabilidade exigidos pelas normativas vigentes aos BTH. Ademais, sua replicabilidade pode ser uma alternativa viável para o gerenciamento de dados eletrônicos em outros serviços de saúde.

**Descritores:** Banco de Tecidos; Obtenção de Tecidos e Órgãos; Gerenciamento de Dados; Armazenamento de Dados; Sistema de Dados.

INTRODUCTION

In recent years, technological advancements and information digitization have driven significant changes in data management by imposing increasingly secure, integrated, and sustainable digital solutions. Within healthcare and research institutions, the use of electronic information management systems has become essential to optimize service quality, information traceability, and the security of data collected from patients and clinical study participants<sup>1</sup>.

Human Tissue Banks (HTBs) are non-profit healthcare institutions responsible for the screening, procurement, processing, quality control, and distribution of human tissues for therapeutic and scientific purposes. The complexity of these processes necessitates a quality management system capable of providing precision and robustness for data collection, management, and analysis, while ensuring compliance with national and international regulatory standards<sup>2</sup>.

Current legislation establishing good practices for human tissues intended for therapeutic use mandates that data management systems, whether in physical or electronic form, must ensure security, integrity, and traceability<sup>3</sup>. In this context, Research Electronic Data Capture (REDCap) is an electronic data management system originally developed by Vanderbilt University for clinical data collection and management, offering a set of integrated features that include the creation of various instruments and projects, access control, information traceability, as well as advanced options for data export, analysis, and custom report generation<sup>4-6</sup>.

In view of this, the present study aims to describe the implementation and validation of REDCap as an electronic data management system in an HTB.

METHODOLOGY

This is a descriptive validation study conducted at an HTB located in the state of São Paulo, Brazil. The validation plan was developed in accordance with the technical and operational criteria established by the Collegiate Board Resolution (*Resolução da Diretoria Colegiada-RDC*) No. 707/2022 of the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária-Anvisa*), which regulates good practices for human tissues intended for therapeutic use<sup>3</sup>.

The standard establishes, among other points:

Article 22. Documents may be in printed, electronic, microfilmed, or other suitable formats, provided they are easily retrievable and their traceability is guaranteed.

— Sole paragraph. In the case of electronic media, the following requirements must be met:

I — Data must be stored in backup copies, and the Tissue Bank must demonstrate that the system is protected against fraud and allows for the identification of data modifications; document management must ensure that documents are prepared in a way that allows for future amendments, when necessary, except for those already completed or whose process is finalized. II — The system must include access management, and the Tissue Bank must provide contingency plans and substitution measures that allow for its operation or alternative means to maintain access to necessary information in the event of system failure.

Article 23. Documents must be protected by physical or electronic means against accidental or intentional damage, in compliance with current fire safety regulations, and must be maintained in environmental conditions compatible with the preservation of their integrity [...]³.

The validation was structured and executed through a pilot project developed throughout 2025. Table 1 presents the analyzed requirements, the corresponding functionality, and the evidence used for validation.

Table 1. Correlation between regulatory requirements and REDCap functionalities evaluated during the validation process.

| Regulatory Requirement              | REDCap Functionality                            | Validation Evidence                              |
|-------------------------------------|-------------------------------------------------|--------------------------------------------------|
| System access and user registration | Institutional user registration and User Rights | Individual registration and permission levels    |
| Data export and backup              | Data Exports and Backup Project                 | Complete data export and project backup          |
| Report generation                   | Project Dashboards                              | Custom report creation                           |
| Traceability                        | Logging                                         | Audit trail of data modifications                |
| Protection against alterations      | Lock Instrument                                 | Locking of completed data collection instruments |

Source: Elaborated by the authors.

Each functionality was validated through operational tests, including live-environment execution testing, confirmation of the traceability of executed actions, and evaluation of compliance with data security, integrity, and availability requirements.

Functionality was considered validated when it fully met the pre-established criteria, without failures that compromised the corresponding regulatory requirement.

The validation process was conducted by a multidisciplinary team composed of HTB professionals responsible for quality management and data management. When necessary, the institution's information technology specialists were consulted for support regarding the platform's computational infrastructure.

## RESULTS

### System access and user registration

Based on information available on the official REDCap Brazil website, the use of the platform is free of charge for non-profit institutions affiliated with the national consortium. In these institutions, system access is restricted and depends on formal authorization requested by the researcher to the REDCap technology administrator<sup>7,8</sup>. The administrator registers users at the institutional level to grant them access to the system. Once a user has been registered, the project administrator adds the user and defines their permission levels, including the ability to restrict functions such as viewing, data editing, and report export. Access expiration dates can also be configured for each user, further ensuring compliance with access control principles (Fig. 1).

During the validation process, testing was performed on the creation, modification, and deletion of users with different permission levels, confirming that the system correctly restricts access according to predefined profiles.

**(a) Project user management menu**

Project: Projeto piloto - Banco de Tecidos Humanos (PID 730)

Logged in as [User] | Log out

My Projects | REDCap Messenger | Contact REDCap administrator

**Project Home and Design**

- Home
- Setup
- Codebook
- Designer
- Dictionary
- Project status: Production

**Data Collection**

- Record Status Dashboard
- Add / Edit Records

**Applications**

- Project Dashboards
- Alerts & Notifications
- Multi-Language Management
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging and Email Logging
- Field Comment Log
- File Repository
- User Rights and DAGs

**User Rights**

This page may be used for granting users access to this project and for managing the user privileges of those users. You may also create roles to which you may assign users (optional). User roles are useful when you will have several users with the same privileges because they allow you to easily add many users to a role in a much faster manner than setting their user privileges individually. Roles are also a nice way to categorize users within a project. In the box below you may add/assign users or create new roles, and the table at the bottom allows you to make modifications to any existing user or role in the project, as well as view a glimpse of their user privileges.

Upload or download users, roles, and assignments

**Add new users:** Give them custom user rights or assign them to a role.

Add new user  + Add with custom rights

OR

Assign new user to role  + Assign to role

**Create new roles:** Add new user roles to which users may be assigned.

Enter new role name  + Create role

(e.g., Project Manager, Data Entry Person)

| Role name<br>(click role name to edit role) | Username or users assigned to a role<br>(click username to edit or assign to role) | Expiration<br>(click expiration date to edit) | Project Design and Setup | User Rights | Data Access Groups | Data Viewing Rights |
|---------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------|--------------------------|-------------|--------------------|---------------------|
| ---                                         |                                                                                    | never                                         | ✓                        | ✓           | ✓                  | 11 View & Edit      |

**(b) Editing existing user**

You may set the rights for the user below by checking the boxes next to the application tools to which you wish to grant them access. You may also grant them or deny them access to individual data collection instruments, if so desired. To save your selections, click the "Save Changes" button at the bottom of the page.

**Editing existing user**

**Basic Privileges**

Expiration Date (if applicable)  (D/M/Y)

**Highest level privileges:**

- Project Design and Setup ☒
- User Rights ☐ No Access ☐ Read Only ☒ Full Access
- Data Access Groups ☒

**Other privileges:**

- Alerts & Notifications ☒
- Calendar ☒
- Add/Edit/Organize Reports ☒ (Also allows user to view ALL reports (but not necessarily all data in the reports))
- Stats & Charts ☒
- Data Import Tool ☒
- Data Comparison Tool ☒
- Logging ☒
- Email Logging ☒

**Privileges for Viewing and Exporting Data**

Data Viewing Rights pertain to a user's ability to view or edit data on pages in the project (e.g., data entry forms, reports). Users with "No Access" Data Viewing Rights for a given instrument will not be able to view that instrument for any record, nor will they be able to view fields from that instrument on a report. Data Export Rights pertain to a user's ability to export data from the project, whether through the Data Exports page, API, Mobile App, or in PDFs of instruments containing record data. Note: Data Viewing Rights and Data Export Rights are completely separate and do not impact one another.

|                                            | Data Viewing Rights   |                       |                                  |                       | Data Export Rights               |                       |                              |                       |
|--------------------------------------------|-----------------------|-----------------------|----------------------------------|-----------------------|----------------------------------|-----------------------|------------------------------|-----------------------|
|                                            | No Access (Hidden)    | Read Only             | View & Edit                      | Delete                | No Access                        | De-identified*        | Remove All Identifier Fields | Full Data Set         |
| TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| DADOS DEMOGRÁFICOS                         | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| TRIAGENS                                   | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| CAPTAÇÃO                                   | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| ARMAZENAMENTO                              | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| PROCESSAMENTO                              | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| CONTROLE DE LOTES                          | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| PÓS-TRANSPLANTE                            | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| NÃO CONFORMIDADES                          | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| PROCESSO FINALIZADO                        | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |
| DADOS DE ARQUIVAMENTO                      | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>        | <input type="radio"/> |

Source: Elaborated by the authors.

Figure 1. Project user management menu (a), Project user permissions (b).

## Data export and backup

REDCap enables data export in various formats (CSV, Excel, XML) in a secure and controlled manner (Fig. 2a). As an additional contingency measure, complete backups of electronic form records can be performed and stored in protected, restricted-access institutional directories (Fig. 2b). This practice serves as a form of decentralized backup to ensure data recovery in the event of technical failures or temporary system unavailability. To assess data integrity following the backup process, export and file recovery tests were conducted.



Source: Elaborated by the authors.

Figure 2. Data export menu (a), Data backup menu (b).

## Report generation

The report generation function in REDCap allows for the creation of customized documents based on user-defined criteria. The system enables both the full extraction of project data and the selection of specific variables, according to analytical objectives (Fig. 3a). Furthermore, the system provides tools for the development of dashboards and interactive charts that are automatically updated upon data entry, enabling continuous monitoring of operational indicators (Fig. 3b). Thus, it is possible to accurately track and extract the production data requested by Anvisa on a semi-annual basis, in addition to other indicators defined by the HTB itself.



Source: Elaborated by the authors.

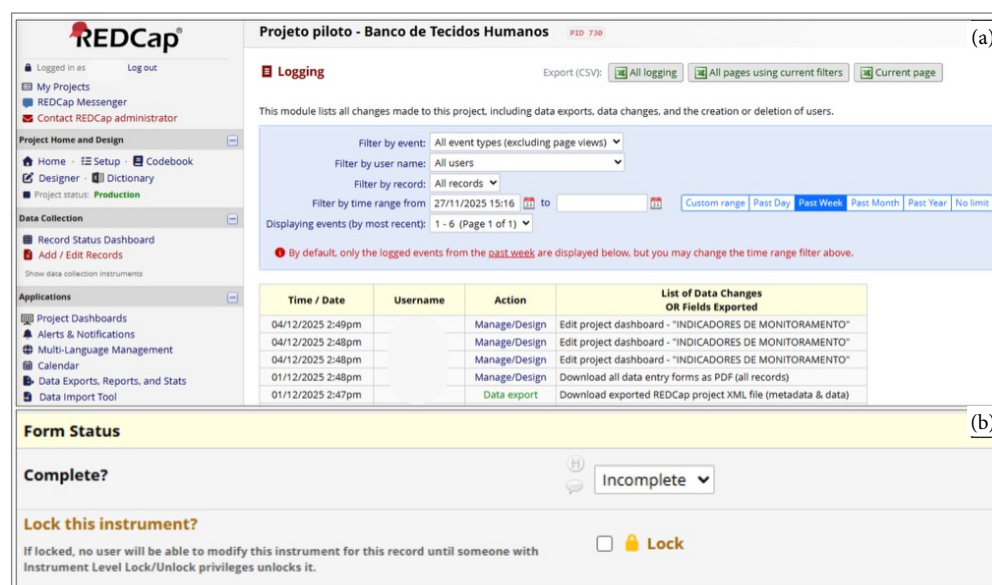
Figure 3. Customized report generation menu (a), Monitoring indicators dashboard (b).

## Traceability

REDCap records all actions performed in the system through audit trails (logs), including access, data entry, edits, and deletions (Fig. 4a). These records can be exported with date filters, enabling precise and chronological analysis of system interactions. Alterations to electronic records were simulated to verify the automatic generation of audit trails containing user identification, date, time, and a description of the executed action.

## Protection against alterations

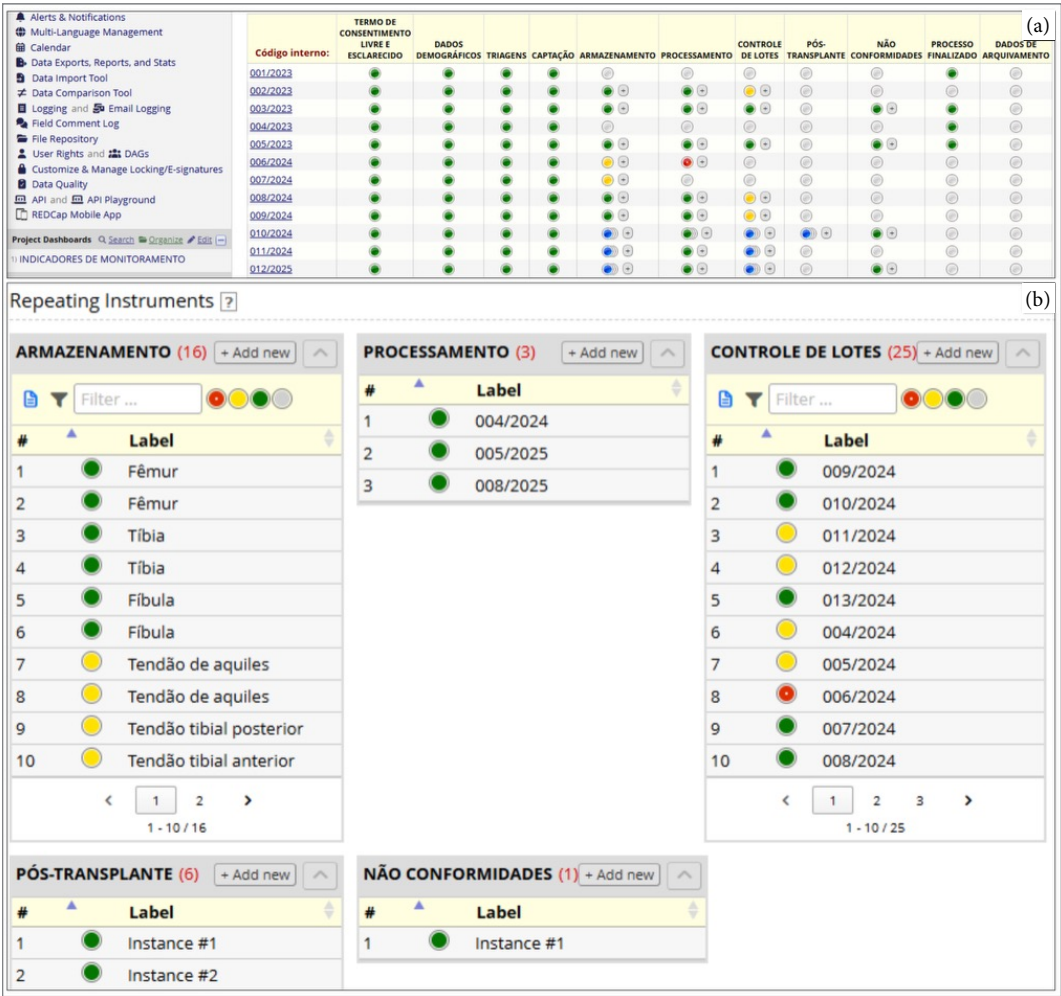
The system provides features to lock electronic instruments after completion, preventing unauthorized subsequent edits. When the lock is enabled, the responsible user's name and the corresponding date are automatically recorded at the bottom of the form (Fig. 4b). After locking the instruments, additional editing tests were performed to verify that unauthorized alterations were prevented.



Source: Elaborated by the authors.

Figure 4. Access, data-entry, and modification log menu for traceability (a), Form lock tool against alterations (b).

The project implementation at the HTB was carried out through a set of 10 electronic forms, totalling 489 fields. These forms cover all steps of the operational workflow, including internal donor code, Informed Consent Form (ICF) registration, donor demographic data, screenings, tissue recovery, storage, processing, production batch control, post-transplantation, non-conformities, and the information required for archiving physical documents (Figs. 5a and 5b).



Source: Elaborated by the authors.

**Figure 5.** Dashboard of all donation and tissue processing steps performed by the Human Tissue Bank (a), Overview of the REDCap interface, demonstrating the organization of electronic instruments related to the registration of a musculoskeletal tissue donor (b).

## DISCUSSION

In Brazil, the lack of a standardized electronic data management system in HTBs represents a major challenge in the face of technological and sustainable advancements. Based on the latest evaluation report published by Anvisa in 2019, it was observed that although HTBs regularly submit production data, their quality is compromised by data-entry errors, incomplete information, and submission delays<sup>9</sup>. These inconsistencies compromise indicator analysis, hinder monitoring, and reduce data reliability<sup>3,9</sup>. Therefore, the importance of a standardized electronic system that improves traceability, minimizes operational errors, and enhances data accuracy is emphasized.

Good practice legislation, while detailing the quality requirements for such systems, does not specify which system may be used. This absence becomes even more critical when considering the financial infeasibility of each HTB developing its own customized platform, given that they are non-profit institutions. The free and voluntary nature of organ and tissue donation, mandated by current legislation, directly impacts the financial self-sufficiency of these institutions<sup>10</sup>. In a study conducted by Maré et al.<sup>11</sup> within an academic health context, the findings indicate that the successful adoption of an electronic data capture system

such as REDCap depends not only on financial and technological availability, but above all on reliable infrastructure, institutional support, and continuous user training.

Given this challenge, adopting free data management platforms is not merely an alternative but an evident necessity. The implementation of software such as REDCap can significantly contribute to HTBs in broadly meeting regulatory requirements and optimizing their operational activities without overburdening already limited budgets. Recently published studies across various healthcare fields have used REDCap as a platform for data collection and management. Meanwhile, the study by Marroquin Rivera et al.<sup>12</sup>, which describes the implementation and use of this software as an electronic data capture tool in a clinical environment focused on mental health, demonstrated that the system was a viable alternative for research in resource-limited contexts by reducing errors associated with paper-based collection and providing security, standardization, and quality control functions for data. Similarly, Rashid et al.<sup>13</sup> demonstrated that the REDCap system can act as a central platform to organize a federated virtual biobank, enabling secure integration of clinical data, record standardization, and public querying without exposing sensitive information.

In Brazil, according to the federal government website, the system was introduced in 2011<sup>14</sup>. Since then, its use has progressively expanded, being incorporated by various hospitals, research centers, and educational institutions across different regions of the country.

Another challenge faced by HTBs is ensuring data security and complying with legislative requirements, which further limits options regarding electronic systems not specifically designed for the needs of tissue banks. Thus, REDCap represents a promising alternative, as it fits the rules required by Brazilian legislation and international regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States, which is one of the most stringent regarding patient data control<sup>14,15</sup>. The results of the present study reinforce compliance with regulatory requirements, as the traceability test demonstrated that the system fully recorded all actions through audit trails, making it possible to verify data accesses, modifications, and deletions.

In the present study, it was possible to demonstrate that REDCap allows each user to be registered individually and their permissions to be configured by the project creator, enabling the identification of the author of any changes made. Furthermore, it is possible to lock information from being altered once it has been filled out and reviewed, ensuring data integrity and reliability. Additionally, the system can perform different types of backups, which adds a layer of protection against the loss of relevant data. Moreover, REDCap does not collect project information, unlike other available tools—for instance, those from Google—which reinforces data privacy in compliance not only with the RDCs [Resolutions of the Collegiate Board of Directors] but also with the General Data Protection Law (*Lei Geral de Proteção de Dados- LGPD*)<sup>16</sup>. In the study conducted by Garcia and Abrahão<sup>5</sup> on REDCap, important features of the system were highlighted, such as access control, audit trails, data security, and flexibility in instrument creation, aspects that also proved central to the HTB's experience.

Beyond security, REDCap does not require users to have programming knowledge to use the platform, featuring various assistance tools that help with program usage. Additionally, it has functions that allow locating and gathering highly relevant information regarding the banks' production numbers, making it easy to quantify how many donors were screened, how many batches were produced, and how many non-conformities were recorded; furthermore, it is possible to automate this process, which is very interesting given that HTBs must report this data to Anvisa semiannually or upon request. Another very useful feature is the creation of tissue request forms, which allow professionals to request batches directly from the bank within current safety standards and enable the bank to automatically send alerts regarding post-transplant information related to possible adverse events, integrating both the management of critical information and the operation of the services provided by the HTB.

Among the observed limitations, the need for continuous staff training stands out, as well as staffing levels below what is necessary for the system to function properly. Given that the activities performed in an HTB are complex and involve a significant volume of data to be collected and managed, these operational limitations can directly impact service quality and the data collected. Similar limitations were also observed in a study conducted by Ngamani et al.<sup>17</sup> on the implementation of REDCap in three healthcare institutions with restricted technological resources. The authors reported the ongoing need for team training to ensure the proper use of REDCap and the importance of a sufficient staff structure to keep the system functioning properly.

Despite the limitations identified in the study, the results indicate that adopting REDCap represents a viable and low-cost solution for standardizing and strengthening information management in HTBs across the country. Partridge and Bardyn<sup>4</sup>, "Partridge and Bardyn<sup>4</sup>, in a study aimed at describing and evaluating the aforementioned system as an electronic data capture tool, highlight that it is more secure than Microsoft Excel and Microsoft Access, and any device can access it with an internet connection and web browser. Its flexible structure, integration capacity, and adherence to good practice requirements enable greater organization, traceability, and consistency of records by reducing errors and enhancing the reliability of the produced information.

## CONCLUSION

The REDCap system demonstrated satisfactory compliance with the security, integrity, and traceability criteria required by current regulations, representing an advance in HTB information management. The digitalization of information not only optimized data management but also directly contributed to minimizing environmental impact by eliminating the need for physical records, reinforcing the service's commitment to sustainable and innovative practices. Furthermore, its replicability can be a viable alternative for electronic data management in other healthcare services.

## CONFLICT OF INTEREST

Nothing to declare.

## AUTHOR'S CONTRIBUTION

**Substantive scientific and intellectual contributions to the study:** Freitas LH Filho, Neves CCS, Mattos GB, Ribeiro PP, Holzhausen HCN, Etchebehere M, Campos GC; **Conception and design:** Freitas LH Filho; **Data analysis and interpretation:** Freitas LH Filho, Neves CCS, Mattos GB, Ribeiro PP, Holzhausen HCN; **Article writing:** Freitas LH Filho, Neves CCS, Mattos GB, Ribeiro PP, Holzhausen HCN; **Critical revision:** Holzhausen HCN; **Final approval:** Freitas LH Filho.

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All data were generated/analyzed in this article.

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## DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE TOOLS

Artificial intelligence tools were used solely for linguistic review.

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