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Informed Consent Form Automated Validation, The Brazilian Rare Disease Network Case Proposal

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Abstract

The informed consent form (ICF) is required for all observational studies involving human subjects in Brazil. Besides the existence of e-Consent technologies, Brazilian guidelines issued by the Ministry of Health, the ICF must be obtained in the physical form in face-face services. Furthermore, the Brazilian Network of Rare Diseases (RARAS) project was proposed in a context marked by a scarcity of structured data on Rare Diseases (RD). One of the main objectives of RARAS is to understand and expose the RD scenario in Brazil. Since one of the stages in the RARAS project requires data collected from a patient's interview, the ICF is mandatory. Therefore, the importance of completeness of participants' process aroused the need of the technical team of RARAS to propose a protocol to automate the validation of scanned physical ICFs. The purpose is based on applying image preprocessing methods and a deep learning model. Regarding previous results in the literature, the expected outcome is to achieve around 90% accuracy in the classification of ICF for the RARAS project.

Keywords : Informed consent; Automated signature detection; Pattern recognition; Rare disease

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Nomenclature

RARAS	Brazilian Rare Disease Network
ICF	Informed Consent Form
RD	Rare disease
GLDP	General Law Data Protection
IT	Information technology

1. Introduction

In the field of ethics, all clinical treatment must follow four main principles: beneficence, nonmaleficence, autonomy, and justice [1]. Those principles are essential to minimize harm, benefit the patient, and respect their preferences and values. According to art. 22 and 34 of the Brazilian Medical Code of Ethics of 2019 [2], it is essential to clarify the diagnosis, prognosis, risks, the treatments and to request the informed consent of the patient or their legal representatives before any procedure, except in imminent risk of life. The ICF protects all involved individuals in the legal process.

Regarding the research area, the ICF is mandatory for all studies involving human subjects and requests the application of an ICF for all participants. In Brazil, the use of a consent term was regulated in the 1980s by the Ministry of Health and the Federal Council of Medicine [3,4]. Both departments established criteria for use in research and care, respectively. Later in 2012, the Ministry of Health established new guidelines and regulations in order to the respect for research participants, the scientific community and the State[5]. Also, in 2018, the Brazilian government proposed the General Law Data Protection (GLDP). The latter law intends to register how the data should be collected and treated to guarantee the security and integrity of the data holder. Although the GLDP is not strict in the health area, it enhances the importance of aligning the expectations of researchers and the participants. Thus, the ICF is essential for the researcher's and patient's security and must comply with the code of ethics and the GLDP [6].

Moreover, with the advance in technology, for an observational study, the usage of computational techniques would be helpful in the detection of signed and unsigned ICFs. Although the literature emphasizes the need for an informed consent form, no study was found to combine machine learning techniques with ICF validation. Regarding signature recognition, most efforts go towards detecting frauds, i.e., evaluating if a single signature is genuine [7,8]. Furthermore, as technology advanced in the recent decades, several electronic consent platforms were developed. The Electronic-Consent (e-Consent) system obtains informed consent using electronic-based processes and systems. For clinical research and trials, electronic consent must mirror paper requirements and present the information at a reading level the subject can understand [10,11].

Despite the adoption of e-Consent being appealing to the clinical research community, it has not been thoroughly evaluated as an alternative to standard paper form. Keeping signed documents archived for possible future usage requires a comprehensive understanding of the risks, benefits, and alternatives to data management. The approach to maintaining the paper ICF is of paramount importance in an era of patient-centered health [12]. Also, in Brazil, a guideline issued by the Ministry of Health through the National Research Ethics Commission [13] established that when research in the biomedical area necessarily requires the presence of the participant, the ICF must be obtained in the physical form. The requirement is presented even if the participant has already registered their consent electronically in a previous research stage.

Moreover, implementing the Citizen's Electronic Health Record in Brazil is still a complex task for the Brazilian Unified Health System (SUS) [14]. With the lack of technical resources in the health units aligned to the need for training of system users [14], implementing an e-Consent form in the medical appointment is a challenge. In this sense, this article aims to establish a protocol for the automated validation of scanned ICF of the Brazilian Network of Rare Diseases (*RARAS*; from the Portuguese: *Rede Nacional de Doenças Raras*) research project [15]. The solution proposed in this work is relevant considering that the RARAS project requires researchers to evaluate ICFs received from all five regions of Brazil and the knowledge that this could be the first attempt to automate the ICF validation, which could benefit other studies.

1.1. Brazilian Network of Rare Diseases

In a context marked by a scarcity of structured data on Rare Diseases (RD) in Brazil [16, 17], the RARAS project was proposed. A RD is a medical condition with low prevalence in a population, but there is no consensus on its definition. The European Union considers a RD as a pathology that affects no more than one person in 2000 [17]. In the United States, a RD is described as a disease that affects less than 200,000 people nationwide [18]. In Brazil, the Ministry of Health conceptualizes a RD using the World Health Organization (WHO) criteria, 1.3 cases per 2000 people [19,20].

The data available in the literature tends to be restricted to specific regions or disorders [21, 22, 23]. Furthermore, it is stated that "the availability of reliable epidemiological data on RD is a crucial and urgent unmet need" [15]. In this context, the main objective of the RARAS is to inquire into epidemiology, clinical condition, diagnostic and therapeutic resources, and costs of RD in Brazil [15]. This data inquiry has already been carried out for approximately two years.

Moreover, the RARAS comprises health centers carrying out RD diagnosis and treatment. Currently, RARAS has 40 voluntary centers spread across all five Brazilian regions, where 36 of them are currently available for data collection. Each of these centers falls into one of three categories: University Hospitals, Rare Diseases Reference Services, and Newborn Screening Reference Services. This project, which encompasses many centers, is funded by the Ministry of Health of Brazil through the National Council for Scientific and Technological Development of Brazil (in Portuguese, *Conselho Nacional de Desenvolvimento Científico e Tecnológico - CNPQ*). Also, it is highlighted that this collaborative network is the first initiative of an extensive epidemiological data collection of RD in Latin America [15]**.** Finally, one of this network's goals is to establish a national database following the guidelines of the Ministry of Health for the computerization of the SUS when implementing the minimum dataset [24].

In the context of data collection, a participant record contains all information that will be used for the research analysis. Many researchers adopt a monitoring process to confirm that the data collected are accurate and reliable and that none have been incorrectly entered or omitted (e.g., due to transcription errors). A combined monitoring strategy is considered acceptable and includes, when possible, single data verification, centralized and risk-based monitoring. This approach usually requires a data categorization into critical (e.g., valid informed consent, evaluation for selection of participants, and adverse events) or non-critical [25].

In this sense, critical data need to be monitored in all study participants, whereas non-critical data are checked in only a small sample. The literature highlights the need to reduce the illegibility, lack of standardization, and omission errors in ICF applications. Although many digital interventions have been developed to deal with these challenges [26], some more significant errors with potential clinical and analytical impact remain unresolved. [27]. Such errors may include ineligible records, the attempt to optimize the centralized monitoring process, managing studies with many institutions, and the handling of large amounts of records and ICFs.

According to guidelines and regulatory standards for research involving human beings described in the Resolution of the National Health Council No. 466/12 and complementary, some situations can be exempt from obtaining informed consent [28]. Some examples are observational, analytical, or descriptive studies that contemplate using the information in medical records, institutional information systems, and/or other sources of data and clinical information available in the institution. The data of such studies should be analyzed anonymously, and the results must be presented in aggregate form, not allowing the identification of research participants. Otherwise, the ICF must be applied for primary data obtained directly through patient interviews [29].

The RARAS project consists of two phases: the retrospective (2018-2019) and the prospective one. While the retrospective phase uses only data from medical reports, i.e., secondary data, the prospective acquires a patient's personal and clinical information during a face-to-face service conducted in 2022, requiring the ICF.

Nevertheless, as the retrospective collected a large number of participants, around 12000 patients, it is vital for the security of the research that all patients or their legal representatives sign the form. However, as all data centers are distributed over the five regions of Brazil with discrepant realities, the conditions of all 40 institutions were evaluated in the rare disease network, as shown in Fig.1.

Fig. 1 shows that only 6 (15%) of the evaluated centers do not have computer access. However, it is possible to notice in Fig. 1 (right) that, even though a computer is available in most of the centers, the clinical interview and the annotated information are written on a paper in 40% of the institutions, a high percentage considering the total number of health centers in the network. These results demonstrate three essential pieces of information: (i) a computer in the center does not guarantee the use of that equipment by the medical staff during the patient's

appointment; (ii) the reality of Brazilian health centers is far from the ideal in terms of the use of technology, and ; (iii) unfortunately, we can not rely on e-Consent to get the participant's signature due to the limited use of computer equipment and the restriction imposed by the National Research Ethics Commission.

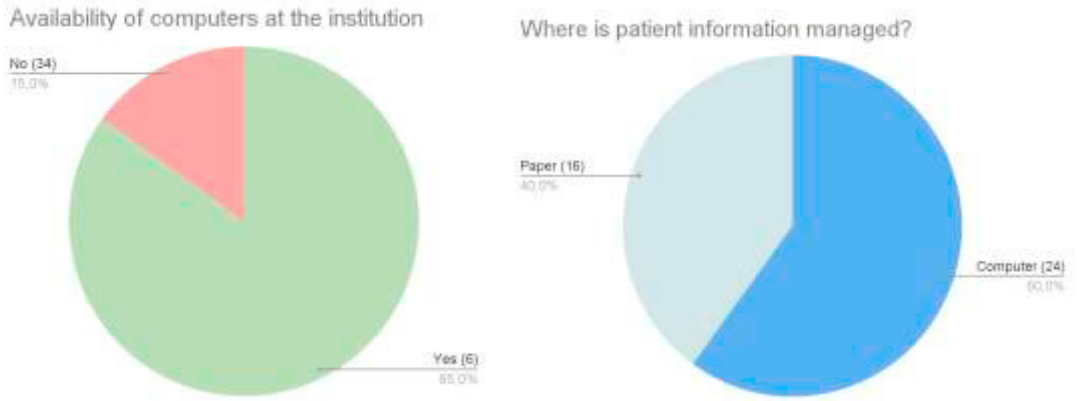

Fig. 1: On the left, the pie charts show the availability of computers in the RARAS institutions, while the graph on the right shows how patient data is managed in the institution.

2. Methods

The following sections describe the proposed protocol and motivation to automate the validation of the ICF in the RARAS project.

2.1. *Data collection*

As mentioned, the RARAS project comprises two phases: the retrospective and the prospective. While the first phase collected over 12000 patients' information from appointments in 2018 and 2019, the prospective phase is based on interviewing the participant to gather more or newer information. The prospective phase is underway and comprises the period of January to September of 2022. Moreover, the set of patients in both phases is not strictly the same, i. e., there are individuals in the second phase that do not participate in the first phase and vice-versa.

For both phases, data is collected in the Research Electronic Data Capture (REDCap) platform. The REDCap is a system designed to eliminate risks associated with paper-based instruments and ensure monitoring processes and data quality [30]. In this way, we designed the electronic Case Report Forms (eCRFs) in REDCap and provided access for the participating health centers to collect RD data in our system. The project's clinical team validated all forms. After that, we stored all the information in a Structured Query Language (SQL) database, so the MySQL system [31] was used once REDCap supported it. For the prospective phase, where new data is collected at patient's appointment, seven surveys are presented to the participant to build the database: identification, socioeconomic information, diagnosis, treatment, comorbidity, internment, and outcome. After the participant has signed the ICF, the document is scanned and uploaded to the REDCap platform. A participant is considered valid in the prospective phase for the later epidemiologic analysis only if he/she was interviewed in a service that diagnoses and treats RD.

Overall, 170 fields are collected for each patient in the RARAS project and later validated by the Information technology (IT) team. The amount of data collected, in contrast to the human resource available in the IT team, also contributes to the development of automated evaluation of the collected data and the ICF.

The diagram of the prospective phase is demonstrated in Fig. 2. First, patient data and signature is collected during the clinical appointment. Then, information is inserted into the REDcap platform as well as the upload of the ICF form. On the other hand, the IT team validates data from all 36 health centers in the network. Considering that the prospective form contains around 150 fields and the IT team must download and evaluate each ICF, the workload is intense, and a semi-automated validation would benefit the process.

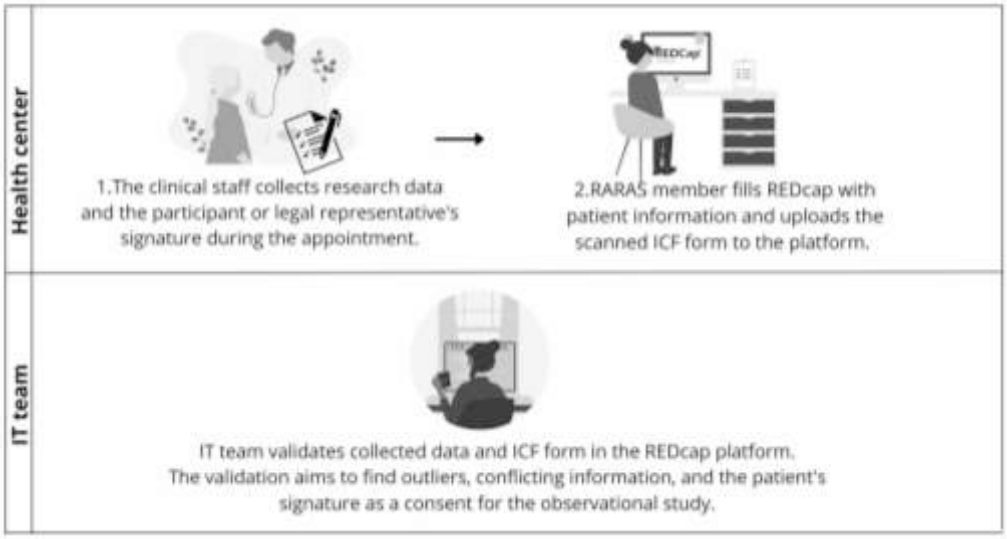

Fig.2: The process of data collection for the RARAS project

2.2 *Proposed protocol for Automated Evaluation of the ICF*

This proposal comprehends four steps for the application of an automated validation of the ICF in the RARAS project:

2.2.1. RARAS training

Typically, task support applications are configured to help the operational or managerial practice of the organizations. Studies have identified that human errors are frequent in clinical contexts. The three most common types of human error in these environments are non-compliance with guidelines, hasty decision-making, and lack of awareness of the responsibilities of each professional [32].

Thus, one of the main concerns and motivations of the IT team in the development of this protocol is the knowledge by experience that RARAS members can submit by mistake:

- ICF without the required signature
- different documents formats
- corrupted files
- documents of different natures, such as other images
- ICF with low contrast and/or brightness
- modified versions of the original ICF

Therefore, the first attempt to minimize possible errors is to develop a guideline to describe best practices and help improve the input data quality for the automated analysis. The guideline was developed and delivered to all members of RARAS and strongly recommends that scanned documents contain:

- good contrast, i.e., a readable text presented
- portable document format (PDF) format
- no structural modifications in the document, such as the font and size of the text
- one page of the ICF by each PDF page (in portrait format)

Although this is not part of automated validation, it is part of the data preparation.

2.2.3. Preprocessing of the ICF documents

After uploading a scanned ICF to the REDCap platform, the IT team stores the files in the internal server, and the validation protocol occurs monthly. Before using a machine learning method, a preprocessing method is applied to enhance the quality and contrast of the image. In this context, two methods are proposed for this step.

First, an image equalization for contrast enhancement is applied to improve the overall image quality [33]. The technique uses a Gaussian Mixture Model (GMM) to understand the image's intensity distribution. The intersection points between pixels and Gaussian components are used to partition the ranges of input intensities. Then, the method used the input ranges and the GMM to transform the gray pixels. The result is an image with better contrast and smoother homogeneous regions such as the background of the article.

Then, to improve the quality of the document, a preprocessing method is applied [34]. The method aims to identify texts in a document and uses a low pass filter, an edge detection method [32], and a thresholding technique to output and reduce small possible noise and outputs a black and white image where letters appear in white whether the background is black. Finally, this is the image used in the automated validation machine learning step.

2.2.4. Computer vision method for automatic validation

This step aims to detect whether the submitted and preprocessed document corresponds to a signed ICF of the RARAS project. As mentioned before, the unsigned document presents a significant legal risk for the project and the security and autonomy of the participants. Usually, in the literature, several authors focus on the signature match for forensic tasks, i. e., trying to check if the signature is legit or a fraud [7,8,9]. However, checking if an entire document is signed or unsigned is still challenging [35].

Therefore, the proposed methodology is based on applying deep learning methods. The idea is to apply a Convolutional Neural Network (CNN) with fully connected layers and binary classification output (signed or unsigned). The proposal concentrates on the early results, which uses convolution layers of size 3x3, 2x2 max pooling, reLU activations, and adam optimizer. The result from the previous approach in single signed documents is over 90% [35].

2.2.5. Confidence evaluation

The model will be trained with labeled data provided by the RARAS and other inconsistent documents labeled as unsigned. Finally, new examples will be added to the prediction every month. The output confidence in the classification will allow the IT team to reduce the workload since the team will accept the classification with a high level of confidence.

The protocol is represented in Fig. 3. First, the clinical staff collects the signatures of participants in the visit. Then, a RARAS member scans the documents according to the guidelines provided by the IT team and submits them to the REDcap platform. In a second moment, uploaded forms are submitted to a preprocessing method and, finally, a deep learning model. The deep learning model was previously trained with signed and unsigned documents. The predictive model outputs the ICF class and the method's confidence level. The IT team manually evaluates all ICFs with a confidence rate lower than 50% to guarantee the completeness of the project.

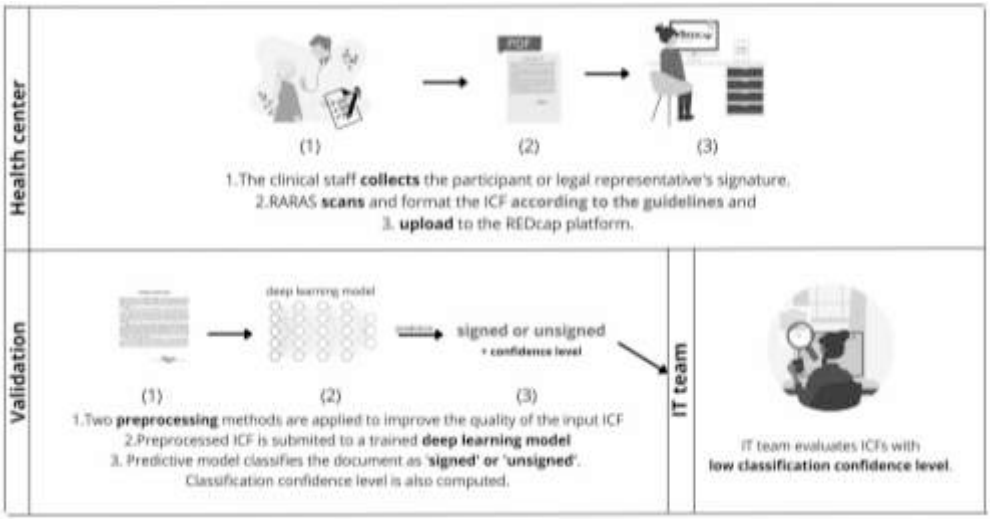

Fig. 3: Proposed protocol for automated validation of RARAS.

3. Expected outcomes

Data mining in RARAS requires the validation of a large amount of data, around 12000 participants in the first phase of the project. Thus, considering the process of manually validating all 170 fields, including the download and check-up of the ICFs, it is valid to worry about the workload in the prospective phase and the quality and security of the observational study that legally requires participant consent [3,4].

The proposed protocol intends to associate available techniques such as preprocessing methods and machine learning to classify ICF methods as signed or unsigned based. Although most of the methods regarding signature checking aim to detect frauds [7,8,9], the method in [35] can detect the presence of a signature in a document with 90% accuracy. Therefore, a similar rate is expected in the proposed protocol.

With the consciousness that all methods have limitations in addition to the importance of guaranteeing the ICF completeness, all forms with low confidence coefficient in the classification are also evaluated by the IT team as shown in Fig. 3.

4. Final considerations

This article proposes an informed consent form automated validation for the Brazilian Rare Disease Network (RARAS). RARAS comprises 40 health centers that join efforts to build knowledge over the RD scenario in Brazil. The project is a joint effort of several specialists to build a database, epidemiologic knowledge, and an observatory over RD in Brazil. As the first organization to capture participants' RD data and to regard the legal requirements for observational studies, it is crucial to guarantee that all subjects or legal representatives have signed the ICF. Furthermore, the proposed protocol is also essential for further projects that require paper scanned signed documents as input for participant validation.

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