### Consent Understanding and Verification for Personalized Assistive Systems

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Abstract:

The rapid adoption of personalized systems, driven by advancements in natural language processing, sensor technologies, and AI, has transformed the role of virtual personal assistants (VPAs), particularly in healthcare. While VPAs promise to enhance patient experiences through tailored support and adaptive workflows, their complexity often results in opaque functionalities hindering user understanding. This lack of transparency poses significant challenges, particularly in the context of informed consent, where users must comprehend the implications of sharing sensitive personal data. Existing consent systems often rely on static declarations and extensive documentation, which overwhelm users and fail to ensure informed decision-making. To address this problem, this paper presents a novel consent management approach integrated into the EREBOTSv3.0, an agent-based GDPR-compliant explainable framework for virtual assistants. The proposed solution introduces (i) an interactive method that structures consent into clear sections with summaries and examples to improve user comprehension and (ii) a question-based verification mechanism that assesses understanding and reinforces knowledge when needed. By leveraging EREBOTS' modular architecture, real-time feedback, and secure data management, the proposed approach enhances transparency, fosters trust, and simplifies the consent understanding for dialog-based healthcare systems. This work lays the foundation for addressing critical challenges at the intersection of personalized AI, healthcare, and data protection.

#### 1 INTRODUCTION

The adoption of personalized systems providing tailored support is rapidly increasing, driven by advances in natural language processing Eguia et al. (2024), sensor technologies Cusack et al. (2024), and artificial intelligence Wang et al. (2021). Virtual personal assistants (VPAs) are particularly promising in delivering impactful, customized outcomes. In healthcare, they hold the potential to enhance patient experiences and improve outcomes by addressing individual needs and supporting complex medical workflows Fang et al. (2024).

Despite these advancements, VPAs are often so-

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phisticated systems with opaque functionalities and decision-making processes that most users struggle to understand. This lack of transparency is especially concerning healthcare, where AI systems are increasingly employed to assist or replace human operators for less safety-critical tasks. Examples include tools promoting healthier habits Cruz Casados et al. (2024), monitoring therapy adherence Ma et al. (2024), providing medication reminders Corbett et al. (2021), and suggesting intervention strategies Sezgin et al. (2020).

These intelligent systems depend on collecting and analyzing personal data provided by patients, with outcomes that can significantly impact users' health and safety. This highlights the critical role of informed consent, a cornerstone of the professional-patient relationship. Informed consent ensures autonomy and addresses the inherent information asymmetry where the professional or service provider holds greater knowledge and authority.

When intelligent systems mediate this relationship, it becomes vital to implement mechanisms that not only disseminate legal documentation but also ensure users comprehend the provided information. These mechanisms mitigate potential adverse consequences arising from misunderstanding or insufficient awareness and reduce developers' liability by demonstrating efforts to inform users effectively. This is especially the case for consent given by patients in clinical settings.

Current consent systems typically rely on static declarations and detailed descriptions Kaye et al. (2014). However, these approaches often overwhelm users with complexity and information overload Schermer et al. (2014), leaving them unable to make informed decisions. As a result, users may inadvertently agree to terms they do not fully understand, risking unintended uses of their data. For instance, sensitive medical data could be shared with third parties without the user's explicit awareness Falagas et al. (2009). This underscores the urgent need for innovative consent solutions that simplify processes while enhancing user comprehension and competence.

To address these challenges, this paper proposes two key contributions: (i) an interactive method for structuring consent into distinct sections with summaries and examples to convey their meaning effectively, particularly in scenarios lacking professional support; and (ii) a question-based verification mechanism to confirm user comprehension, supplemented by reinforcement measures to address gaps in understanding. To test the overall system architecture, we integrate it into the EREBOTSv3.0 framework, designed to ensure users are thoroughly informed about data usage and to promote long-term understanding of consent. The EREBOTSv3.0 framework is a sophisticated multi-agent system for developing modular and explainable virtual assistants. It employs a multi-agent architecture, where each user is represented by a personal agent managing individual interactions for personalized, adaptive experiences. Additional agents, such as a gateway agent, facilitate seamless communication between front-end interfaces (e.g., mobile apps) and back-end systems. EREBOTS adheres to principles of modularity and data protection, supporting plug-and-play components for customizable workflows and employing GDPR-compliant databases like Pryv to securely manage sensitive data. This ensures transparency in data processing and robust data protection.

By leveraging EREBOTS' modularity and realtime feedback mechanisms, the proposed consent system offers a seamless and customizable user experience. It addresses critical challenges in healthcare, such as ensuring transparency in data usage and fostering trust. This approach simplifies the consent process while laying the foundation for user-friendly and reliable solutions in dialog-based healthcare systems.

The remainder of this paper is organized as follows. Section 2 reviews the relevant state-of-the-art. Section 3 describes the system architecture and module behaviors. Finally, Section 4 discusses the contributions and their potential impact and outlines future works concluding the paper.

#### 2 STATE OF THE ART

The increasing reliance on digital systems for data management has heightened the importance of robust consent mechanisms, particularly in sensitive domains such as healthcare and conversational AI. This section reviews advancements in consent management systems, their application in assistive technologies, and ongoing challenges in ensuring informed and verifiable consent.

# 2.1 Consent Information in Modern Systems

Consent management has emerged as a central component of online systems, driven by the latent value of user data and the increasing diversity of its applications. A key regulatory framework underpinning consent management is the General Data Protection Regulation (GDPR)Robol et al. (2022). The advent of digitalization has catalyzed research into Dynamic Consent Management Systems (DCMS). These systems enable users to continually manage and update their consent preferences, offering them greater control over their personal data in real time Albanese et al. (2020). By leveraging online and mobile platforms, consent forms can be stored electronically, allowing users to review and modify their preferences at any time. These platforms also facilitate direct communication with researchers, enabling users to ask questions, request additional information, or specify preferences for future research projects. Furthermore, DCMS can accommodate diverse consent modalities—such as broad consent, specific consent, or meta-consent-tailored to the research context Budin-Ljøsne et al. (2017). Technological advancements have significantly enhanced the usability and security of consent management systems. Blockchain technology, for example, is increasingly employed to ensure the immutability, traceability, and accessibility of consent and data records Albanese et al. (2020). Simultaneously, privacy-preserving techniques such as differential privacy and zero-knowledge proofs are being utilized to safeguard data confidentiality Khalid et al. (2023a). Research has demonstrated that interactive platforms and multimedia tools improve user satisfaction and comprehension of the consent process. Moreover, user-centered and transparent design methodologies have been shown to strengthen trust in digital services Gesualdo et al. (2021). The healthcare sector represents a critical application domain for DCMS, where robust confidentiality measures are essential to safeguard patient privacy. These systems ensure that data is utilized strictly within the scope of the granted consent, thereby mitigating risks such as privacy breaches and identity theft Khalid et al. (2023b).

# 2.2 Consent in Assistive Conversational Systems

Conversational systems, including voice assistants and chatbots, are increasingly utilized across various healthcare applications, such as telerehabilitation and accessibility. These AI-driven systems offer unique opportunities to enhance the consent process by addressing comprehension challenges during user interactions. AI-powered conversational agents can present the consent process in incremental steps, allowing users to digest information at their own pace. Moreover, the ability to interact with these systems and pose questions in real time helps resolve ambiguities. By designing these chatbots as friendly research assistants that (pro)actively engage users, patients feel more involved and are encouraged to participate actively Xiao et al. (2023). These systems provide patients with continuous access to detailed information, eliminating the reliance on time-constrained human interactions. Additionally, conversational agents can adapt their responses to the patient's level of language comprehension, thereby alleviating the burden on medical personnel while empowering patients to make informed decisions Allen et al. (2024). Ethical and law-compliant considerations remain essential in the design and implementation of such systems. Concerns surrounding privacy, algorithmic fairness, and the potential for misunderstandings in agent-user interactions necessitate the adoption of transparent, user-centered design processes. This is particularly critical when developing assistive technologies for vulnerable populations, such as older adults or individuals with cognitive impairments. To address these challenges, iterative development and active involvement of end users are essential Wangmo et al. (2019).

### 2.3 Challenges in Consent Comprehension and Verification

Both clinical and non-clinical domains face significant challenges in ensuring the comprehension and verification of informed consent Manson and O'Neill (2007), a cornerstone of patient autonomy Harish et al. (2015). Despite its importance, numerous studies reveal persistent deficiencies in the informed consent process (ICP), undermining its legal validity and ethical integrity Delany (2005).

A primary issue is the limited comprehension of consent information by participants. Research indicates that many individuals fail to grasp critical aspects of consent, such as the purpose of a study, associated risks, and the concept of randomization. A systematic review by Pietrzykowski and Smilowska (2021) found that fewer than half of the participants could recall essential study details, including risks and the voluntary nature of participation. Similarly, Wisgalla and Hasford (2022) highlighted that consent documents are often excessively lengthy and written in complex language. This complexity makes such documents challenging to understand even for individuals with advanced education, such as those holding PhDs. Consequently, such structures can obscure critical information for laypersons or individuals with limited literacy, contributing to widespread misunderstandings. Nearly 45% of participants in clinical research, for instance, are unable to identify a single risk associated with the studies in which they participate. Another critical challenge is cognitive and informational overload. The extensive and intricate nature of consent information can overwhelm patients, hindering their ability to provide truly informed consent. This phenomenon, termed "informational overload", is well-documented by Bester et al. (2016), who emphasize that excessive details can render the ICP ineffective.

To address these challenges, strategies such as the teach-back method have been proposed. This technique involves asking patients to reiterate the information they have received in their own words, allowing misunderstandings to be identified and corrected proactively. A study on surgical education demonstrated that the teach-back method significantly improved patients' understanding of risks and benefits while enhancing their trust in medical professionals. These findings underscore the positive impact of active engagement and repetition on the informed consent process Seely et al. (2022).

# 3 ARCHITECTURE AND IMPLEMENTATION

Figure 1 illustrates the extension of the EREBOTS framework with a dynamic consent management system. This modular, agent-based platform supports the creation of GDPR-compliant virtual assistants, incorporating both core modules (which facilitate the underlying communication mechanisms) and custom modules (such as integrating an Explainable AI (XAI) engine for user-oriented explanations Buzcu et al. (2024)). The framework's customization and modularity allow for plug-and-play extensions, including finite state machines (FSMs), user profiling systems, and feedback management. Its adaptability, transparency, and one-to-one user-agent mapping make it an ideal candidate for integrating a customized consent management system.

### 3.1 Pipeline

Consent management is integrated as an optional module into the core functionality of the personal agents (PAs) within the EREBOTS architecture. This pipeline maintains consistency across all PAs to ensure fairness and observability. Figure 2 depicts the entire consent management process, which can be divided into four main stages based on user interaction.

#### 1. Initialization:

- The user connects to the PA, creating a new entry with private information in Pryv.
  - The user receives an explanation of the chatbot's purpose and interaction instructions.

#### 2. Consent Process:

- If no consent process is defined (see [Consent process not defined]), the interaction proceeds without user input. Otherwise, the consent process begins following the welcome message (explained in Section 3.2).
- User consent is gathered in incremental steps (see [Process consent steps]). At each stage, the user is prompted to indicate their understanding of the system's implications.
- If the user declines any part of the consent (see [Consent part not accepted]), the process terminates, and the PA stops processing messages.
- Upon completion, the consent is stored in Pryv for compliance and future interactions.

#### 3. User Profiling & Task Execution:

• The system transitions to the profiling state, where ProfilingFSM is used to create a custom user profile stored in Pryv.

 The PA switches to the customized Conversational State Machine (CSM) defined by the developer, marking the start of the PA's main task.

#### 3.2 The Consent FSM

The Consent FSM manages user interactions throughout the consent process. Each state represents a segment of the consent form or a related question. Configuration is managed via a web interface and stored in two YAML files: one for consent segments and one for questions. These files are validated by experts to ensure accuracy. The FSM loads all states at startup, and user responses determine the transition to the next state. Consent is gathered in two key moments: (i) before account registration, where consent segments are proposed alongside examples and brief explanations, and (ii) during usage of the VPa, where follow-up questions further elaborate on the initial consent.

Consent Segmentation. The user is presented with sections of the consent form that can be accepted or rejected, as per legal requirements European Parliament and European Council (2016). Upon acceptance, the FSM proceeds to the next section or begins providing services. Rejection at any point terminates the process, and the decision is stored in the privacy-preserving database, Pryv<sup>1</sup>. If consent is withdrawn at any point, the chatbot stops, ceasing all operations. If new consent is provided (the consent process can be restarted at any time), the services are reactivated.

Informed consent is a critical legal principle in the EU, safeguarding autonomy and personal data European Parliament and European Council (2016). It must be given freely, explicitly, and with clear information, ensuring the user comprehends the terms European Commission (2018); European Parliament and European Council (2016). This is especially important in AI systems, where ensuring real understanding-not just acceptance to proceed—poses a significant challenge. To enhance comprehension, the consent information is organized into discrete blocks (e.g., data collected, purpose, risks). The moment of consent should be clearly distinct from other interactions, and design elements such as text segmentation and visual cues can aid Insights from cognitive science and psychology can inform the design, ensuring users are not overwhelmed with technical language. A summary of key concepts may also be provided if necessary. The FSM validates user responses: correct

<sup>1</sup>https://www.pryv.com/

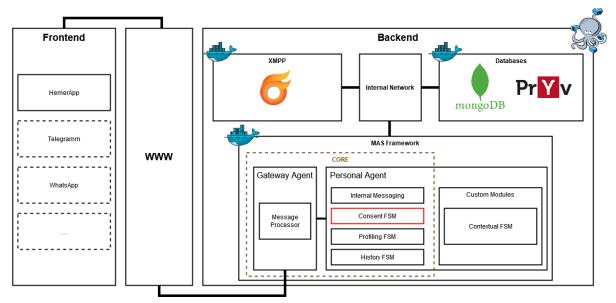


Figure 1: Architecture of the EREBOTS Framework.

answers transition to the next state, while incorrect ones prompt the user to review and provide a new response. Once all consent sections are accepted, the user's consent is stored in Pryv. If consent is modified or new segments are added or changed, they will be presented to the user upon reconnecting. The user must review and either accept or reject the updates. If rejected, the chatbot stops operating.

Consent Verification. After consent is given, periodic checks will be conducted to ensure the user's understanding remains (or is) accurate. To do so, throughout the system use, users will be prompted with questions to verify their understanding of the consented terms. If any misunderstandings are detected, relevant information will be provided to resolve them. Once clarified, users can modify or reconfirm their consent. The consent validation process includes multiple question types: (i) True/False, to verify correctness; (ii) numerical answers, such as time periods; and (iii) open-ended responses, such as specific terms. Future work will address the timing and frequency of questions, as well as which ones to prompt and when to re-prompt given users or categories of users.

#### 4 DISCUSSION & CONCLUSIONS

This paper presents a dynamic approach to consent management that addresses key challenges, including mitigating the information overload inherent in traditional models, verifying the actual understanding of consent, and reinforcing correct understanding over time. Central to the proposed system is a stepwise approach to presenting consent, which breaks down complex and monolithic terms into smaller, more digestible sections. By segmenting the consent process into manageable parts, users are more likely to understand the information they are consenting to. Additionally, alongside a straightforward presentation of the terms (to comply with legal requirements), the system guides users step-by-step and offers simplified explanations, examples, and aggregated information for those less familiar with formal terminology. This approach reduces the risk of misunderstanding or unintentional, uninformed consent.

The proposed system is integrated within the EREBOTS v3.0 framework, a modular, agent-based platform that allows for flexible adaptation to dynamic consent management needs. By default, this system adheres to GDPR-compliant standards, ensuring that privacy is maintained throughout the process. The modularity of the system facilitates not only the development and configuration of the consent communication process but also enables personalized verification of users' understanding of consent. This is achieved through periodic follow-up questions, reinforcing comprehension and ensuring that consent is granted only after users fully understand its implications.

A key feature of this model is its balance between offering users adequate time to review the consent process and avoiding information overload. By breaking consent into smaller, digestible steps and incorporating regular checks on user understanding, the

#### PΑ ConsentFSM ProfilingFSM ContextualFSM Connect to PA Create new entry in Pryv Send welcome message Start consent process alt [Consent process defined] Send first consent message [Process consent steps] Respond to consent step [Consent part not accepted] Abort process alt Notify user and stop processing Continue process Consent process complete Save consent to Pryv Skip consent process [Profiling process defined] Start profiling process [Process profiling questions Ask profiling question Provide response Process and store response Profiling process complete Save profil to Pryv Switch to customized CSM Begin main chatbot task

#### First connection to PA full pipeline

Figure 2: Sequence Diagram of the Pipeline Flow.

system significantly reduces the risk of uninformed consent, a common issue in many existing systems. This iterative review process enables the early identification of gaps in understanding, preventing misinterpretations before they lead to uninformed decision-making.

Despite its advantages, the use of AI-based consent management raises concerns regarding potential persuasive techniques that could influence user decisions. It is critical to ensure that the iterative nature of the consent process does not inadvertently coerce users into accepting terms they do not fully comprehend. Maintaining the integrity of informed consent requires that the process remains free from undue influence. To address this, the system incorporates transparent, well-defined mechanisms that track both the information provided and the manner in which it is delivered. This transparency ensures that the system is subject to rigorous oversight, reducing the trust gap that might arise in the absence of human-human interactions (such as a doctor explaining terms in simpler language). Furthermore, the system enhances humanhuman interactions by mitigating the risk of coercive behaviors—often difficult to detect and prove in traditional settings. In this way, the AI system offers a more efficient means of ensuring the reliability and legitimacy of consent, promoting ethical standards and user autonomy.

In summary, the proposed dynamic consent management system, with its step-by-step design and continuous verification of understanding, holds promise for enhancing both user trust and the security of the consent process. The system's modular architecture enables a flexible and adaptable approach that prevents cognitive overload while supporting informed decision-making. This approach not only addresses the limitations of traditional consent systems, particularly in complex environments such as healthcare, but also complies with legal and ethical standards, ensuring that consent is fully informed and free from coercion.

The development of this system within the ERE-BOTS v3.0 framework represents a significant advancement in consent management. The interactive, user-centered design, coupled with continuous comprehension checks, provides a comprehensive solution to the challenges posed by conventional consent systems. Future work will focus on refining the indi-

vidual components of the consent process in collaboration with legal AI experts, creating testable consent-related questions and examples, and conducting initial trials in the healthcare sector as part of a European project. These trials will offer valuable insights into the system's real-world effectiveness and its potential for broader adoption.

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